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FEDERAL REGISTER

Vol. 77 Friday,

No. 222 November 16, 2012

Book 1 of 2 Books

Pages 68679–68890

OFFICE OF THE FEDERAL REGISTER

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

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DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

7 CFR Part 3434

RIN 0524–AA39

Hispanic-Serving Agricultural Colleges and Universities (HSACU)

AGENCIES: National Institute of Food and Agriculture, USDA.

ACTION: Final rule.

SUMMARY: This rule updates our regulations to show a list of institutions that are granted HSACU certification by the Secretary and are eligible for HSACU programs for the period starting October 1, 2012 and ending September 30, 2013.

DATES: This rule is effective November 16, 2012 and applicable October 1, 2012.

FOR FURTHER INFORMATION CONTACT: Matthew Lockhart; Senior Policy Specialist; National Institute of Food and Agriculture; U.S. Department of Agriculture; STOP 2299; 1400 Independence Avenue SW.; Washington, DC 20250–2299; Voice: 202–559–5088; Fax: 202–401–7752; Email: *mlockhart@nifa.usda.gov*.

SUPPLEMENTARY INFORMATION:

HSACU Institutions for Fiscal Year 2013

This rule makes changes to the existing list of institutions in Appendix B of 7 CFR part 3434. The list of institutions is amended to reflect the institutions that are granted HSACU certification by the Secretary and are eligible for HSACU programs for the period starting October 1, 2012, and ending September 30, 2013.

Certification Process

As stated in 7 CFR part 3434, an institution must meet the following criteria to receive HSACU certification: (1) Be a Hispanic-Serving Institution (HSI), (2) offer agriculture-related degrees, and (3) award at least 15% of agriculture-related degrees to Hispanic students over the two most recent academic years.

NIFA obtained the latest report from the U.S. Department of Education's National Center for Education Statistics that lists all HSIs and the degrees conferred by these institutions (completions data) during the 2010–11 academic year. NIFA used this report to identify HSIs that conferred a degree in an instructional program that appears in Appendix A of 7 CFR part 3434 and to confirm that over the 2009–10 and 2010–11 academic years at least 15% of the degrees in agriculture-related fields were awarded to Hispanic students.

The updated list of HSACUs is based on (1) completions data from 2009–10 and 2010–11, and (2) enrollment data from Fall 2011. NIFA identified 80 institutions that will meet the eligibility criteria and receive HSACU certification for FY 2013 (October 1, 2012 to September 30, 2013).

Appeal Process

NIFA will permit HSIs that are not granted HSACU certification to submit an appeal within 30 days of the publication of this notice. The appellant must submit a request for review to the NIFA official specified in this notice with details on the nature of the disagreement and include supporting documents.

Classification

This rule relates to internal agency management. Accordingly, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity for comment are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register**. This rule also is exempt from the provisions of Executive Order 12866. This action is not a rule as defined by the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.,* or the Congressional Review Act, 5 U.S.C. 801 *et seq.,* and thus is exempt from the provisions of those Acts. This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 3434

Administrative practice and procedure; Agricultural research, education, extension; Hispanic-Serving Institutions; Federal assistance.

Title 7, part 3434 of the Code of Federal Regulations is amended accordingly as set forth below:

PART 3434—HISPANIC-SERVING AGRICULTURAL COLLEGES AND UNIVERSITIES CERTIFICATION PROCESS

■ 1. The authority citation for Part 3434 continues to read as follows:

Authority: 7 U.S.C. 3103.

■ 2. Revise Appendix B to part 3434 to read as follows:

Appendix B to Part 3434—List of HSACU institutions, 2012–2013.

The institutions listed in this appendix are granted HSACU certification by the Secretary and are eligible for HSACU programs for the period starting October 1, 2012, and ending September 30, 2013. Institutions are listed alphabetically under the state of the school's location, with the campus indicated where applicable.

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Central Arizona College
Phoenix College
Pima Community College

California (26)

Allan Hancock College
Bakersfield College
California State Polytechnic University-Pomona
California State University-Bakersfield
California State University-Fresno
California State University-Fullerton
California State University-Long Beach
California State University-Monterey Bay
California State University-San Bernardino
College of the Sequoias
Fullerton College
Golden West College
Hartnell College
Imperial Valley College
MiraCosta College
Modesto Junior College
Monterey Peninsula College
Mt. San Antonio College
Porterville College
Reedley College
San Diego Mesa College
San Joaquin Delta College
Santa Ana College
Southwestern College
West Hills College Coalinga
Whittier College

Colorado (1)

Trinidad State Junior College

Florida (4)

Florida International University
Miami Dade College
Nova Southeastern University
Saint Thomas University

Illinois (2)

City Colleges of Chicago-Harold Washington College
Triton College

New Mexico (8)

Central New Mexico Community College
Eastern New Mexico University-Main Campus
New Mexico Highlands University
New Mexico Institute of Mining and Technology
Northern New Mexico College
Santa Fe Community College
University of New Mexico-Main Campus
Western New Mexico University

New York (4)

CUNY Bronx Community College
CUNY City College
CUNY LaGuardia Community College
Mercy College

Puerto Rico (15)

Bayamon Central University
Institute Tecnologico de Puerto Rico-Manati
Inter American University of Puerto Rico-Aguadilla
Inter American University of Puerto Rico-Bayamon
Inter American University of Puerto Rico-Metro
Inter American University of Puerto Rico-Ponce
Inter American University of Puerto Rico-San German
Pontifical Catholic University of Puerto Rico-Ponce
Universidad Del Turabo
Universidad Metropolitana
University of Puerto Rico-Arecibo
University of Puerto Rico-Humacao
University of Puerto Rico-Medical Sciences Campus
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University of Puerto Rico-Utuado

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Lee College
Midland College
Palo Alto College
South Plains College
Southwest Texas Junior College
Texas A&M International University
Texas A&M University-Corpus Christi
Texas A&M University-Kingsville
Texas State Technical College-Harlingen
University of Texas at Brownsville
University of Texas at El Paso
University of Texas at San Antonio
University of Texas—Pan American
University of Houston
University of the Incarnate Word

Washington (1)

Wenatchee Valley College

Done in Washington, DC, this 26th day of October, 2012.

Sonny Ramaswamy,

Director, National Institute of Food and Agriculture.

[FR Doc. 2012–27739 Filed 11–15–12; 8:45 am]

BILLING CODE 3410–22–P

FEDERAL RESERVE SYSTEM

12 CFR Part 263

[Docket No. R–1451]

Rules of Practice for Hearings

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System (the Board) is amending its rules of practice and procedure to adjust the amount of each civil money penalty (CMP) provided by law within its jurisdiction to account for inflation. This action is required under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996.

DATES: This rule is effective November 16, 2012.

FOR FURTHER INFORMATION CONTACT: Katherine H. Wheatley, Associate General Counsel (202) 452–3779, or Mehrnoush Bigloo, Attorney (202) 475–6361, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551. For users of Telecommunication Device for the Deaf (TDD) only, contact (202) 263–4869.

SUPPLEMENTARY INFORMATION:

Federal Civil Penalties Inflation Adjustment Act

The Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 *note* (''FCPIA Act'' or the ''Act''), as amended by the Debt Collection Improvement Act of 1996, requires Federal agencies to adjust, by regulation, the CMPs within their jurisdiction by a prescribed inflation adjustment at least once every four years. The Board made its last adjustment to its CMPs on October 6, 2008, *see* 73 FR 58,032, and on September 13, 2011, it incorporated into its regulation the penalties applicable to savings and loan holding companies over which it obtained supervisory authority pursuant to section 312 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, *see* 76 FR 56,604. The Board is issuing this final rule pursuant to the FCPIA Act to set forth the newly-adjusted CMPs which will apply to violations that occur after the rule's effective date.

The FCPIA Act defines the inflation adjustment as a cost-of-living adjustment based on the percentage change in the Consumer Price Index between June of the calendar year in which the particular CMP was last set or adjusted and June of the calendar year preceding the current adjustment (in this case, June 2011). The Act specifies the use of the Consumer Price Index for All Urban Consumers (CPI–U) published by the Department of Labor. Accordingly, to obtain the percent inflation adjustment for each CMP within the Board's jurisdiction, we calculated the percent change in the CPI–U between June of the year in which the CMP was last adjusted and June 2011.[1] Then, using the relevant percent inflation adjustment, we calculated the inflation increase for each CMP.[2] The Act requires the rounding of any calculated increase pursuant to the method prescribed in Section 5(a) of the Act.[3] In the case of the majority of the Board's CMPs, the calculated increase was rounded down to zero, resulting in no adjustment to the CMP. These unadjusted penalties include the penalty for certain late, false or misleading reports under 12 U.S.C. 324, the first and second tier penalties under 12 U.S.C. 504, 505, 1817(j)(16), 1818(i)(2), and 1972(2)(F), the penalties under 12 U.S.C. 1820(k)(6)(A)(ii), 1832(c), 1847(b), 3110(a), 334, 374a, 1884, 3909(d), 1467a(i)(2), 1467a(i)(3), and 1467a(r)(2), the second tier penalties under 12 U.S.C. 1847(d) and 3110(c), the penalties under 15 U.S.C.

[1] This resulted in a 3.2 percent inflation adjustment for penalties that were last adjusted in 2008, a 19 percent inflation adjustment for penalties that were last adjusted in 2004, a 30.9 percent inflation adjustment for penalties that were last adjusted in 2000, and a 44 percent inflation adjustment for penalties that were last adjusted in 1996.

[2] Because the Biggert-Waters Flood Insurance Reform Act of 2012, Public Law 112–141, 126 Stat. 405, amended 42 U.S.C. 4012a(f)(5) by increasing the CMP for each violation under 42 U.S.C. 4012a(f) to $2,000, the Board did not calculate an inflation adjustment for this CMP. It should also be noted that the amendment to 42 U.S.C. 4012a(f)(5) removed the $100,000 calendar-year limit on penalties assessed against any regulated lending institution or enterprise.

[3] Section 5(a) of the Act requires that any calculated increase be rounded to the nearest multiple of: $10 in the case of penalties less than or equal to $100; $100 in the case of penalties greater than $100 but less than or equal to $1,000; $1,000 in the case of penalties greater than $1,000 but less than or equal to $10,000; $5,000 in the case of penalties greater than $10,000 but less than or equal to $100,000; $10,000 in the case of penalties greater than $100,000 but less than or equal to $200,000; and $25,000 in the case of penalties greater than $200,000. 28 U.S.C. 2461 *note,* Sec. 5(a).

78u–2(b)(1) and (2), and the penalty for a natural person under 15 U.S.C. 78u–2(b)(3). The penalties that are not adjusted at this time because of this rounding formula will be subject to adjustment at the next adjustment cycle to take account of the entire period since their last adjustment.

The following is an example of the methodology for adjusting CMPs, using the penalty for a first tier violation of 12 U.S.C. 1847(d). First, because that CMP was last adjusted in 2000, we calculated the percent increase between the CPI–U for June 2000 (172.4) and the CPI–U for June 2011 (225.72). We then took that percentage (30.9%) and multiplied it by the current CMP amount of $2,200 to obtain an inflation increase of $679.80. Because the current CMP amount is greater than $1,000 but less than $10,000, the Act requires us to round the inflation increase to the nearest multiple of $1,000. Rounding $679.80 to the nearest multiple of $1,000 yields $1,000. Accordingly, the increase to the $2,200 penalty for a first tier violation of 12 U.S.C. 1847(d) is $1,000, resulting in an adjusted CMP of $3,200.

Administrative Procedure Act

This rule is not subject to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 553, requiring notice, public participation, and deferred effective date. The FCPIA Act provides Federal agencies with no discretion in the adjustment of CMPs to the rate of inflation, and it also requires that adjustments be made at least every four years. Moreover, this regulation is ministerial and technical. For these reasons, the Board finds good cause to determine that public notice and comment for this new regulation is unnecessary, impracticable, and contrary to the public interest, pursuant to the APA, 5 U.S.C. 553(b)(3)(B). These same reasons also provide the Board with good cause to adopt an effective date for this regulation that is less than 30 days after the date of publication in the **Federal Register**, pursuant to the APA, 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* applies only to rules for which an agency publishes a general notice of proposed rulemaking. Because the Board has determined for good cause that a notice of proposed rulemaking for this rule is unnecessary, the Regulatory Flexibility Act does not apply to this final rule.

Paperwork Reduction Act

There is no collection of information required by this final rule that would be subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

List of Subjects in 12 CFR Part 263

Administrative practice and procedure, Claims, Crime, Equal Access to Justice, Lawyers, Penalties.

Authority and Issuance

For the reasons set forth in the preamble, the Board of Governors amends 12 CFR part 263 as follows:

PART 263—RULES OF PRACTICE FOR HEARINGS

■ 1. The authority citation for part 263 continues to read as follows:

Authority: 5 U.S.C. 504, 554–557; 12 U.S.C. 248, 324, 504, 505, 1464, 1467, 1467a, 1468, 1817(j), 1818, 1820(k), 1828(c), 1829(e), 1831o, 1831p–1, 1847(b), 1847(d), 1884(b), 1972(2)(F), 3105, 3107, 3108, 3349, 3907, 3909, 4717; 15 U.S.C. 21, 78(1), 78o–4, 78o–5, 78u–2; 28 U.S.C. 2461 *note;* 31 U.S.C. 5321; and 42 U.S.C. 4012a.

■ 2. Section 263.65 is revised to read as follows:

§ 263.65 Civil penalty inflation adjustments.

(a) *Inflation Adjustments.* In accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 *note,* the Board has set forth in paragraph (b) of this section the adjusted maximum amounts for each civil money penalty provided by law within the Board's jurisdiction. The authorizing statutes contain the complete provisions under which the Board may seek a civil money penalty. The adjusted civil money penalties apply only to violations occurring after the effective date of this rule.

(b) *Maximum civil money penalties.* The maximum civil money penalties as set forth in the referenced statutory sections are as follows:

(1) 12 U.S.C. 324:

(i) Inadvertently late, false or misleading reports, *inter alia*—$3,200.

(ii) Other late, false or misleading reports, *inter alia*—$32,000.

(iii) Knowingly or recklessly false or misleading reports, *inter alia*—$1,425,000.

(2) 12 U.S.C. 504, 505, 1817(j)(16), 1818(i)(2) and 1972(2)(F):

(i) First tier—$7,500.

(ii) Second tier—$37,500.

(iii) Third tier—$1,425,000.

(3) 12 U.S.C. 1820(k)(6)(A)(ii)—$275,000.

(4) 12 U.S.C. 1832(c)—$1,100.

(5) 12 U.S.C. 1847(b), 3110(a)—$37,500.

(6) 12 U.S.C. 1847(d), 3110(c):

(i) First tier—$3,200.

(ii) Second tier—$32,000.

(iii) Third tier—$1,425,000.

(7) 12 U.S.C. 334, 374a, 1884—$110.

(8) 12 U.S.C. 3909(d)—$1,100.

(9) 15 U.S.C. 78u–2:

(i) 15 U.S.C. 78u–2(b)(1)—$7,500 for a natural person and $70,000 for any other person.

(ii) 15 U.S.C. 78u–2(b)(2)—$70,000 for a natural person and $350,000 for any other person.

(iii) 15 U.S.C. 78u–2(b)(3)—$140,000 for a natural person and $700,000 for any other person.

(10) 42 U.S.C. 4012a(f)(5)—$2,000.

(11) 12 U.S.C. 1467a(i):

(i) 12 U.S.C. 1467a(i)(2)—$32,500.

(ii) 12 U.S.C. 1467a(i)(3)—$32,500.

(12) 12 U.S.C. 1467a(r):

(i) 12 U.S.C. 1467a(r)(1)—$3,200.

(ii) 12 U.S.C. 1467a(r)(2)—$32,500.

(iii) 12 U.S.C. 1467a(r)(3)—$1,425,000.

By order of the Board of Governors of the Federal Reserve System, November 9, 2012.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2012–27857 Filed 11–15–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0652; Airspace Docket No. 12–ACE–4]

Amendment of Class E Airspace; Anthony, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace at Anthony, KS. Additional controlled airspace is necessary to accommodate new Area Navigation (RNAV) Standard Instrument Approach Procedures at Anthony Municipal Airport. The FAA is taking this action to enhance the safety and management of Instrument Flight Rule (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: Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone 817–321–7716.

SUPPLEMENTARY INFORMATION:

History

On August 2, 2012, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend Class E airspace for the Anthony, KS, area, creating additional controlled airspace at Anthony Municipal Airport (77 FR 45983) Docket No. FAA–2012–0652. 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 E airspace designations are published in paragraph 6005 of FAA Order 7400.9W dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by amending Class E airspace extending upward from 700 feet above the surface to accommodate new standard instrument approach procedures at Anthony Municipal Airport, Anthony, KS. This action is necessary for the safety and management of IFR operations at the airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. 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 that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

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

* * * * *

ACE KS E5 Anthony, KS [Amended]

Anthony Municipal Airport, KS
(Lat. 37°09′31″ N., long. 98°04′47″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Anthony Municipal Airport, and within 2 miles each side of the 000° bearing from the airport extending from the 6.4-mile radius to 12 miles north of the airport.

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

David P. Medina,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2012–27834 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–1436; Airspace Docket No. 11–ACE–29]

Amendment of Class E Airspace; Guthrie, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace at Guthrie, IA. Decommissioning of the Guthrie Center non-directional radio beacon (NDB) at Guthrie County Regional Airport has made reconfiguration necessary for standard instrument approach procedures and for the safety and management of Instrument Flight Rule (IFR) operations at the airport. Geographic coordinates of the airport are also adjusted.

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

SUPPLEMENTARY INFORMATION:

History

On August 2, 2012, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend Class E airspace for the Guthrie, IA, area, creating additional controlled airspace at Guthrie County Regional Airport (77 FR 45987) Docket No. FAA–2011–1436. 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 E airspace designations are published in paragraph 6005 of FAA Order 7400.9W dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by

amending Class E airspace extending upward from 700 feet above the surface to accommodate new standard instrument approach procedures at Guthrie County Regional Airport, Guthrie, IA. Airspace reconfiguration is necessary due to the decommissioning of the Guthrie Center NDB and the cancellation of the NDB approach. Controlled airspace is necessary for the safety and management of IFR operations at the airport. Geographic coordinates of the airport are also updated to coincide with the FAA's aeronautical database.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. 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 that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

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

* * * * *

ACE IA E5 Guthrie, IA [Amended]

Guthrie County Regional Airport, IA
(Lat. 41°41′13″ N., long. 94°26′06″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Guthrie County Regional Airport.

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

David P. Medina,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2012–27843 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0654; Airspace Docket No. 12–ACE–3]

Amendment of Class E Airspace; Forest City, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace at Forest City, IA. Additional controlled airspace is necessary to accommodate new Area Navigation (RNAV) Standard Instrument Approach Procedures at Forest City Municipal Airport. The Forest City nondirectional beacon's (NDB) geographic coordinates are also adjusted. The FAA is taking this action to enhance the safety and management of Instrument Flight Rule (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: Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone 817–321–7716.

SUPPLEMENTARY INFORMATION:

History

On August 16, 2012, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend Class E airspace for the Forest City, IA, area, creating additional controlled airspace at Forest City Municipal Airport (77 FR 49399) Docket No. FAA–2012–0654. 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 E airspace designations are published in paragraph 6005 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 the Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by amending Class E airspace extending upward from 700 feet above the surface to accommodate new standard instrument approach procedures at Forest City Municipal Airport, Forest City, IA. This action is necessary for the safety and management of IFR operations at the airport. Geographic coordinates of the Forest City NDB are updated to coincide with the FAA's aeronautical database.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. 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 that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

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

* * * * *

ACE IA E5 Forest City, IA [Amended]

Forest City Municipal Airport, IA
(Lat. 43°14′05″ N., long. 93°37′27″ W.)
Forest City NDB
(Lat. 43°14′09″ N., long. 93°37′15″ W.)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of Forest City Municipal Airport, and within 4 miles each side of the 347° bearing from the airport extending from the 6.9-mile radius to 10.6 miles north of the airport, and within 2.6 miles each side of the 162° bearing from the Forest City NDB extending from the 6.9-mile radius to 7.4 miles southeast of the airport.

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

David P. Medina,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2012–27836 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

[Docket No. OSHA–2011–0184]

RIN 1218–AC65

Updating OSHA Standards Based on National Consensus Standards; Head Protection

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule; confirmation of effective date.

SUMMARY: OSHA is confirming the effective date of its direct final rule that revises the Head Protection standards for general industry, shipyard employment, marine terminals, longshoring, and construction by updating the reference to a standard published by a standards-developing organization, the American National Standards Institute. In the June 22, 2012, direct final rule, OSHA stated that it would withdraw the companion proposed rule and confirm the effective date of the direct final rule if the Agency received no significant adverse comments. OSHA did not receive significant adverse comments on the direct final rule. Therefore, OSHA is confirming that the direct final rule became effective on September 20, 2012.

DATES: The direct final rule published on June 22, 2012 (77 FR 37587), was effective on September 20, 2012. For the purposes of judicial review, OSHA considers November 16, 2012, as the date of issuance.

ADDRESSES: In compliance with 28 U.S.C. 2112(a), OSHA designates the Associate Solicitor of Labor for Occupational Safety and Health as the recipient of petitions for review of the final standard. Contact Joseph M. Woodward, Associate Solicitor, at the Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–5445.

FOR FURTHER INFORMATION CONTACT: *General information and press inquiries:* Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999.

Technical information: Ken Stevanus, Directorate of Standards and Guidance, Room N–3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2260; fax: (202) 693–1663.

SUPPLEMENTARY INFORMATION:

Copies of this Federal Register notice: Electronic copies of this *Federal Register* notice are available at *http://www.regulations.gov*. This *Federal Register* notice, as well as news releases and other relevant information, also is available at OSHA's Web page at *http://www.osha.gov*.

Confirmation of the effective date: On June 22, 2012, OSHA published a direct final rule (DFR) in the **Federal Register** that revised its Head Protection standards for general industry at 29 CFR 1910.135, shipyard employment at 29 CFR 1915.155, marine terminals at 29 CFR 1917.93, longshoring at 29 CFR 1918.103, and construction at 29 CFR 1926.100 by updating a reference to the American National Standards Institute (ANSI) head protection standard (*see* 77 FR 37587). In the DFR, OSHA deleted a reference to ANSI Z89.1–1986, and replaced it with a reference to ANSI Z89.1–2009. In addition, in the DFR, OSHA deleted references to ANSI Z89.1–1969 and ANSI Z89.2–1971 in its construction standard at 29 CFR 1926.100, and replaced them with the same three references specified in the

general industry, shipyard employment, marine terminals, and longshoring head-protection standards.

In that **Federal Register** document, OSHA also stated that it would confirm the effective date of the DFR if the Agency received no significant adverse comments. OSHA received two comments on the DFR, neither of which were significant adverse comments (*see* Document IDs OSHA–2011–0184–0003 and –0004). To the contrary, both comments supported the DFR.

List of Subjects in 29 CFR Parts 1910, 1915, 1917, 1918, and 1926

Head protection, Incorporation by reference, Occupational safety and health, Safety.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this final rule. OSHA is issuing this final rule pursuant to 29 U.S.C. 653, 655, and 657, 5 U.S.C. 553, Secretary of Labor's Order 1–2012 (77 FR 3912), and 29 CFR part 1911.

Signed at Washington, DC, on November 8, 2012.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2012–27792 Filed 11–15–12; 8:45 am]

BILLING CODE 4510–26–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in December 2012. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective December 1, 2012.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for December 2012.[1]

The December 2012 interest assumptions under the benefit payments regulation will be 0.75 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for November 2012, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during December 2012, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE–EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 230, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates For PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
230	12–1–12	1–1–13	0.75	4.00	4.00	4.00	7	8

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

■ 3. In appendix C to part 4022, Rate Set 230, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates For Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
230	12–1–12	1–1–13	0.75	4.00	4.00	4.00	7	8

Issued in Washington, DC, on this 7th day of November 2012.

Laricke Blanchard,

Deputy Director for Policy, Pension Benefit Guaranty Corporation.

[FR Doc. 2012–27753 Filed 11–15–12; 8:45 am]

BILLING CODE 7709–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0951; FRL–9361–3]

Xylenesulfonic Acid, Sodium Salt; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of xylenesulfonic acid, sodium salt (also known as sodium xylene sulfonate) (CAS Reg. No. 1300–72–7) when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, diary processing equipment, and food processing equipment and utensils at 500 parts per million (ppm) utensils. The firm Exponent on behalf of Ecolab Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium xylene sulfonate.

DATES: This regulation is effective November 16, 2012. Objections and requests for hearings must be received on or before January 15, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0951, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The 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 Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Mark Dow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–5533; email address: *dow.mark@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2011–0951 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 15, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0951, by one of the following methods:

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

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL–9335–9), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7936) by Exponent on behalf of Ecolab Inc. (370 N. Wabasha Street, St. Paul, MN 55102). The petition requested that 40 CFR 180.940(a) be amended by an exemption from the requirement of a tolerance for residues of xylene sulfonic acid, sodium salt (also known as sodium xylene sulfonate; CAS no. 1300–72–7) when used as an inert ingredient as an antimicrobial agent in pesticide formulations applied to ''food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils'' at a maximum of 500 ppm. That notice referenced a summary of the petition prepared by Exponent on behalf of Ecolab Inc. (370 N. Wabasha Street, St. Paul, MN 55102), the petitioner, which is available in the docket, *http://www.regulations.gov.* Sodium xylene sulfonate is currently approved for use in pesticide formulations applied to growing crops and animals under the existing exemptions from the requirement of a tolerance given at 40 CFR 180.920 and 40 CFR 180.930. Sodium xylene sulfonate is currently approved as an inert ingredient under 40 CFR 180.940(c) for use in food contact surface sanitizing solutions applied to food processing equipment and utensils at an end-use concentration not to exceed 62 ppm. The current petition seeks to expand the existing use of sodium xylene sulfonate to include use on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. Hence, the petition requests the establishment of an exemption covering this new use in 40 CFR 180.940(a). There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sodium xylene sulfonate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with sodium xylene sulfonate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by sodium xylene sulfonate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Sodium xylene sulfonate has low acute toxicity by the oral, dermal and inhalation route of exposure. Sodium xylene sulfonate is a slight skin and mild eye irritant. Based upon information regarding sodium toluene sulfonate, sodium xylene sulfonate is negative for dermal sensitization. Several subchronic studies via the oral route of exposure are available in the database. In two 14-day toxicity studies in mice and rats, no significant treatment related toxicity was observed at doses up to 4% in the diet (approximately 4,000 milligrams/kilogram/day (mg/kg/day)) in mice. In rats, there were some mortalities which were not observed in a dose-related manner and losses of body weight that were probably due to palatability of the test article. In a repeat toxicity study in rats, mortality was not observed at doses up to 4% in the diet. A 90-day subchronic toxicity study was conducted in Wistar rats with doses of sodium xylene sulfonate up to 5% in

the diet. A decreased in relative spleen weight of females, along with some clinical chemistry and hematology changes were observed at the highest dose (3,454 mg/kg/day). In a separate 90-day toxicity study in rats and mice, no treatment related effects were observed in mice and rats given sodium xylene sulfonate in the diet at 2% (approximately 2,439 and 2,467 mg/kg/day in mice and rats, respectively). Dermal toxicity studies for 17 days and 90 days duration were conducted in mice and rats. No systemic toxicity was observed in mice and rats exposed dermally to sodium xylene sulfonate at doses up to 1,620 and 500 mg/kg/day in mice and rats, respectively. The results of a 2-year dermal toxicity study showed no evidence of skin neoplasms or any other neoplasms at doses up to 727 and 240 mg/kg/day in mice and rats, respectively. Additionally, the Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified.

Sodium xylene sulfonate was tested for its mutagenic potential in various *in vivo* and *in vitro* genotoxicity assays. It gave a negative response in a mouse lymphoma assay, the Ames assay, Sister Chromatid Exchange assay, (positive at cytotoxic concentrations only), a Chromosome Aberration Test and three mouse micronucleus assays. Therefore, sodium xylene sulfonate is not likely to be mutagenic.

There are no reproductive toxicity studies for sodium xylene sulfonate. However, the Organisation for Economic Co-operation and Development (OECD) Screening Information Dataset (SIDS) Assessment included reviews of a 91-day oral rat feeding study with sodium cumene sulfonate, a 90-day feeding study with sodium xylene sulfonate (mice and rats), and the 2-year dermal studies with sodium xylene sulfonate (mice and rats) which included examination of the reproductive organs of both sexes. There was no evidence from these studies to suggest that sodium xylene sulfonate would have an adverse effect on reproductive organs by either the oral or dermal route. No developmental toxicity studies in rats and rabbits are available in the sodium xylene sulfonate database. However, a developmental study with the rat is available for a surrogate chemical, calcium xylene sulfonate. In this study the NOAEL for maternal and fetal toxicity was the highest dose tested; 3,000 mg/kg/day which correspond to 936 mg/kg bw/day. Based on the calcium xylene sulfonate OECD Guideline study, there is no evidence to consider these materials as being developmental toxicants. There is no evidence in the sodium xylene sulfonate database that sodium xylene sulfonate is an immunotoxin.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

No endpoint of concern following a single dose was identified in the available database. The Agency identified a NOAEL of 763 mg/kg bw/day for systemic toxicity, which was selected from an oral subchronic study. Effects observed in this study were a decrease in spleen weight in females along with some clinical chemistry and hematology changes at the LOAEL of 3,454 mg/kg bw/day. No adverse effects were reported in males. This study was used for chronic dietary exposure assessment. An uncertainty factor of 100X is applied (10X for interspecies extrapolation and 10X for intraspecies variability). Based on the physicochemical data and lack of systemic toxicity in the available dermal toxicity studies, EPA concluded that there is no need to conduct quantitative dermal risk exposure assessment. For several reasons, no additional uncertainty factor is necessary for the use of subchronic study data for chronic exposure assessment. First there was a wide dose spread between the toxic effects seen at the LOAEL of 3,454 mg/kg/day and the NOAEL of 763 mg/kg/day. Second, the changes observed in clinical chemistry and hematological parameters were small in magnitude and no effects on organs were observed in the study. Therefore, the changes observed were not considered toxicologically significant. Finally, the NOAEL in a separate 90-day study in rats was 2,467 mg/kg/day indicating the lower NOAEL value in the selected study is an artifact of dose selection. Therefore, EPA concluded that there is no need to add an additional uncertainty factor for use of short-term study for long-term exposure assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sodium xylene sulfonate, EPA considered exposure under the proposed exemption from the requirement of a tolerance (40 CFR 180.940(a)) and as an inert ingredient used in pesticide formulations applied to growing crops and animals under the existing exemptions from the requirement of a tolerance given at 40 CFR 180.920 and 40 CFR 180.930. EPA assessed dietary exposures from sodium xylene sulfonate in food as follows:

In the absence of actual dietary exposure data resulting from this proposed use the EPA has utilized a conservative, health-protective method of estimating dietary intake that is based upon conservative assumptions related to the amount of residues that can be transferred to foods as a result of the proposed use of sodium xylene sulfonates in food contact sanitizing pesticide products. This same methodology has been utilized by EPA in estimating dietary exposures to antimicrobial pesticides used in food-handling settings. The Agency believes the assumptions used to estimate chronic dietary exposures lead to an extremely conservative assessment of chronic dietary risk due to a series of compounded conservatisms as described in the unit. First, when a surface is treated with a disinfectant, a quantity of the disinfectant remains on the surface (Residual Solution). In the absence of any other data, EPA has used an estimated worst-case concentration of 1 mg of solution per square centimeter (cm^2) of treated surface area for this quantity. Second, the conservatism of this methodology is compounded by EPA's decision to assume a worst case scenario that all food that an individual consumes will

come into contact with 4,000 cm^2 of sanitized non-porous food-contact surfaces. This contact area represents all the surface area from silverware, china, and glass used by a person who regularly eats three meals per day at an institutional or public facility. The surface area of counter tops that comes in contact with food is expected to be smaller than the surface area for food utensils. As a conservative estimate, EPA assumed that 2,000 cm^2 of treated counter top surface area, comes into contact with an individual's food per day. Third, EPA assumes that 100% of the material present on food contact surfaces will migrate to food. A complete description of the approach used to assess dietary exposures resulting from food contact sanitizing solution uses of sodium xylene sulfonates can be found at *http://www.regulations.gov* in document Decision Document for Petition Number 1E7936, pp. 16 of 30 in docket ID number EPA–HQ–OPP–2011–0951.

In conducting the acute and chronic dietary exposure assessments for sodium xylene sulfonate, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data are available for sodium xylene sulfonate. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms.

First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 50% of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity.

Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100% of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient.

In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues of magnitude higher than actual residues in food when distributed in commerce. Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for sodium xylene sulfonate, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for sodium xylene sulfonate. These values were directly entered into the dietary exposure model. Further details of this drinking water analysis can be found at *http://www.regulations.gov* in document ''Decision Document for Petition Number 1E7936'', pp. 16 of 30 in docket ID number EPA–HQ–OPP–2011–0951.

The proposed use of sodium xylene sulfonate will not result in its presence in surface water or ground water and therefore not contribute to dietary exposure.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Sodium xylene sulfonate is not used as an inert ingredient in pesticide products that are registered for specific uses that may result in either indoor and outdoor residential exposures. However, sodium xylene sulfonate is used as a component of personal care products. The OECD SIDS Assessment estimated highest human exposures resulting from personal care product use. The exposure estimates ranged from 0.02–0.14 mg/kg/day for shampoos and hair conditioners to 0.11–0.17 mg/kg/day for liquid face and hand soaps. Exposure estimates for cleaning product use and residuals on clothing range from 0.01–0.08 mg/kg/day. All exposure evaluations included conservative (protective) input assumptions (e.g., all modeled human exposures are conservative due to the use of a default assumption of 100% absorption). However, the physicochemical data and available toxicological data suggest that dermal absorption is likely to be minimal. Based on the lack of concern for dermal toxicity and the low estimates of residential exposure, a quantitative residential risk assessment was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other

substances that have a common mechanism of toxicity.''

EPA has not found sodium xylene sulfonate to share a common mechanism of toxicity with any other substances, and sodium xylene sulfonate does not appear to produce a toxic metabolite produced by other substances. However, there are other chemicals belonging to the xylene sulfonate class of chemicals that may have a similar toxicity profile but these chemicals will be used as an alternative to sodium xylene sulfonate. Therefore, a cumulative risk assessment was not performed. Furthermore, the cPAD for pesticidal uses occupies only 7% of the cPAD for the general population and any potential increase in exposure to this class of chemicals will still be below any levels of concern. For the purposes of this tolerance action, therefore, EPA has assumed that sodium xylene sulfonate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There are no reproductive toxicity studies reported for sodium xylene sulfonate. However, no effects on reproductive organs were observed at very high doses in number of studies such as a 91-day oral rat feeding study with sodium cumene sulfonate, the 90-day feeding study with sodium xylene sulfonate, and the 2-year dermal studies with sodium xylene sulfonate. Based on the above evidence, EPA concluded that sodium xylene sulfonate is not likely to be reproductive toxicant. This conclusion is in agreement with the OECD conclusion that there is no evidence to suggest that sodium xylene sulfonate would have an adverse effect on reproductive organs.

In a developmental toxicity study in rats with calcium xylene sulfonate, no maternal or developmental effects were observed at doses of 3,000 mg/kg/day (equal to 936 mg/kg/day corrected for purity of test material).

There is no evidence of prenatal or postnatal sensitivity as a result of exposure to sodium xylene sulfonate.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to [1X]. That decision is based on the following findings:

i. Available studies included several 90-day toxicity studies via oral and dermal routes, chronic studies, mutagenicity battery, a developmental study in rats and metabolism studies. These studies provide an adequate characterization of sodium xylene sulfonate toxicity.

ii. There is no indication that sodium xylene sulfonate is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. No reproductive toxicity study or developmental toxicity study are available for sodium xylene sulfonate. However, the concern for increased susceptibility of infants and children exposure to sodium xylene sulfonate are low because no effects on reproductive parameters were observed in various oral toxicity studies and the developmental toxicity in rats for a surrogate chemical show lack of systemic toxicity at doses up to 936 mg/kg/day (mentioned under pre and post natal susceptibility).

iv. No evidence of immunotoxicity was observed in the database except slightly decreased in spleen weight was observed at the LOAEL of 3,454 mg/kg bw/day. There are no concerns for immunotoxicity and an immunotoxicity study is not required because the slight decreased in spleen weights were observed at high doses without any evidence of histopathological findings.

v. No additional uncertainty factor is needed for the use of subchronic study data for chronic exposure assessment. The rational for this decision is provided in Unit IV.B.

vi. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to sodium xylene sulfonate in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by sodium xylene sulfonate.

E. Aggregate Risks and Determination of Safety

Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, sodium xylene sulfonate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sodium xylene sulfonate from food and water including those uses for which tolerance exemptions under 40 CFR (180. 910, and 40 CFR 180.930 exist) will utilize 7% of the cPAD for the U.S. population and 26% of the cPAD for children 1–2 years old, the population subgroup receiving the greatest exposure. There are no residential uses for sodium xylene sulfonate.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, sodium xylene sulfonate is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective

cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for sodium xylene sulfonate.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, sodium xylene sulfonate is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for sodium xylene sulfonate.

5. *Aggregate cancer risk for U.S. population.* Based upon no evidence of carcinogenicity in two adequate rodent carcinogenicity studies via the dermal route of exposure, negative response for mutagenicity in a battery of genotoxicity tests, and lack of any structural alerts for carcinogenicity, sodium xylene sulfonate is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to sodium xylene sulfonate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of xylene sulfonic acid, sodium salt in or on any food commodities. EPA is establishing a limitation on the amount of xylene sulfonic acid, sodium salt that may be used in pesticide formulations. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution for which the final end use concentration of xylene sulfonic acid, sodium salt in antimicrobial, food contact surface sanitizing solutions would exceed 500 ppm.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for sodium xylene sulfonate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for xylenesulfonic acid, sodium salt (CAS Reg. No. 1300–72–7) when used as an inert ingredient in antimicrobial formulations in pesticide formulations applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils at a maximum of 500 parts per million of final solution. Additionally the exemption from the requirement of a tolerance for xylenesulfonic acid under 40 CFR 180.940(c), can be removed as the establishment of a broader exemption from the requirement of a tolerance for xylenesulfonic acid under 180.940(a) obviates the need for 40 CFR 180.940(c) tolerance exemption.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 1, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.940 is amended by adding the entry ''Xylenesulfonic acid, sodium salt'' to the table in paragraph (a) and removing the entry for ''Xylenesulfonic acid'' in the table in paragraph (c) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

(a) * * *

Pesticide chemical	CAS Reg. No.	Limits
*	*	* * * * *
Xylenesulfonic acid, sodium salt.	1300–72–7	When ready for use, the end-use concentration is not to exceed 500 ppm.

* * * * *

[FR Doc. 2012–27406 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–1029; FRL–9368–2]

1,4-Dimethylnaphthalene; Amendment to an Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-dimethylnaphthalene (1,4-DMN) by expanding the current exemption to include all sprouting root and tuber vegetables (EPA Crop Group 01) and all bulb vegetables (EPA Crop Group 03). On behalf of D-I-1-4, Inc., a division of 1,4Group, Inc., Technology Sciences Group, Inc. (TSG) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting that EPA amend the existing exemption from the requirement of a tolerance for 1,4-DMN. This regulation eliminates the need to establish a maximum permissible level for residues of 1,4-DMN under the FFDCA.

DATES: This regulation is effective November 16, 2012. Objections and requests for hearings must be received on or before January 15, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–1029, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The 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 Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Colin G. Walsh, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–0298; email address: *walsh.colin@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2011–1029 in the subject line on

the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 15, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–1029, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL–9335–9), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F7920) by TSG, Agent, 712 Fifth Street, Suite A, Davis, CA 95616, on behalf of D-I-1-4, Inc., a division of 1,4Group, Inc., P.O. Box 860, Meridian, ID 83680. The petition requested that 40 CFR 180.1142 be amended by expanding the current exemption to include all sprouting root, tuber, and bulb crops, thus establishing an exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-DMN, when applied postharvest to all sprouting root, tuber, and bulb crops in accordance with good agricultural practices. This notice referenced a summary of the petition prepared by the petitioner TSG, on behalf of D-I-1-4, Inc., a division of 1,4Group, Inc., which is available in the docket via *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.'' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider ''available information concerning the cumulative effects of [a particular pesticide's] * * * residues and other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

EPA established a tolerance exemption for 1,4-DMN in a Final Rule published in the **Federal Register** on February 8, 1995, (60 FR 7456–7457) (FRL–4932–4), which supported the plant growth regulator postharvest use on potatoes. The toxicological data submitted to support the previous tolerance exemption included the following: Acute (six-pack) toxicity, three mutagenicity studies, and a report of no hypersensitivity incidents for 1,4-DMN. The mutagenicity studies included an Ames test, an *in vitro* test for unscheduled DNA synthesis, and an *in vivo* micronucleus assay. All of the studies/information submitted to support the previous tolerance exemption indicated a lack of toxicity hazards for mammals, and EPA concluded that there is a reasonable certainty of no harm to humans, including infants and children, from the proposed food uses of 1,4-DMN. This amendment proposes to expand the tolerance exemption when applied postharvest to all sprouting root, tuber, and bulb crops in accordance with good agricultural practices. In support of this expansion of the tolerance exemption, new data have been generated by the petitioner and reviewed by EPA to address the developmental toxicity (OCSPP Guideline No. 870.3700) data requirement (the study was not submitted for the previous tolerance exemption). In addition, the petitioner submitted the following studies that were not required by EPA for this expansion of the tolerance exemption: *In vivo* unscheduled DNA synthesis, *in vitro* skin absorption, dermal sensitization, one-generation reproductive toxicity, and a combined chronic toxicity/carcinogenicity (OCSPP Guideline Nos. 870.5550, 870.7600, 870.2600, 870.3800, and 870.4300, respectively). The developmental data are required when the use of the substance under widespread and commonly recognized practices may reasonably be expected to result in significant exposure to humans, specifically females of child-bearing age. The rest of the toxicological profile as stated in the February 8, 1995 issue of the **Federal Register**, and referenced herein, has not changed. The data submitted for the previous tolerance exemption include the acute toxicity (six-pack) studies, three mutagenicity studies, and a report of no hypersensitivity incidents for 1,4-DMN. A copy of the February 8, 1995 final rule document (60 FR 7456–7457) and risk assessments cited herein (Refs. 1 and 2) are located under docket ID number EPA–HQ–OPP–2011–1029.

As discussed in the **Federal Register** of February 8, 1995 (60 FR 7456) and risk assessments (Refs. 1 and 2), 1,4-DMN is naturally occurring and has a nontoxic mode of action. 1,4-DMN is

found naturally occurring in potatoes (60 FR 7456) and detected in various other crops including cocoa, coffee, apples, corn, raisins, tomatoes, apricots, peaches, pear juice, eggplants, green peppers, star fruit, tea, radishes, oranges, cinnamon, poppies, and red beans (Ref. 1). When conditions are right for sprouting, the potato metabolizes 1,4-DMN to a low enough level so that sprouting can occur. 1,4-DMN is applied to postharvest sprouting root, tuber, and bulb stored crops at a level, generally 20 parts per million (ppm) up to 4 applications during a storage season, to continue to inhibit sprouting.

As stated previously in this Unit, new toxicity data have been submitted in support of the request by the petitioner to expand the current tolerance exemption to cover all sprouting root, tuber, and bulb crops. These data include: (1) A prenatal developmental toxicity study and (2) additional data not required by EPA, but used to further support the developmental data and this expansion of the tolerance exemption. All new data, coupled with the data submitted to support the previous tolerance exemption (60 FR 7456), confirm the minimal human health hazard effects, as reported in the original assessment of the tolerance exemption, associated with dietary exposures of 1,4-DMN and fully demonstrate the lack of mammalian toxicity. Summaries of the new toxicological data submitted in support of the expansion of the tolerance exemption follow.

A. Developmental Toxicity

A new developmental study (Master Record Identification (MRID) Number 48590905) was performed for 1,4-DMN to support the expansion of the tolerance exemption. 1,4-DMN was administered by oral gavage to female rabbits at the dose levels of 0, 25, 80, or 250 milligrams/per/day (mg/kg/day) (23 rabbits per test group) over gestation days 6 through 28. No treatment-related clinical signs were noted during the study, and gross necropsy findings were limited to those rabbits that underwent abortion (Ref. 1). The gross necropsy findings consisted of changes in the gastrointestinal tract (dilatation of stomach and/or intestines) and were likely related to the lack of eating prior to and during the abortion. Mean food consumption was significantly reduced in the 250 mg/kg/day treated doses shortly after treatment initiation (over gestation days 6 to 9 and 9 to 12). This reduction in food consumption was likely treatment-related. Corollary reductions in mean body weight gain were observed in the 250 mg/kg/day treated group over gestation days 6 to 9. Alterations in uterus weight were not observed, nor were changes seen in maternal body weight or body weight gain when corrected for uterus weight. As such, the changes seen early on in gestational body weight gain were considered to be solely associated with maternal toxicity. Therefore, the lowest observed adverse effect level (LOAEL) for maternal toxicity of 1,4-DMN in rats is 250 mg/kg/day based on reduced food consumption and reduced body weight gain. The no observed adverse effect level (NOAEL) for maternal toxicity is 80 mg/kg/day based on no effects observed at this dose.

For developmental toxicity, no treatment-related differences in litter viability were detected at any dose level tested. The number of male, female, and total fetuses (sexes combined) were similar across the treatment and control groups and average fetal weights were unaffected. No structural alterations, including gross external, visceral, skeletal, and cephalic, were evident from the fetal examinations; as such, 1,4-DMN did not produce any frank malformations and was not teratogenic. Based on no effects observed for developmental toxicity at any doses tested, the NOAEL for developmental toxicity is greater than 250 mg/kg/day (highest dose tested). The LOAEL was not identified for developmental toxicity, suggesting that the test animals could have tolerated a higher dose.

Based on the developmental toxicity data submitted for this expansion to the tolerance exemption, which showed no adverse effects at the highest dose tested, 250 mg/kg/day, there are sufficient data and information to confirm that 1,4-DMN is not a developmental toxicant. Therefore, the consumption of food commodities that have been treated with 1,4-DMN when used as a pesticide is safe and will not result in any harm to human health, specifically women of child-bearing age, from dietary exposure.

B. Additional Toxicity Data

Additional toxicity data for 1,4-DMN that were not required by EPA to support this expansion of the tolerance exemption were submitted by the petitioner. The additional data include the following: Unscheduled DNA synthesis (mutagenicity), *in vitro* skin absorption, dermal sensitization, one-generation reproductive toxicity, and a combined chronic toxicity/carcinogenicity study (OCSPP Guideline Nos. 870.5550, 870.7600, 870.2600, 870.3800, and 870.4300, respectively). Although the developmental data submitted were sufficient to support this expansion of the tolerance exemption, EPA has used this data, along with the required data submitted to support the previous tolerance exemption (60 FR 7456), to confirm that the consumption of food commodities that have been treated with 1,4-DMN when used as a pesticide is safe and will not result in any harm to human health from dietary exposure.

1. An *in vivo* unscheduled DNA synthesis in rats (MRID 48590902) showed no genotoxicity activity in rat livers when given a single dose of 1,4-DMN up to the limit dose of 1,000 mg/kg (Ref. 1). These results, combined with the lack of mutagenic and genotoxic effects observed in the bacterial reverse mutation (Ames) test, *in vitro* unscheduled DNA synthesis in mammalian cells, and *in vivo* mammalian erythrocyte micronucleus test submitted to support the previous tolerance exemption (60 FR 7456), confirm that 1,4-DMN is not a mutagen.

2. An *in vitro* precutaneous absorption test (MRID 48590903) in humans showed that the mean total dermal absorption of 1,4-DMN was 2.5% of the dose applied (Ref. 1). Based on the relatively low absorption of 1,4-DMN and the data submitted to support the previous tolerance exemption (60 FR 7456), which included an acute dermal toxicity study that showed a low acute dermal toxicity (median lethal dose $(LD)_{50} > 2,000$ mg/kg), 1,4-DMN is not considered a dermal toxicant.

3. A dermal sensitization test (MRID 48590904) utilizing the Local Lymph Node Assay (LLNA) method showed that 1,4-DMN is not a dermal sensitizer (Ref. 1). The dermal sensitization test utilizing the Buehler method submitted to support the previous tolerance exemption (60 FR 7456) also showed that 1,4-DMN is not a dermal sensitizer.

4. A one-generation reproductive toxicity study (MRID 48590906) was conducted on rats to assess systemic, developmental, and reproductive toxicity. 1,4-DMN was administered in the diet at the dose concentrations of 0, 500, 2,000, and 7,500 ppm with each dose group consisting of 24 males and 24 female rats. The results of the study showed that the NOAEL for systemic toxicity was 2,000 ppm (equivalent to 121 to 207 mg/kg/day in parental male and female rats and 184 to 213 mg/kg/day in F_1 males and females, respectively) and the LOAEL was 7,500 ppm based on a single histological change in the kidney of one, 7,500 ppm treated rat (Ref. 1). The NOAEL and LOAEL for developmental toxicity were also 2,000 ppm and 7,500 ppm, respectively, based on delayed vaginal

patency and preputial separation in the 7,500 ppm group; although, the delay in development was considered secondary to body weight effects that were attributed to reduced food consumption. The NOAEL for reproductive toxicity was 7,500 ppm (equivalent to 441 to 591 mg/kg/day in parental male and female rats and 776 to 839 mg/kg/day in F_1 males and females, respectively) based on the lack of change in reproductive endpoints such as mating performance, fertility, fecundity, litter survival, sperm morphology/vaginal cytology as well as the lack of histological change in the reproductive organs. The LOAEL was not identified for reproductive toxicity, suggesting that the test animals could have tolerated a higher dose.

Based on the reproductive toxicity data submitted for this expansion to the tolerance exemption, which showed no adverse reproductive effects at the highest dose tested, 7,500 ppm (equivalent to 441 to 591 mg/kg/day in parental male and female rats and 776 to 839 mg/kg/day in F_1 males and females, respectively), there are sufficient data and information to confirm that 1,4-DMN is not a reproductive toxicant, and that consumption of food commodities that have been treated with this substance when used as a pesticide is safe and will not result in any harm to human health from dietary exposure.

5. A combined chronic toxicity and carcinogenicity study (MRID 48590907) was conducted on rats (65 rats/sex/group for carcinogenicity and 20 rats/sex/group for chronic toxicity) to assess the chronic toxicity and carcinogenicity potential for 1,4-DMN. 1,4-DMN was administered in the diet of rats 7 days/week for a minimum of 52 weeks (chronic toxicity phase) or 104 weeks (carcinogenicity phase), at the dose concentrations of 0, 150, 500, and 3,750 ppm, equivalent to the dose concentrations of 0, 10, 33, and 250 mg/kg/day. For the chronic study, decreased food consumption with concurrent decreases in body weight and body weight gain were noted in the 250 mg/kg/day dose group. Minimal to moderate histologic test material-related effects in the kidney (proteinosis, papillary necrosis and karyomegaly) were noted in male rats at 250 mg/kg/day, while minimal to mild karyomegaly was noted in the kidney of female rats administered 1,4-DMN at dosages of 33 or 250 mg/kg/day. Based on the results of the chronic toxicity study, the NOAEL for chronic toxicity was 33 mg/kg/day for males and 10 mg/kg/day for females. For the carcinogenicity study, no incidences of carcinogenicity were noted in rats in any of the dose concentrations after the 97 weeks and 104 weeks of treatment for female and male rats, respectively.

Based on the results of the carcinogenicity data submitted for this expansion to the tolerance exemption, which showed that there was no evidence of carcinogenicity at the highest dose tested, 3,750 ppm (equivalent to 250 mg/kg/day), there are sufficient data and information to confirm that 1,4-DMN is not a carcinogen, and that consumption of food commodities that have been treated with this substance when used as a pesticide is safe and will not result in any harm to human health from dietary exposure.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Dietary risks to humans are considered negligible based on the lack of significant dietary toxicological endpoints for 1,4-DMN, its non-toxic mode of action, and the fact that it is applied to postharvest root, tuber, and bulb crops at the relatively low application rate of 20 ppm up to four applications during the storage season. No significant acute, subchronic, mutagenic, developmental, chronic, or carcinogenicity dietary toxicity hazards were identified in the studies submitted to support this expansion of the tolerance exemption or the previous tolerance exemption (60 FR 7456). The submitted data and information for this expansion of the tolerance exemption show that any residues of 1,4-DMN found in or on the sprouting root, tuber, and bulb crops are far below any toxicological endpoints identified in this expansion of the tolerance exemption or in the previous tolerance exemption (60 FR 7456) and confirm 1,4-DMN's lack of dietary toxicity hazards for mammals (Ref. 2).

1. *Food.* The petitioner submitted a scientific literature summary of the natural occurrence of 1,4-DMN in food crops (MRID 48653101) to support the expansion of the tolerance exemption from postharvest use on potatoes only, which are found in EPA Crop Group 01, to include all other sprouting root and tuber vegetables in the same EPA Crop Group 01 and all bulb vegetables (EPA Crop Group 03). Bulb vegetables include garlic, leek, onion, rakkyo, and shallot. As stated in the summary, 1,4-DMN has been detected in various crops including cocoa, coffee, apples, corn, raisins, tomatoes, apricots, peaches, pear juice, eggplants, green peppers, star fruit, tea, radishes (EPA Crop Group 01), oranges, cinnamon, poppies, and red beans (Ref. 1). It is likely that 1,4-DMN occurs naturally in other crops not listed in the literature summary, including crops in EPA Crop Group 01 (besides the already listed potatoes and radishes), and bulb crops in EPA Crop Group 03. The literature summary also indicated that the isomers of dimethylnaphthalene were shown to be present in various crops; however, the research indicates that it is extremely difficult to measure the amounts of the natural occurrence due to the volatility of the dimethylnaphthalene isomers, and any amounts reported are most likely an underestimation of the actual amount naturally present in the crop. As stated in Unit III of this final rule, the previous tolerance exemption (60 FR 7456) indicated that 1,4-DMN is found naturally occurring in potatoes. When conditions are right for sprouting, the potato metabolizes 1,4-DMN to a low enough level so that sprouting can occur. 1,4-DMN is applied to postharvest potatoes at a level, generally 20 ppm up to four applications during a storage season, to maintain 1,4-DMN at a sufficient concentration in the potato to continue to inhibit sprouting.

Based on the submitted data and information for this expansion of the tolerance exemption, any residues of 1,4-DMN found in or on the sprouting root, tuber, and bulb crops are far below any toxicological endpoints identified in this expansion of the tolerance exemption or in the previous tolerance exemption (60 FR 7456). These toxicological endpoints identified in Unit III of this final rule include: Maternal toxicity NOAEL of 80 mg/kg/day, developmental toxicity NOAEL greater than 250 mg/kg/day, reproductive toxicity NOAEL of 7,500 ppm (equivalent to 441 to 591 mg/kg/day in parental male and female rats and 776 to 839 mg/kg/day in F_1 males and females, respectively), and chronic toxicity NOAEL of 33 mg/kg/day (500 ppm) for males and 10 mg/kg/day (150 ppm) for females. The previous tolerance exemption showed an acute oral toxicity LD_{50} of 2,730 mg/kg/day. In addition, under the conditions of the respective studies, there were no signs of mutagenicity or carcinogenicity for 1,4-DMN. In summary, the toxicity data

submitted for 1,4-DMN, the natural occurrence of the substance in the various crops listed in this section, the nontoxic mode of action, the volatility of the isomers of dimethylnaphthalene, and the fact that it is applied to postharvest root, tuber, and bulb crops at the relatively low application rate of 20 ppm up to four applications during the storage season, demonstrate a lack of aggregate dietary risk that is sufficient to support this expansion of the tolerance exemption.

2. *Drinking water exposure.* No new drinking water exposure is expected to result from the new food uses of 1,4-DMN. Exposure of humans to 1,4-DMN in drinking water is highly unlikely since the products are labeled for postharvest application to sprouting root, tuber, and bulb crops stored in indoor facilities and are not applied directly to crops in the field. The data and information demonstrate a lack of aggregate dietary risk via drinking water and is sufficient to support this expansion of the tolerance exemption.

B. Other Non-Occupational Exposure

No new non-occupational exposure is expected to result from the new food uses of 1,4-DMN. No health risks are expected from any non-occupational exposure to 1,4-DMN based on the data submitted for the previous tolerance exemption (60 FR 7456) and for this expansion of the tolerance exemption.

1. *Dermal exposure.* No new non-occupational dermal exposure is expected to result from the new food uses of 1,4-DMN resulting from this expansion of the tolerance exemption. Any new dermal exposure associated with this expansion of the tolerance exemption is expected to be occupational in nature.

2. *Inhalation exposure.* No new non-occupational inhalation exposure is expected to result from the new food uses of 1,4-DMN resulting from this expansion of the tolerance exemption. Any new inhalation exposure associated with this expansion of the tolerance exemption is expected to be occupational in nature.

V. Cumulative Effects from Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information concerning the cumulative effects of [a particular pesticide's] * * * residues and other substances that have a common mechanism of toxicity.''

EPA has not found 1,4-DMN to share a common mechanism of toxicity with any other substances, and 1,4-DMN does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 1,4-DMN does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Relevant data and information submitted for the previous tolerance exemption (60 FR 7456) and for this expansion of the tolerance exemption indicate that 1,4-DMN has negligible acute, subchronic, mutagenic, developmental, chronic, or carcinogenicity toxicity hazards. Moreover, 1,4-DMN has a nontoxic mode of action and naturally occurs in various crops as listed in Unit IV.A.1. Therefore, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of 1,4-DMN. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because the data and information available on 1,4-DMN do not demonstrate significant toxic potential to mammals. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated above, and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 1,4-DMN.

VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of 1,4-DMN. Therefore, the existing exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-DMN, when applied postharvest to potatoes is amended by establishing the exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-DMN, when applied postharvest to sprouting root, tuber, and bulb crops in accordance with good agricultural practices.

IX. References

The following references used in this document and the previous Final Rule published in the **Federal Register** on February 8, 1995, (60 FR 7456) (FRL–4932–4) are in the OPP docket listed under docket ID EPA–HQ–OPP–2011–1029 and may be seen by accessing the *www.regulations.gov* Web site.

1. U.S. EPA. 2012. Memorandum from Gina M. Burnett to Colin Walsh. Science Review of Tolerance Petition 1F7920,

Intended to Expand the Use of 1,4-Dimethylnaphthalene to Include Use on All Root and Tuber Vegetables (Crop Group 01) and Bulb Vegetables (Crop Group 03); Label Amendments for 67727–1, –3 and –4 Upon Tolerance Amendment Approval. U.S. Environmental Protection Agency, Office of Pesticide Programs. March 16, 2012.

2. U.S. EPA. 2012. Memorandum from Russell S. Jones, Ph.D., to Colin Walsh. Science Review of Registrant's Response to Deficiencies in Tolerance Petition 1F7920, Intended to Expand the Use of 1,4-Dimethylnaphthalene to Include Use on All Root and Tuber Vegetables (Crop Group 01) and Bulb Vegetables (Crop Group 03); Label Amendments for 67727–1, –3 and –4 Upon Tolerance Amendment Approval. U.S. Environmental Protection Agency, Office of Pesticide Programs. June 21, 2012.

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 26, 2012.

Keith A. Mathews,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Revise § 180.1142 to read as follows:

§ 180.1142 1,4-Dimethylnaphthalene; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of the plant growth regulator, 1,4-dimethylnaphthalene (1,4-DMN), when applied postharvest to all sprouting root, tuber, and bulb crops in accordance with good agricultural practices.

[FR Doc. 2012–27809 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2012–0003; Internal Agency Docket No. FEMA–8255]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *http://www.fema.gov/fema/csb.shtm.*

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Federal Insurance and Mitigation

Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/ cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region IV				
South Carolina:				
Greeleyville, Town of, Williamsburg County.	450188	July 15, 1975, Emerg; June 25, 1976, Reg; November 16, 2012, Susp.	November 16, 2012 ..	November 16, 2012.
Hemingway, Town of, Williamsburg County.	450189	July 25, 1975, Emerg; April 2, 1986, Reg; November 16, 2012, Susp.	.....do*	Do.
Kingstree, Town of, Williamsburg County.	450190	December 20, 1974, Emerg; September 1, 1987, Reg; November 16, 2012, Susp.	.....do	Do.
Lane, Town of, Williamsburg County.	450191	July 23, 1975, Emerg; August 5, 1986, Reg; November 16, 2012, Susp.	.....do	Do.

State and location	Community No.	Effective date authorization/ cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Stuckey, Town of, Williamsburg County.	450192	July 17, 1975, Emerg; September 1, 1986, Reg; November 16, 2012, Susp.	.....do	Do.
Williamsburg County, Unincorporated Areas..	450187	March 12, 1975, Emerg; February 6, 1991, Reg; November 16, 2012, Susp.	.....do	Do.
Region IX				
California:				
Grover Beach, City of, San Luis Obispo County.	060306	March 27, 1975, Emerg; August 1, 1984, Reg; November 16, 2012, Susp.	.....do	Do.
San Luis Obispo, City of, San Luis Obispo County.	060310	August 3, 1973, Emerg; April 16, 1979, Reg; November 16, 2012, Susp.	.....do	Do.
San Luis Obispo County, Unincorporated Areas.	060304	June 26, 1974, Emerg; July 5, 1982, Reg; November 16, 2012, Susp.	.....do	Do.

* -do- = Ditto.
Code for reading third column: Emerg. —Emergency; Reg. —Regular; Susp. —Suspension.

Dated: November 9, 2012.

David L. Miller,

Associate Administrator, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2012–27846 Filed 11–15–12; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

RIN 0750–AH79

Defense Federal Acquisition Regulation Supplement: New Free Trade Agreement—Panama (DFARS Case 2012–D044)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule.

SUMMARY: DoD is issuing an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement the United States-Panama Trade Promotion Agreement. This Trade Promotion Agreement is a free trade agreement that provides for mutually non-discriminatory treatment of eligible products and services from Panama.

DATES: *Effective date:* November 16, 2012.

Comment date: Comments on the interim rule should be submitted in writing to the address shown below on or before January 15, 2013, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2012–D044, using any of the following methods:

Regulations.gov: http://www.regulations.gov. Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2012–D044'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2012–D044.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2012–D044'' on your attached document.

Email: dfars@osd.mil. Include DFARS Case 2012–D044 in the subject line of the message.

Fax: 571–372–6094.

Mail: Defense Acquisition Regulations System, Attn: Ms. Amy Williams, OUSD(AT&L)DPAP/DARS, Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov*, including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov*, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, Defense Acquisition Regulations System, OUSD(AT&L)DPAP/DARS, Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060. Telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

This interim rule amends DFARS part 252 to implement the United States-Panama Trade Promotion Agreement Implementation Act (Pub. L. 112–43) (19 U.S.C. 3805 note).

This Trade Promotion Agreement is designated in the FAR as the Panama Free Trade Agreement (FTA). The FTA provides for—

- Waiver of the applicability of the Buy American statute (41 U.S.C. chapter 83) for some foreign supplies and construction materials from Panama; and
- Applicability of specified procurement procedures designed to ensure fairness in the acquisition of supplies and services (see FAR 25.408).

II. Discussion and Analysis

This interim rule adds Panama to the definition of ''Free Trade Agreement country'' in multiple locations in the DFARS. The Panama FTA covers acquisitions of supplies and services equal to or exceeding $202,000. The Panama FTA threshold for supplies and services is higher than the threshold for supplies and services for most of the FTAs ($77,494), and equals the Bahrain, Morocco, and Peru FTA thresholds for supplies and services ($202,000). Therefore, for acquisition less than $202,000 (or $100,000 for Korea), all FTAs are applicable except for the Bahrain, Korea, Morocco, Panama, and Peru FTAs.

Because the Panama FTA's construction threshold of $7,777,000 is the same as the WTO GPA threshold, no new clause alternates are required for the Balance of Payments Program—

Construction Material under Trade Agreements clause (DFARS 252.225–7045).

There are also conforming changes to the clause at DFARS 252.212–7001, Contract Terms and Conditions Required to Implement Statutes or Executive Orders Applicable to Defense Acquisitions of Commercial Items.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Although the rule now opens up Government procurement to the goods and services of Panama at or above the threshold of $202,000, DoD does not anticipate any significant economic impact on U.S. small businesses. The Department of Defense only applies the trade agreements to the non-defense items listed at DFARS 225.401–70, and acquisitions that are set aside or provide other forms of preference for small businesses are exempt. FAR 19.502–2 states that acquisitions that do not exceed $150,000 (with some exceptions) are automatically reserved exclusively for small business concerns. Therefore, DoD has not performed an Initial Regulatory Flexibility Analysis. DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2012–D044), in correspondence.

V. Paperwork Reduction Act

This rule affects the certification and information collection requirements in the provisions at DFARS 252.225–7020 and 252.225–7035, currently approved under OMB Control Number 0704–229, titled Defense Federal Acquisition Regulation Supplement part 225, Foreign Acquisition, and related clauses, in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The impact, however, is negligible, because it is just a question of under which category offered goods from Panama would be listed. The rule also affects DFARS 252.225–7018, which is a variant of the Buy American-trade agreements certifications already approved, which was issued as an interim rule under DFARS Case 2011–D046 (76 FR 78858, December 20, 2011).

VI. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense that urgent and compelling reasons exist to promulgate this interim rule without prior opportunity for public comment. This action is necessary because the Free Trade Agreement with Panama, for which the President signed the implementing legislation into law on October 21, 2012 (Pub. L. 112–043), took effect on October 31, 2012. This is a reciprocal agreement, approved by Congress and the President of the United States. It is important for the United States Government to honor its new trade obligations to Panama, as Panama in turn honors the new trade obligations to the United States. However, pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), DoD will consider public comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 48 CFR Part 252

Government procurement.

Manuel Quinones,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 252 is amended as follows:

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for 48 CFR part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

252.212–7001 [Amended]

■ 2. Section 252.212–7001 is amended as follows:

■ a. The clause heading is amended by removing the clause date ''(JUN 2012)'' and adding ''(NOV 2012)'' in its place.

■ b. Paragraph (b)(12) is amended by removing the clause date ''(JUN 2012)'' and adding ''(NOV 2012)'' in its place.

■ c. Paragraph (b)(13)(i) is amended by removing the clause date ''(JUN 2012)'' and adding ''(NOV 2012)'' in its place.

■ d. Paragraphs (b)(16)(i), (iii), (v), and (vi) are amended by removing the clause date ''(JUN 2012)'' and adding ''(NOV 2012)'' in its place.

■ 3. Section 252.225–7017 is amended—

■ a. In the clause heading, by removing the clause date ''(AUG 2012)'' and adding ''(NOV 2012)'' in its place;

■ b. In paragraph (a):

■ i. In the definition of ''designated country'', paragraph (ii), by adding in alphabetical order the country ''Panama,'';

■ ii. In the definition of ''Free Trade Agreement country'', by adding in alphabetical order the country ''Panama,''; and

■ iii. By adding in alphabetical order a definition for ''Panamanian photovoltaic device'';

■ c. By revising paragraphs (c)(3)and (4).

The additions and revisions read as follows:

252.225–7017 Photovoltaic Devices.

* * * * *

(a) * * *

''Panamanian photovoltaic device'' means an article that—

(i) Is wholly manufactured in Panama; or

(ii) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in Panama into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

* * * * *

(c) * * *

(3) $77,494 or more but less than $100,000, then the Contractor shall utilize under this contract only domestic photovoltaic devices, qualifying country photovoltaic devices, or Free Trade Agreement country photovoltaic devices (other than Bahrainian, Korean, Moroccan, Panamanian, or Peruvian photovoltaic devices), unless, in its offer, it specified utilization of other foreign photovoltaic devices in paragraph (c)(4)(ii) of the Photovoltaic Devices—Certificate provision of the solicitation. If the Contractor certified in its offer that it will utilize a qualifying country photovoltaic device or a Free Trade

Agreement country photovoltaic device (other than a Bahrainian, Korean, Moroccan, Panamanian, or Peruvian photovoltaic device), the Contractor shall utilize a qualifying country photovoltaic device; a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Korean, Moroccan, Panamanian, or Peruvian photovoltaic device), or, at the Contractor's option, a domestic photovoltaic device;

(4) $100,000 or more but less than $202,000, then the Contractor shall utilize under this contract only domestic photovoltaic devices, qualifying country photovoltaic devices, or Free Trade Agreement country photovoltaic devices (other than Bahrainian, Moroccan, Panamanian or Peruvian photovoltaic devices), unless, in its offer, it specified utilization of other foreign photovoltaic devices in paragraph (c)(4)(ii) of the Photovoltaic Devices—Certificate provision of the solicitation. If the Contractor certified in its offer that it will utilize a qualifying country photovoltaic device or a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Moroccan, Panamanian, or Peruvian photovoltaic device), the Contractor shall utilize a qualifying country photovoltaic device; a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Moroccan, Panamanian, or Peruvian photovoltaic device), or, at the Contractor's option, a domestic photovoltaic device; or

* * * * *

■ 4. Section 252.225–7018 is amended by removing the clause date ''(MAY 2012)'' and adding ''(NOV 2012)'' in its place and revising paragraphs (a), (c)(4), and (c)(5) to read as follows:

252.225–7018 Photovoltaic Devices—Certificate.

* * * * *

(a) *Definitions.* ''Bahrainian photovoltaic device,'' ''Canadian photovoltaic device,'' ''Caribbean Basin photovoltaic device,'' ''designated country,'' ''domestic photovoltaic device,'' ''foreign photovoltaic device,'' ''Free Trade Agreement country,'' ''Free Trade Agreement photovoltaic device,'' ''Korean photovoltaic device,'' ''least developed country photovoltaic device,'' ''Moroccan photovoltaic device,'' ''Panamanian photovoltaic device,'' ''Peruvian photovoltaic device,'' ''photovoltaic device,'' ''qualifying country,'' ''qualifying country photovoltaic device,'' ''United States,'' ''U.S.-made photovoltaic device,'' and ''WTO GPA country photovoltaic device'' have the meanings given in the Photovoltaic Devices clause of this solicitation.

* * * * *

(c) * * *

(4) If $77,494 or more but less than $100,000—

____(i) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a domestic photovoltaic device; a qualifying country (except Australian or Canadian) photovoltaic device; a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Korean, Moroccan, Panamanian, or Peruvian photovoltaic device) [*Offeror to specify country of origin*_____]; or

____(ii) The offered foreign photovoltaic devices (other than those from countries listed in paragraph (c)(4)(i) of this provision) are the product of _____. [*Offeror to specify country of origin, if known, and provide documentation that the cost of a domestic photovoltaic device would be unreasonable in comparison to the cost of the proposed foreign photovoltaic device.*]

(5) If $100,000 or more but less than $202,000—

____(i) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a domestic photovoltaic device; a qualifying country (except Australian or Canadian) photovoltaic device; a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Moroccan, Panamanian, or Peruvian photovoltaic device) [*Offeror to specify country of origin*_____]; or

____(ii) The offered foreign photovoltaic devices (other than those from countries listed in paragraph (c)(4)(i) of this provision) are the product of _____. [*Offeror to specify country of origin, if known, and provide documentation that the cost of a domestic photovoltaic device would be unreasonable in comparison to the cost of the proposed foreign photovoltaic device.*]

* * * * *

■ 5. Section 252.225–7021 is amended by removing the clause date ''(JUN 2012)'' and adding ''(NOV 2012)'' in its place, and in paragraph (a), in the definition for ''designated country,'' by revising paragraph (ii) to read as follows:

252.225–7021 Trade agreements.

* * * * *

(a) * * *

''Designated country'' means—

* * * * *

(ii) A Free Trade Agreement country (Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Panama, Peru, or Singapore);

* * * * *

■ 6. Section 252.225–7035 is amended by—

■ a. Removing the clause date ''(JUN 2012)'' and adding ''(NOV 2012)'' in its place;

■ b. Adding the paragraph designation ''(a)'' to the ''Definitions'' paragraph;

■ c. Revising newly designated paragraph (a) and paragraphs (b) and (c); and

■ d. Revising alternates I, II, IV, and V.

The revisions read as follows:

252.225–7035 Buy American—Free Trade Agreements—Balance of Payments Program Certificate.

* * * * *

(a) *Definitions.* ''Bahrainian end product,'' ''commercially available off-the-shelf (COTS) item,'' ''component,'' ''domestic end product,'' ''Free Trade Agreement country,'' ''Free Trade Agreement country end product,'' ''foreign end product,'' ''Moroccan end product,'' ''Panamanian end product,'' ''Peruvian end product,'' ''qualifying country end product,'' and ''United States,'' as used in this provision, have the meanings given in the Buy American—Free Trade Agreements—Balance of Payments Program clause of this solicitation.

(b) *Evaluation.* The Government—

(1) Will evaluate offers in accordance with the policies and procedures of Part 225 of the Defense Federal Acquisition Regulation Supplement; and

(2) For line items subject to Free Trade Agreements, will evaluate offers of qualifying country end products or Free Trade Agreement country end products other than Bahrainian end products, Moroccan end products, Panamanian end products, or Peruvian end products without regard to the restrictions of the Buy American or the Balance of Payments Program.

(c) *Certifications and identification of country of origin.* (1) For all line items subject to the Buy American—Free Trade Agreements—Balance of Payments Program clause of this solicitation, the offeror certifies that—

(i) Each end product, except the end products listed in paragraph (c)(2) of this provision, is a domestic end product; and

(ii) Components of unknown origin are considered to have been mined, produced, or manufactured outside the United States or a qualifying country.

(2) The offeror shall identify all end products that are not domestic end products.

(i) The offeror certifies that the following supplies are qualifying country (except Australian or Canadian) end products:

(*Line Item Number*)

(*Country of Origin*)

(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products other than Bahrainian end products, Moroccan end products, Panamanian end products or Peruvian end products:

(*Line Item Number*)

(*Country of Origin*)

(iii) The following supplies are other foreign end products, including end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (ii) of the definition of ''domestic end product'':

(*Line Item Number*)

(*Country of Origin* (If known))

* * * * *

ALTERNATE I (NOV 2012)

As prescribed in 225.1101(10)(ii), substitute the phrase ''Canadian end product'' for the phrases ''Bahrainian end product,'' ''Free Trade Agreement country,'' ''Free Trade Agreement country end product,'' ''Moroccan end product,'' ''Panamanian end product,'' and ''Peruvian end products'' in paragraph (a) of the basic provision; substitute the phrase ''Canadian end products'' for the phrase ''Free Trade Agreement country end products other than Bahrainian end products, Moroccan end products, or Peruvian end products'' in paragraphs (b)(2) and (c)(2)(ii) of the basic provision; and delete the phrase ''Australian or'' from paragraph (c)(2)(i) of the basic provision.

ALTERNATE II (NOV 2012)

As prescribed in 225.1101(10)(iii), add the terms ''South Caucasus/Central and South Asian (SC/CASA) state'' and ''South Caucasus/Central and South Asian (SC/CASA) state end product'' in paragraph (a) and substitute the following paragraphs (b)(2) and (c)(2)(i) for paragraphs (b)(2) and (c)(2)(i) of the basic clause.

(b)(2) For line items subject to Free Trade Agreements, will evaluate offers of qualifying country end products, SC/CASA state end products, or Free Trade Agreement country end products other than Bahrainian end products, Moroccan end products, Panamanian end products, or Peruvian end products without regard to the restrictions of the Buy American or the Balance of Payments Program.

(c)(2)(i) The offeror certifies that the following supplies are qualifying country (except Australian or Canadian) or SC/CASA state end products:

(*Line Item Number*)

(*Country of Origin*)

(End of provision)

* * * * *

ALTERNATE IV (NOV 2012)

As prescribed in 225.1101(10)(v), add a definition of ''Korean end product'' in paragraph (a) of the basic provision; substitute the phrase ''Free Trade Agreement country end products other than Bahrainian end products, Korean end products, Moroccan end products, Panamanian end products, or Peruvian end products'' for the phrase ''Free Trade Agreement country end products other than Bahrainian end products, Moroccan end products, Panamanian end products, or Peruvian end products'' in paragraphs (b)(2) and (c)(2)(ii) of the basic provision.

ALTERNATE V (NOV 2012)

As prescribed in 225.1101(10)(vi), substitute the following paragraphs (a), (b)(2), (c)(2)(i), and (c)(2)(ii) for paragraphs (a), (b)(2), (c)(2)(i), and (c)(2)(ii) of the basic clause:

(a) *Definitions.* ''Bahrainian end product,'' ''commercially available off-the-shelf (COTS) item,'' ''component,'' ''domestic end product,'' ''Free Trade Agreement country,'' ''Free Trade Agreement country end product,'' ''foreign end product,'' ''Korean end product,'' ''Moroccan end product,'' ''Panamanian end product,'' ''Peruvian end product,'' ''qualifying country end product,'' ''South Caucasus/Central and South Asian (SC/CASA) state end product,'' and ''United States,'' as used in this provision, have the meanings given in the Buy American Act—Free Trade Agreements—Balance of Payments Program clause of this solicitation.

(b)(2) For line items subject to Free Trade Agreements, will evaluate offers of qualifying country end products, SC/CASA state end products, or Free Trade Agreement end products other than Bahrainian end products, Korean end products, Moroccan end products, Panamanian end products, or Peruvian end products without regard to the restrictions of the Buy American Act or the Balance of Payments Program.

(c)(2)(i) The offeror certifies that the following supplies are qualifying country (except Australian or Canadian) or SC/CASA state end products:

(*Line Item Number*)

(*Country of Origin*)

(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products other than Bahrainian end products, Korean end products, Moroccan end products, Panamanian end products, or Peruvian end products:

(*Line Item Number*)

(*Country of Origin*)

■ 7. Section 252.225–7036 is amended by

■ a. Removing the clause date ''(JUN 2012)'' and adding ''(NOV 2012)'' in its place;

■ b. In paragraph (a), in the definition of ''Free Trade Agreement country,'' adding in alphabetical order the country of ''Panama,'';

■ c. In paragraph (a), adding in alphabetical order a definition for ''Panamanian end product''; and

■ d. Revising paragraph (c) and ALTERNATE II, IV, and V.

The additions and revisions read as follows:

252.225–7036 Buy American—Free Trade Agreements—Balance of Payments Program.

* * * * *

(a) * * *

''Panamanian end product'' means an article that—

(i) Is wholly the growth, product, or manufacture of Panama; or

(ii) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in Panama into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to its supply, provided that the value of those incidental services does not exceed the value of the product itself.

* * * * *

(c) The Contractor shall deliver under this contract only domestic end

products unless, in its offer, it specified delivery of qualifying country end products, Free Trade Agreement country end products other than Bahrainian end products, Moroccan end products, Panamanian end products, or Peruvian end products, or other foreign end products in the Buy American—Free Trade Agreements—Balance of Payments Program Certificate provision of the solicitation. If the Contractor certified in its offer that it will deliver a qualifying country end product or a Free Trade Agreement country end product other than a Bahrainian end product, a Moroccan end product, a Panamanian end product, or a Peruvian end product, the Contractor shall deliver a qualifying country end product, a Free Trade Agreement country end product other than a Bahrainian end product, a Moroccan end product, a Panamanian end product, or a Peruvian end product, or, at the Contractor's option, a domestic end product.

* * * * *

ALTERNATE II (NOV 2012)

As prescribed in 225.1101(11)(i)(A), add the following new definitions to paragraph (a) and substitute the following paragraph (c) for paragraph (c) of the basic clause:

(a) ''South Caucasus/Central and South Asian (SC/CASA) state'' means Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Pakistan, Tajikistan, Turkmenistan, or Uzbekistan.

''South Caucasus/Central and South Asian (SC/CASA) state end product'' means an article that—

(i) Is wholly the growth, product, or manufacture of an SC/CASA state; or

(ii) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in an SC/CASA state into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to its supply, provided that the value of those incidental services does not exceed the value of the product itself.

(c) The Contractor shall deliver under this contract only domestic end products unless, in its offer, it specified delivery of qualifying country end products, SC/CASA state end products, Free Trade Agreement country end products other than Bahrainian end products, Moroccan end products, Panamanian end products, or Peruvian end products, or other foreign end products in the Buy American—Free Trade Agreements—Balance of Payments Program Certificate provision of the solicitation. If the Contractor certified in its offer that it will deliver a qualifying country end product, SC/CASA state end products, or a Free Trade Agreement country end product other than a Bahrainian end product, a Moroccan end product, a Panamanian end product, or a Peruvian end product, the Contractor shall deliver a qualifying country end product, an SC/CASA state end product, a Free Trade Agreement country end product other than a Bahrainian end product, a Moroccan end product, a Panamanian end product, or a Peruvian end product or, at the Contractor's option, a domestic end product.

* * * * *

ALTERNATE IV (NOV 2012)

As prescribed in 225.1101(11)(i)(C), add the following definition to paragraph (a) and substitute the following paragraph (c) for paragraph (c) of the basic clause:

(a) ''Korean end product'' means an article that—

(i) Is wholly the growth, product, or manufacture of Korea; or

(ii) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in Korea (Republic of) into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to its supply, provided that the value of those incidental services does not exceed the value of the product itself.

(c) The Contractor shall deliver under this contract only domestic end products unless, in its offer, it specified delivery of qualifying country end products, Free Trade Agreement country end products other than Bahrainian end products, Korean end products, Moroccan end products, Panamanian end products, or Peruvian end products, or other foreign end products in the Buy American—Free Trade Agreements—Balance of Payments Program Certificate provision of the solicitation. If the Contractor certified in its offer that it will deliver a qualifying country end product or a Free Trade Agreement country end product other than a Bahrainian end product, a Korean end product, a Moroccan end product, a Panamanian end product, or a Peruvian end product, the Contractor shall deliver a qualifying country end product, a Free Trade Agreement country end product other than a Bahrainian end product, a Korean end product, a Moroccan end product, a Panamanian end product, or a Peruvian end product, or, at the Contractor's option, a domestic end product.

ALTERNATE V (NOV 2012)

As prescribed in 225.1101(11)(i)(C), add the following new definitions to paragraph (a) and substitute the following paragraph (c) for paragraph (c) of the basic clause:

(a) ''Korean end product'' means an article that—

(i) Is wholly the growth, product, or manufacture of Korea; or

(ii) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in Korea (Republic of) into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to its supply, provided that the value of those incidental services does not exceed the value of the product itself.

''South Caucasus/Central and South Asian (SC/CASA) state'' means Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Pakistan, Tajikistan, Turkmenistan, or Uzbekistan.

''South Caucasus/Central and South Asian (SC/CASA) state end product'' means an article that—

(i) Is wholly the growth, product, or manufacture of an SC/CASA state; or

(ii) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in an SC/CASA state into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to its supply, provided that the value of those incidental services does not exceed the value of the product itself.

(c) The Contractor shall deliver under this contract only domestic end products unless, in its offer, it specified delivery of qualifying country end products, SC/CASA state end products, Free Trade Agreement country end products other than Bahrainian end products, Korean end products, Moroccan end products, Panamanian end products, or Peruvian end products, or other foreign end products in the Buy American—Free Trade Agreements—Balance of Payments Program Certificate provision of the solicitation. If the Contractor certified in its offer that it will deliver a qualifying country end product, SC/CASA state end products, or a Free Trade Agreement country end product other than a Bahrainian end product, a Korean end product, a Moroccan end product, a Panamanian end product, or a Peruvian end product, the Contractor shall deliver a qualifying country end product, an SC/CASA state end product, a Free Trade Agreement country end product other than a Bahrainian end product, a Korean end product, a Moroccan end product, a Panamanian end product, or a Peruvian end product or, at the Contractor's option, a domestic end product.

■ 8. Section 252.225–7045 is amended by—

■ a. Removing the clause date ''(MAY 2012)'' and adding ''(NOV 2012)'' in its place; and

■ b. Revising paragraph (a)(2) of the definition for ''designated country'' to read as follows:

252.225–7045 Balance of Payments Program—Construction Material Under Trade Agreements.

* * * * *

(a) * * *

''Designated country'' means—

* * * * *

(2) A Free Trade Agreement country (Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Panama, Peru, or Singapore);

* * * * *

[FR Doc. 2012–27749 Filed 11–15–12; 8:45 am]

BILLING CODE 5001–06–P

Proposed Rules

Federal Register
Vol. 77, No. 222
Friday, November 16, 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.

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1739

RIN 0572–AC30

Community Connect Broadband Grant Program

AGENCY: Rural Utilities Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Utilities Service (RUS), a Rural Development agency of the United States Department of Agriculture (USDA), hereinafter referred to as RUS or the Agency, amends its regulations for the Community-Oriented Connectivity Broadband Grant Program (Community Connect Grant Program). The purpose of this regulatory change is to provide the Agency the ability to target limited resources to geographical as well as technological areas of need.

This rule is not applicable to Community Connect grant applications filed for funding prior to the publication of a Notice of Funds Availability (NOFA) under this regulation.

DATES: Comments must be submitted on or before January 15, 2013.

ADDRESSES: Submit comments by either of the following methods:

- *Federal eRulemaking Portal* at *http://www.regulations.gov*. Follow instructions for submitting comments.
- *Postal Mail/Commercial Delivery:* Please send your comment addressed to Michele Brooks, Director, Program Development and Regulatory Analysis, USDA Rural Development, 1400 Independence Avenue, STOP 1522, Room 5159, Washington, DC 20250–1522.

Additional information about the Agency and its programs is available on the Internet at *http://www.rurdev.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Kenneth Kuchno, Director, Broadband Division, USDA Rural Utilities Service, STOP 1599, 1400 Independence Avenue SW., Washington, DC 20250–1599, Telephone (202) 690–4673, Facsimile (202) 690–4389. Email address: *kenneth.kuchno@wdc.usda.gov*.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be not significant for purposes of Executive Order 12866, and therefore has not been reviewed by the Office of Management and Budget (OMB).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance (CFDA) Program number assigned to the Community Connect Grant Program is 10.863. The Catalog is available on the Internet at *http://www.cfda.gov*.

Executive Order 12372

This program is not subject to the requirements of Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' as implemented under USDA's regulations at 7 CFR part 3015.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. The Agency has determined that this rule meets the applicable standards provided in section 3 of the Executive Order. In addition, all state and local laws and regulations that are in conflict with this rule will be preempted. No retroactive effect will be given to this rule and, in accordance with section 212(e) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6912(e)), administrative appeal procedures, must be exhausted before an action against the Department or its agencies may be initiated.

Executive Order 13132, Federalism

The policies contained in this rule do not have any substantial direct effect on 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. Nor does this rule impose substantial direct compliance costs on state and local governments. Therefore, consultation with states is not required.

Regulatory Flexibility Certification

Pursuant to 5 U.S.C. 553(a)(2), this rule related to grants is exempt from the rulemaking requirements of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*), including the requirement to provide prior notice and an opportunity for public comment. Because this rule is not subject to a requirement to provide prior notice and an opportunity for public comment pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable.

Unfunded Mandates

This rule contains no Federal mandates (under the regulatory provision of Title II of the Unfunded Mandates Reform Act of 1995) for State, local, and tribal governments or the private sector. Therefore, this final rule is not subject to the requirements of sections 202 and 205 of the Unfunded Mandates Reform Act of 1995.

Environmental Impact Statement

This rule has been examined under Agency environmental regulations at 7 CFR part 1794. The Administrator has determined that this action is not a major Federal action significantly affecting the environment. Therefore, in accordance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an Environmental Impact Statement or Assessment is not required.

Information Collection and Recordkeeping Requirements

This rule contains no new reporting or recordkeeping burdens under OMB control number 0572–0127 that would require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Executive Order 13175

Executive Order 13175 imposes requirements on Rural Development in the development of regulatory policies that have tribal implications or preempt tribal laws. Rural Development has determined that this proposed rule does not have a substantial direct effect on one or more Indian tribe(s) or on either the relationship or the distribution of powers and responsibilities between the Federal Government and Indian tribes. Additionally, two of the changes contained in this rule (rural eligibility based on a place recognized by the census or the Rand McNally™ Atlas and priorities for substantially underserved trust areas) in part respond to comments and suggestions the

Agency has received from tribal leaders and personnel through consultation, listening sessions and meetings. Thus, this rule is not subject to the requirements of Executive Order 13175. If a tribe determines that this rule has implications of which Rural Development is not aware and would like to engage in consultation with Rural Development on this rule, please contact Rural Development's Native American Coordinator at (720) 544–2911 or *AIAN@wdc.usda.gov*.

E-Government Act Compliance

Rural Development is committed to the E-Government Act, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

Background/Overview

The Rural Utilities Service, a Rural Development agency of the United States Department of Agriculture (the Agency) works to improve the quality of life in rural America by providing investment capital, in the form of loans and grants, for the deployment of rural telecommunications, broadband, electric, water and environmental infrastructure. Financial assistance is provided to rural utilities; municipalities; commercial corporations; limited liability companies; public utility districts; Indian tribes; and cooperative, nonprofit, limited-dividend, or mutual associations. In order to achieve the goal of increasing economic opportunity in rural America, the Agency finances infrastructure that enables access to seamless, nation-wide telecommunications and broadband networks. With access to the same advanced telecommunications networks of its urban counterparts, especially broadband networks designed to accommodate distance learning, telework, e-government and telemedicine, rural America will see improving educational opportunities, health care, economies, safety and security, and ultimately higher employment. Of particular concern to the Agency are communities where broadband service is not available and where population densities are such that the cost of deployment to them is so high that build-out of infrastructure is unlikely. The Agency is committed to helping rural communities gain access to affordable, reliable, advanced communications services, comparable to those available throughout the rest of the United States, to provide a healthy, safe and prosperous place to live and work.

The Community Connect Grant Program was started as a Pilot Program. After administering the program as a pilot program for two years, the Agency proposed rules for the program and on July 28, 2004, the program was formally implemented. The regulations were amended to clarify, among other things, which rural communities are eligible under the program. The main purpose of this grant program is the construction of broadband facilities in areas where no broadband exists today with a secondary benefit of providing for a community center that provides free broadband service to all critical community facilities in the proposed funded service area for a two year period.

Discussion of Changes

The new rule addresses several areas to streamline and improve the program for applicants and the Agency, with the goal of bringing broadband to unserved communities. The new rules provide flexibility to address the dynamic broadband needs of rural Americans and enhance the Agency's ability to target funds to areas where they are needed the most. The new rules also seek to make the application process easier for applicants and evaluators. For example, a single concise project summary and map can be used to inform USDA Rural Development State Directors of pending applications within their states as well as the general public. Major changes include:

1. *Proposed Funded Service Territory.* Since its inception, the Community Connect Grant Program only permitted applicants to use grant funds to serve a single community which included a place recognized by the census or the Rand McNally™ Atlas. This approach, while administratively simple did not accommodate some of the most rural communities which are not census designated places or recognized by a commercial Atlas. It also precluded applicants from developing new service territories in a logical and cost effective manner to maximize the benefit of the grant. The new rule will allow applicants to define their proposed funded service area by utilizing the web based RUS mapping tool. By allowing an applicant the ability to define the exact service area, it is important to note that all premises in the service area must be offered service at the Broadband Grant Speed. The NOFA will set the minimum and maximum dollar amounts per application.

2. *Matching Fund Simplification.* The current program requires applicants to provide a match equal to 15 percent of the requested funding to be used only for eligible grant purposes. The new rule maintains the current program's 15 percent matching requirement but clarifies that the match must be in cash and can also be used to fund operations of the project. This change gives applicants new flexibility on the use of matching funds and is administratively simpler for applicants, reviewers and the Agency. Clarifying that the match must be in cash available at closing, the new rule removes uncertainty related to valuing and qualifying in-kind contributions. Notwithstanding the 15 percent match, all applicants must be able to demonstrate that they have sufficient resources to construct, manage and sustain the project through and beyond completion.

3. *Scoring Simplification.* The current program scores and ranks applications on three criteria: (a) Rurality; (b) economic need; and (c) benefits. The metrics used for economic need (Median Household Income) and rurality (census and Rand McNally™) at times did not fully accommodate situations where there was a high need for assistance. The criteria may not have adequately measured need, for example, in a small community with substantial unemployment and a high cost of living, or in a community that was so small, rural and remote that the community was not recognized as a census designated place; or a community which is small and with very low-income, but in a county which as a whole has a high median household income. The new criteria focuses on ranking completed applications based on the community connectivity benefits of the project to the proposed funded service area. In making a final selection among and between applications with comparable rankings, the Administrator will take into consideration: (a) Service provided to communities in persistent poverty counties; (b) service provided to communities in out-migration communities; (c) the rurality of the proposed funded service area; (d) the speed of service provided by the project; (e) service to substantially underserved trust areas; (f) services provided to persons with disabilities; and (g) any other socio-economic factors that may be described in the NOFA to differentiate and rank applications.

List of Subjects in 7 CFR 1739

Broadband; Grant programs—Communications; Rural areas; Telecommunications; and Telephone.

For reasons set forth in the preamble, the Rural Utilities Service proposes to

amend Chapter XVII of title 7 of the Code of Federal Regulations by revising part 1739.

1. Revise Part 1739 to read as follows:

PART 1739—BROADBAND GRANT PROGRAM

Subpart A—Community Connect Grant Program

Secs.
1739.1 Purpose.
1739.2 Funding availability and application dates and submission.
1739.3 Definitions.
1739.4–1739.8 [Reserved]
1739.9 USDA Rural Development State Director notification.
1739.10 Eligible applicant.
1739.11 Eligible Community Connect Competitive Grant Project.
1739.12 Eligible grant purposes.
1739.13 Ineligible grant purposes
1739.14 Matching contributions.
1739.15 Completed application.
1739.16 Review of grant applications.
1739.17 Scoring of applications.
1739.18 Grant documents.
1739.19 Reporting and oversight requirements.
1739.20 Audit requirements.
1739.21 OMB control number.

Authority: Title III, Pub. L. 108–199, 118 Stat. 3.

Subpart A—Community Connect Grant Program

§ 1739.1 Purpose.

(a) The provision of broadband service is vital to the economic development, education, health, and safety of rural Americans. The purpose of the Community Connect Grant Program is to provide financial assistance in the form of grants to eligible applicants that will provide, on a ''community-oriented connectivity'' basis, broadband service that fosters economic growth and delivers enhanced educational, health care, and public safety benefits. The Agency will give priority to rural areas that have the greatest need for broadband services, based on the criteria contained herein and in the Notice of Funds Availability (hereinafter referred to as NOFA) published in the **Federal Register**.

(b) Grant authority will be used for the deployment of service to all premises in eligible rural areas at the Broadband Grant Speed on a ''community-oriented connectivity'' basis. In addition to providing service to all premises the ''community-oriented connectivity'' concept will stimulate practical, everyday uses and applications of broadband by cultivating the deployment of new broadband services that improve economic development and provide enhanced educational and health care opportunities in rural areas. Such an approach will also give rural communities the opportunity to benefit from the advanced technologies that are necessary to achieve these goals.

§ 1739.2 Funding availability and application dates and submission.

(a) The Agency will periodically publish, (usually on an annual basis) in the **Federal Register**, a NOFA that will set forth the total amount of funding available; the maximum and minimum funding for each grant; funding priority; the application submission dates; and the appropriate addresses and agency contact information. The NOFA will also outline and explain the procedures for submission of applications, including electronic submissions. The Agency may publish more than one NOFA should additional funding become available.

(b) Notwithstanding paragraph (a) of this section, the Agency may, in response to a surplus of qualified eligible applications which could not be funded from the previous fiscal year, decline to publish a NOFA for the following fiscal year and fund said applications without further public notice.

§ 1739.3 Definitions.

As used in this subpart:

Agency or *RUS* shall mean the Rural Utilities Service, which administers the United States Department of Agriculture (USDA) Rural Development Utilities Programs.

Broadband Service means any terrestrial technology having the capacity to provide transmission facilities that enable subscribers of the service to originate and receive high-quality voice, data, graphics, and video at the minimum rate of data transmission described in the NOFA. The broadband service speed may be different from the broadband grant speed for the Community Connect program.

Broadband Grant Speed means the minimum bandwidth described in the NOFA that an applicant must propose to deliver to every customer in the proposed funded service area in order for the Agency to approve a broadband grant. The Broadband Grant Speed may be different for fixed and mobile broadband services and from the minimum rate of data transmission required to determine the availability of broadband service when qualifying a service area.

Community Center means a building within the Proposed Funded Service Area that provides access to the public, or a section of a public building with at least two (2) Computer Access Points and wireless access, that is used for the purposes of providing free access to and/or instruction in the use of broadband Internet service, and is of the appropriate size to accommodate this purpose. The community center must be open and accessible to area residents before, during, and after normal working hours and on Saturdays or Sunday.

Computer Access Point means a new computer terminal with access to service at the Broadband Grant Speed.

Critical Community Facilities means the Community Center; any public school, public education center, public library, public medical clinic, public hospital, community college, public university; or law enforcement, fire or ambulance station in the Proposed Funded Service Area.

Eligible Applicant shall have the meaning as set forth in § 1739.10.

Eligible Grant Purposes shall have the meaning as set forth in § 1739.12.

Matching Contribution means the applicant's qualified contribution to the Project, as outlined in § 1739.14 of this part.

Project means the delivery of service at the Broadband Grant Speed financed by the grant and Matching Contribution for the Proposed Funded Service Area.

Proposed Funded Service Area (PFSA) means the contiguous geographic area within an eligible Rural Area or eligible Rural Areas, in which the applicant proposes to provide service at the Broadband Grant Speed.

Rural Area means any area, as confirmed by the latest decennial census of the Bureau of the Census, which is not located within:

(i) A city, town, or incorporated area that has a population of greater than 20,000 inhabitants; or

(ii) An urbanized area contiguous and adjacent to a city or town that has a population of greater than 50,000 inhabitants. For purposes of the definition of rural area, an urbanized area means a densely populated territory as defined in the latest decennial census of the U.S. Census Bureau.

§§ 1739.4–1739.8 [Reserved]

§ 1735.9 USDA Rural Development State Director notification.

Applicants shall complete a notification form which will be a public document that the RUS provides to USDA Rural Development State Directors and others in the state(s) of the proposed funded service area. The notification shall include a brief project description and the location of the proposed funded service area.

§ 1739.10 Eligible applicant.

To be eligible for a Community Connect competitive grant, the applicant must:

(a) Be legally organized as an incorporated organization, an Indian tribe or tribal organization, as defined in 25 U.S.C. 450b(b) and (c), a state or local unit of government, or other legal entity, including cooperatives or private corporations or limited liability companies organized on a for-profit or not-for-profit basis.

(b) Have the legal capacity and authority to own and operate the broadband facilities as proposed in its application, to enter into contracts and to otherwise comply with applicable federal statutes and regulations.

(c) As required by the Office of Management and Budget (OMB), all applicants for grants must supply a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying. The Standard Form 424 (SF–424) contains a field for you to use when supplying your DUNS number. Obtaining a DUNS number costs nothing and requires a short telephone call to Dun and Bradstreet. Please see *http://www.grants.gov/applicants/request_duns_number.jsp* for more information on how to obtain a DUNS number or how to verify your organization's number.

(d) Register in the System for Award Management (SAM) (formerly Central Contractor Registry (CCR).

(1) In accordance with 2 CFR part 25, applicants, whether applying electronically or by paper, must be registered in the SAM prior to submitting an application. Applicants may register for the SAM at *https://www.sam.gov/*.

(2) The SAM registration must remain active, with current information, at all times during which an entity has an application under consideration by an agency or has an active Federal Award. To remain registered in the SAM database after the initial registration, the applicant is required to review and update, on an annual basis from the date of initial registration or subsequent updates, its information in the SAM database to ensure it is current, accurate and complete.

§ 1739.11 Eligible Community Connect Competitive Grant Project.

To be eligible for a Community Connect competitive grant, the Project must:

(a) Serve a PFSA in which Broadband Service does not currently exist.;

(b) Offer service at the Broadband Grant Speed to all residential and business customers within the PFSA;

(c) Offer free service at the Broadband Grant Speed to all Critical Community Facilities located within the PFSA for at least 2 years starting from the time service becomes available to each Critical Community Facility; and

(d) Provide a Community Center with at least two (2) Computer Access Points and wireless access at the Broadband Grant Speed, free of all charges to all users for at least 2 years.

§ 1739.12 Eligible grant purposes.

Grant funds may be used to finance the following:

(a) The construction, acquisition, or leasing of facilities, including spectrum, land or buildings, used to deploy service at the Broadband Grant Speed to all residential and business customers located within the Proposed Funded Service Area and all participating Critical Community Facilities, including funding for up to ten Computer Access Points to be used in the Community Center. Leasing costs will only be covered through the advance of funds period included in the award documents;

(b) The improvement, expansion, construction, or acquisition of a Community Center and provision of Computer Access Points. Grant funds for the Community Center will be limited to ten percent of the requested grant amount;

(c) The cost of providing the necessary bandwidth for service free of charge to the Critical Community Facilities for 2 years.

§ 1739.13 Ineligible grant purposes.

Operating expenses not specifically permitted in § 1739.12.

§ 1739.14 Matching contributions.

(a) At the time of closing of the award, the awardee must contribute or demonstrate available cash reserves in an account(s) of the awardee equal to at least 15% of the grant. Matching contributions must be used solely for the Project and shall not include any financial assistance from federal sources unless there is a federal statutory exception specifically authorizing the federal financial assistance to be considered as such. An applicant must provide evidence of its ability to comply with this requirement in its application.

(b) At the end of every calendar quarter, the award must submit a schedule to RUS that identifies how the match contribution was used to support the project until the total contribution is expended.

§ 1739.15 Completed application.

Applications should be prepared in conformance with the provisions of this part and all applicable USDA regulations, including 7 CFR parts 3015, 3016, and 3019. Applicants must also conform to the requirements of the individual NOFA to be published when funds are available for the program, and are advised to use the Agency's Application Guide for this program, found at the Agency's Web site. The application guide contains instructions and forms, as well as other important information needed to prepare an application and may be updated periodically. Paper copies of the application guide can be requested by contacting the, Director, Broadband Division at the following address: Stop 1599, South Agriculture Building, Room 2868, Washington, DC 20250. Completed applications must include the following documentation, studies, reports and information, in form and substance satisfactory to the Agency:

(a) *An Application for Federal Assistance.* A completed Standard Form 424;

(b) *An executive summary of the Project.* A general project overview that addresses the following categories:

(1) A description of why the Project is needed;

(2) A description of the applicant;

(3) An explanation of the total Project costs;

(4) A general overview of the broadband telecommunications system to be developed, including the types of equipment, technologies, and facilities to be used;

(5) Documentation describing the procedures used to determine the unavailability of existing Broadband Service; and

(6) A list of the Critical Community Facilities that will take service from the Applicant at the Broadband Grant Speed, and evidence that any remaining Critical Community Facility located in the PFSA has rejected the offer;

(c) *Scoring Criteria Documentation.* A narrative, with documentation where necessary, addressing the elements listed in the scoring criteria of § 1739.17;

(d) *System design.* A system design of the Project that is economical and practical, including a detailed description of the facilities to be funded, technical specifications, data rates, and costs. In addition, a network diagram detailing the prosed sytem must be provided. The system design must also address the environmental requirements specified in 7 CFR 1794;

(e) *Service Area Demographics.* The following information about the PFSA:

(1) A map, submitted electronically through RUS' web-based Mapping Tool,

which identifies the Rural Area boundaries of the PFSA; and

(2) The total population, number of households, and number of businesses located within the PFSA;

(f) *Scope of work.* A description of the scope of work, which at a minimum must include:

(1) The specific activities and services to be performed under the Project;

(2) Who will carry out the activities and services;

(3) A construction build-out schedule and project milestones, showing the time-frames for accomplishing the Project objectives and activities on a quarterly basis; and

(4) A budget for all capital and administrative expenditures reflecting the line item costs for Eligible Grant Purposes and other sources of funds necessary to complete the Project;

(g) *Community-Oriented Connectivity Plan.* A community-oriented connectivity plan consisting of the following:

(1) A listing of all participating Critical Community Facilities to be connected. The applicant must also provide documentation that it has consulted with the appropriate agent of every Critical Community Facility in the PFSA, and must provide statements from each one as to its willingness to participate, or not to participate, in the proposed Project;

(2) A description of the services the applicant will make available to local residents and businesses; and

(3) A list of any other telecommunications provider (including interexchange carriers, cable television operators, enhanced service providers, wireless service providers and providers of satellite services) that is participating in the delivery of services and a description of the consultations and the anticipated role of such provider in the Project;

(h) *Financial information and sustainability.* A narrative description demonstrating the sustainability of the Project: from the commencement of construction to completion, and beyond the grant period; the sufficiency of resources; how and when the matching requirement is met; and the expertise necessary to undertake and complete the Project. The following financial information is required:

(1) If the applicant is an existing company, it must provide complete copies of audited financial statements, if available, for the two fiscal years preceding the application submission. If audited statements are unavailable, the applicant must submit unaudited financial statements for those fiscal years. Applications from start-up entities must, at minimum, provide an opening balance sheet dated within 30 days of the application submission date; and

(2) Annual financial projections in the form of balance sheets, income statements, and cash flow statements for a forecast period of five years, which prove the sustainability of the Project for that period and beyond. These projections must be inclusive of the applicant's existing operations and the Project, and must be supported by a detailed narrative that fully explains the methodology and assumptions used to develop the projections, including details on the number of subscribers projected to take the applicant's services. Applicants submitting multiple applications for funding must demonstrate that each Project is feasible and sustainable on its own, funds are available to cover each of the matching requirements and that all Projects for which funding is being requested are financially feasible as a whole;

(i) *Statement of Experience.* A statement of experience which includes information on the owners' and principal employees' relevant work experience that would ensure the success of the Project. The applicant must also provide a written narrative demonstrating its capability and experience, if any, in operating a broadband telecommunications system;

(j) *Legal Authority.* Evidence of the applicant's legal authority and existence, and its ability to enter into a grant agreement with the RUS, and to perform the activities proposed under the grant application;

(k) *Additional Funding.* Evidence that funding agreements have been attained, if the Project requires funding commitment(s) from sources other than the grant. An applicant submitting multiple applications for funding must demonstrate its financial wherewithal to support all applications, if accepted, and that it can simultaneously complete and operate all of the Projects under consideration. Additionally, commitments for outside funding must be explicit that they will be available if all applications are not funded;

(l) *Federal Compliance.* Evidence of compliance with other federal statutes and regulations including, but not limited to the following:

(1) 7 CFR part 15, subpart A—Nondiscrimination in Federally Assisted Programs of the Department of Agriculture—Effectuation of Title VI of the Civil Rights Act of 1964;

(2) 7 CFR part 3015—Uniform Federal Assistance Regulations;

(3) 2 CFR part 417—Nonprocurement Debarment and Suspension;

(4) 7 CFR part 3018—New Restrictions on Lobbying;

(5) 2 CFR part 421—Requirements for Drug-Free Workplace (Financial Assistance);

(6) Certification regarding Architectural Barriers;

(7) Certification regarding Flood Hazard Precautions;

(8) An environmental report/questionare, in accordance with 7 CFR part 1794;

(9) A certification that grant funds will not be used to duplicate lines, facilities, or systems providing Broadband Service;

(10) Federal Obligation Certification on Delinquent Debt; and

(11) Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants.

§ 1739.16 Review of grant applications.

(a) All applications for grants must be delivered to the Agency at the address and by the date specified in the NOFA (*see* § 1739.2) to be eligible for funding. The Agency will review each application for conformance with the provisions of this part, and may contact the applicant for clarification of information in the application.

(b) Incomplete applications as of the deadline for submission will not be considered. If an application is determined to be incomplete, the applicant will be notified in writing and the application will be returned with no further action.

(c) If the Agency determines that the Project is technically or financially infeasible or unsustainable, the Agency will notify the applicant, in writing, and the application will be returned with no further action.

(d) Applications conforming with this part will be evaluated competitively by the Agency and will be ranked in accordance with § 1739.17 below. Applications will then be awarded generally in rank order until all grant funds are expended, subject to subparagraphs (e) and (f) below.

(e) In addition to scoring, the Agency may take geographic distribution into consideration when making final award determinations.

(f) An award may be made out of rank order if a higher ranked application would require an award that exceeded available funding or would consume a disproportionate amount of funds available relative to its ranking.

(g) The Agency reserves the right to offer an applicant a lower amount than proposed in the application.

§ 1739.17 Scoring of applications.

The ranking of the ''community-oriented connectivity'' benefits of the

Project will be based on documentation in support of the need for services, benefits derived from the proposed services, characteristics of the PFSA, local community involvement in planning and implementation of the Project, and the level of experience of the management team. In ranking applications the Agency will consider the following criteria based on a scale of 100 possible points:

(a) An analysis of the challenges of the following criteria, laid out on a community-wide basis, and how the Project proposes to address these issues (up to 50 point):

(1) The economic characteristics;

(2) Educational challenges;

(3) Health care needs; and

(4) Public safety issues;

(b) The extent of the Project's planning, development, and support by local residents, institutions, and Critical Community Facilities. Documentation must include evidence of community-wide involvement, as exemplified by community meetings, public forums, and surveys. In addition, applicants should provide evidence of local residents' participation in the Project planning and development (up to 40 points).

(c) The level of experience and past success of operating broadband systems for the management team. (up to 10 points)

(d) In making a final selection among and between applications with comparable rankings and geographic distribution, the Administrator may take into consideration the characteristics of the PFSA. Only information provided in the application will be considered. Applicants should therefore specifically address each of the following criteria to differentiate their applications:

(i) Persistent poverty counties that will be served within the PFSA;

(ii) Out-migration Communities that will be served within the PFSA;

(iii) The rurality of the PFSA;

(iv) The speed of service provided by the project;

(v) Substantially underserved trust areas that will be served within the PFSA;

(vi) Community members with disabilities that will be served within the PFSA; and

(vi) Any other additional factors that may be outlined in the NOFA.

§ 1739.18 Grant documents.

The terms and conditions of grants shall be set forth in grant documents prepared by the Agency. The documents shall require the applicant to own all equipment and facilities financed by the grant. Among other matters, the Agency may prescribe conditions to the advance of funds that address concerns regarding the Project feasibility and sustainability. The Agency may also prescribe terms and conditions applicable to the construction and operation of the Project and the delivery of service at the Broadband Grant Speed to eligible Rural Areas, as well as other terms and conditions applicable to the individual Project. Dividend distributions will not be allowed until all grant funds and matching contributions have been expended.

§ 1739.19 Reporting and oversight requirements.

(a) A project performance activity report will be required of all recipients on an annual basis until the Project is complete and the funds are expended by the applicant. The reporting period will start with the calendar year the award is made and continue for every calendar year through the term of the award. The report must be submitted by January 31 of the following year if the reporting period. Recipients are to submit an original and one copy of all project performance reports, including, but not limited to, the following:

(1) A comparison of actual accomplishments to the objectives established for that period;

(2) A description of any problems, delays, or adverse conditions which have occurred, or are anticipated, and which may affect the attainment of overall Project objectives, prevent the meeting of time schedules or objectives, or preclude the attainment of particular Project work elements during established time periods. This disclosure shall be accompanied by a statement of the action taken or planned to resolve the situation; and

(3) Objectives and timetable established for the next reporting period.

(b) A final project performance report must be provided by the recipient. It must provide an evaluation of the success of the Project in meeting the objectives of the program. The final report may serve as the last annual report.

(c) The Agency will monitor recipients, as it determines necessary, to assure that Projects are completed in accordance with the approved scope of work and that the grant is expended for Eligible Grant Purposes.

(d) Recipients shall diligently monitor performance to ensure that time schedules are being met, projected work within designated time periods is being accomplished, and other performance objectives are being achieved.

(e) The applicant must have the necessary processes and systems in place to comply with the reporting requirements for first-tier sub-awards and executive compensation under the Federal Funding Accountability and Transparency Act of 2006 in the event the applicant receives funding unless such applicant is exempt from such reporting requirements pursuant to 2 CFR part 170, § 170.110(b). The reporting requirements under the Transparency Act pursuant to 2 CFR part 170 are as follows:

(1) First Tier Sub-Awards of $25,000 or more in non-Recovery Act funds (unless they are exempt under 2 CFR part 170) must be reported by the Recipient to *http://www.fsrs.gov* no later than the end of the month following the month the obligation was made.

(2) The Total Compensation of the Recipient's Executives (5 most highly compensated executives) must be reported by the Recipient (if the Recipient meets the criteria under 2 CFR part 170) to *http://www.ccr.gov* by the end of the month following the month in which the award was made.

(3) The Total Compensation of the Subrecipient's Executives (5 most highly compensated executives) must be reported by the Subrecipient (if the Subrecipient meets the criteria under 2 CFR part 170) to the Recipient by the end of the month following the month in which the subaward was made.

§ 1739.20 Audit requirements.

A grant recipient shall provide the Agency with an audit for each year in which a portion of the financial assistance is expended, in accordance with the following:

(a) If the recipient is a for-profit entity, an existing Telecommunications or Electric Borrower with the Agency, or any other entity not covered by the following paragraph, the recipient shall provide an independent audit report in accordance with 7 CFR part 1773, ''Policy on Audits of the Agency's Borrowers.''

(b) If the recipient is a State or local government, or non-profit organization, the recipient shall provide an audit in accordance with 7 CFR part 3052, ''Audits of States, Local Governments, and Non-Profit Organizations.''

§ 1739.21 OMB Control Number.

The information collection requirements in this part are approved by the Office of Management and Budget (OMB) and assigned OMB control number 0572–0127.

Dated: September 21, 2012.

John Charles Padalino,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2012–27631 Filed 11–15–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–1163; Directorate Identifier 2011–NM–246–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) that applies to all Airbus Model A330–200 and –300 series airplanes; and Model A340–200, –300, –500, and –600 series airplanes. The existing AD currently requires a one-time detailed inspection of both main landing gear (MLG) bogie beams in the region of the bogie stop pad for detection of deformation and damage, and corrective actions if necessary. Since we issued that AD, we have received reports of corroded bogie stop pads, including some with cracking. This proposed AD would add Model A330–200 Freighter series airplanes to the applicability. For certain airplanes, this proposed AD would also add repetitive inspections for damage and corrosion of the sliding piston sub-assembly, with new related investigative and corrective actions. We are proposing this AD to detect and correct deformation or damage under the bogie stop pad of both MLG bogie beams, which could result in a damaged bogie beam and consequent detachment of the beam from the airplane or collapse of the MLG and departure of the airplane from the runway.

DATES: We must receive comments on this proposed AD by December 31, 2012.

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

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

For service information identified in this proposed AD, contact Airbus SAS—Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1138; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2012–1163; Directorate Identifier 2011–NM–246–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

On January 14, 2010, we issued AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010). That AD required actions intended to address an unsafe condition on Airbus Model A330–200 and –300 series airplanes; and Model A340–200, –300, –500, and –600 series airplanes.

Since we issued AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010), the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2011–0211, dated October 31, 2011 (referred to after this as ''the MCAI''), to supersede EASA AD 2008–0223, dated December 15, 2008 (referred to in the existing AD), and correct an unsafe condition for the specified products. The MCAI states:

> During a scheduled maintenance inspection on the MLG [main landing gear], the bogie stop pad was found deformed and cracked. Upon removal of the bogie stop pad for replacement, the bogie beam was also found cracked.
>
> Laboratory investigation indicates that an overload event has occurred and no fatigue propagation of the crack was evident.
>
> A second bogie beam crack has subsequently been found on another aeroplane, located under a bogie stop pad which only had superficial paint damage.
>
> This condition, if not detected and corrected, could result in the aeroplane departing the runway or to the bogie detaching from the areoplane or gear collapses, which would all constitute unsafe conditions at speeds above 30 knots.
>
> As a precautionary measure, EASA AD 2008–0223 [which corresponds to FAA AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010] required one-time detailed inspections under the bogie stop pad of both MLG bogie beams and, in case deformation or damage is detected, to apply the associated repair.
>
> Numerous bogie stop pad were found corroded and a few cracked as a result of the one-time inspection required by EASA AD 2008–0223 on A330, A340–200, and A340–300 aeroplanes.
>
> For the reasons describe above, this [EASA] AD, which supersedes EASA AD 2008–0223:
>
> —Retains the initial inspection requirement of EASA AD 2008–0223 for A330, A340–200, and A340–300 aeroplanes.
>
> —Introduces a repetitive detailed visual inspection for A330, A340–200, and A340–300 aeroplanes.
>
> —Retains the requirement of EASA AD 2008–0223 for A340–500 and A340–600 aeroplanes, for which further mandatory requirements might follow in future mandatory requirements might follow in future depending on the results of the one-time mandatory inspection in place.

The required actions include repetitive detailed inspections for

damage and corrosion of the sliding piston sub-assembly, with new related investigative and corrective actions. Related investigative actions include a test for indications of corrosion and damage to the bogie assembly base material, and a magnetic particle inspection for cracks, corrosion, and damage of the bogie beam. Corrective actions include repairing affected parts.

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

Relevant Service Information

Airbus has issued the following service bulletins:

- Airbus Mandatory Service Bulletin A330–32–3220, Revision 01, dated October 5, 2011 (for Model A330–200 and –300 series airplanes).
- Airbus Mandatory Service Bulletin A330–32–3248, including Appendix 1, dated October 5, 2011 (for Model A330–200, –200 Freighter, and –300 series airplanes).
- Airbus Mandatory Service Bulletin A340–32–4286, including Appendix 1, dated October 5, 2011 (for Model A340–200 and –300 series airplanes).

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

FAA's Determination and Requirements of This Proposed AD

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

Differences Between Proposed AD and Service Information

Although the service information specifies to contact the manufacturer for instructions to repair certain conditions, this proposed AD would require repairing those conditions using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA (or its delegated agent).

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 67 products of U.S. registry.

The actions that are required by AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010), and retained in this proposed AD take about 2 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 $170 per product.

We estimate that it would take about 16 work-hours per product to comply with the new basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $91,120, or $1,360 per product.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010), and adding the following new AD:

Airbus: Docket No. FAA–2012–1163; Directorate Identifier 2011–NM–246–AD.

(a) Comments Due Date

We must receive comments by December 31, 2012.

(b) Affected ADs

This AD supersedes AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010).

(c) Applicability

This AD applies to all Airbus Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 series airplanes; and Model A340–211, –212, –213, –311, –312, –313 series airplanes; and A340–541 and –642 airplanes; certificated in any category; all serial numbers.

(d) Subject

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

(e) Reason

This AD was prompted by reports of corroded bogie stop pads, some with cracking. We are issuing this AD to detect and correct deformation or damage under the bogie stop pad of both main landing gear (MLG) bogie beams, which could result in a damaged bogie beam and consequent detachment of the beam from the airplane or collapse of the MLG and departure of the airplane from the runway.

(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 One-Time Inspection and Corrective Actions, With Revised Service Information

This paragraph restates the requirements of paragraph (f)(1) of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010), with revised service information. For Model A330–200 and –300 series airplanes, and Model A340–200, –300, –500, and –600 series airplanes, except as required by paragraph (i) of this AD: At the applicable compliance time specified in paragraph (g)(1), (g)(2), (g)(3), (g)(4), (g)(5), or (g)(6) of this AD, perform one-time detailed inspections of both MLG bogie beams in the region of the bogie stop pad for detection of deformation and damage, and apply the applicable corrective actions, in accordance with the Accomplishment Instructions of the applicable service bulletin specified in paragraph (g)(7) of this AD. Do all applicable corrective actions before further flight.

(1) Airplanes with 22 months or less and 2,500 flight cycles or less from the first flight with the original bogie beam as of March 4, 2010 (the effective date of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010)): Not earlier than 2,500 flight cycles or 22 months on the original bogie beam, whichever occurs first, but not later than 40 months from first flight.

(2) Airplanes with 22 months or less and 2,500 flight cycles or less from the installation date of a new bogie beam in service as of March 4, 2010 (the effective date of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010)): Not earlier than 2,500 flight cycles or 22 months from the installation date of the new bogie beam, whichever occurs first, but not later than 40 months from the installation date of a new bogie beam in service.

(3) Airplanes with 22 months or less and 2,500 flight cycles or less from the installation date of an overhauled bogie beam in service as of March 4, 2010 (the effective date of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010)): Not earlier than 2,500 flight cycles or 22 months from the installation date of the overhauled bogie beam in service, whichever occurs first, but not later than 40 months from the installation date of the overhauled bogie beam in service.

(4) Airplanes with more than 22 months or more than 2,500 flight cycles from the first flight with the original bogie beam, as of March 4, 2010 (the effective date of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010)): Within 18 months after March 4, 2010 (the effective date of AD 2010–02–10).

(5) Airplanes with more than 22 months or more than 2,500 flight cycles from the installation date of a new bogie beam in service, as of March 4, 2010 (the effective date of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010)): Within 18 months after March 4, 2010 (the effective date of AD 2010–02–10).

(6) Airplanes with more than 22 months or more than 2,500 flight cycles from the installation date of an overhauled bogie beam in service, as of March 4, 2010 (the effective date of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010)): Within 18 months after March 4, 2010 (the effective date of AD 2010–02–10).

(7) Use the applicable service information to accomplish the actions required by paragraph (g) of this AD.

(i) For Model A330–200 and –300 series airplanes: Airbus Mandatory Service Bulletin A330–32–3220, dated October 10, 2008; or Airbus Mandatory Service Bulletin A330–32–3220, Revision 01, dated October 5, 2011.

(ii) For Model A340–200 and –300 series airplanes: Airbus Mandatory Service Bulletin A340–32–4264, dated October 10, 2008.

(iii) For Model A340–500 and –600 series airplanes: Airbus Mandatory Service Bulletin A340–32–5087, dated October 10, 2008.

(h) Retained Reporting Requirement

This paragraph restates the requirements of paragraph (f)(2) of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010). Report the results of the inspection required by paragraph (g) of this AD, including no findings, to Airbus, Customer Services Directorate, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex France; Attn: SEDCC1 Technical Data and Documentation Services; fax (+33) 5 61 93 28 06; email *sb.reporting@airbus.com*; at the applicable time specified in paragraph (h)(1) or (h)(2) of this AD.

(1) If the inspection is done on or after March 4, 2010 (the effective date of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010)): Submit the report within 30 days after doing the inspection.

(2) If the inspection was done prior to March 4, 2010 (the effective date of AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010)): Submit the report within 30 days after March 4, 2010 (the effective date of AD 2010–02–10).

(i) New Inspections of Beams That Have Not Been Inspected as of the Effective Date of This AD

For bogie beams on which the inspection required by paragraph (g) of this AD has not been accomplished as of the effective date of this AD: At the later of the times specified in paragraphs (i)(1) and (i)(2) of this AD, perform one-time detailed inspections of both main landing gear bogie beams in the region of the bogie stop pad for detection of deformation and damage, and apply the applicable corrective actions, in accordance with the Accomplishment Instructions of the applicable service information specified in paragraph (i)(3) of this AD. Do all applicable corrective actions before further flight.

(1) At the applicable time in paragraph (i)(1)(i) or (i)(1)(ii) of this AD.

(i) For bogie beams that have not been overhauled: Not earlier than 2,500 flight cycles or 22 months, whichever occurs first, on a bogie beam since its first flight on an airplane since new, but not later than 40 months since its first flight on an airplane since new.

(ii) For bogie beams that have been overhauled: Not earlier than 2,500 flight cycles or 22 months, whichever occurs first, on a bogie beam since its first flight on an airplane after its most recent overhaul, but not later than 40 months since its first flight on an airplane after its most recent overhaul.

(2) Within 90 days after the effective date of this AD.

(3) Use the applicable service information specified in paragraph (i)(3)(i), (i)(3)(ii), or (i)(3)(iii) of this AD, to accomplish the actions required by paragraph (i) of this AD.

(i) For Model A330–200 and –300 series airplanes: Airbus Mandatory Service Bulletin A330–32–3220, Revision 01, dated October 5, 2011.

(ii) For Model A340–200 and –300 series airplanes: Airbus Mandatory Service Bulletin A340–32–4264, dated October 10, 2008.

(iii) For Model A340–500 and –600 series airplanes: Airbus Mandatory Service Bulletin A340–32–5087, dated October 10, 2008.

(j) New Repetitive Inspections

Except for bogie beams that have been inspected as specified in Airbus Mandatory Service Bulletin A340–32–5087: At the later of the times specified in paragraphs (j)(1) and (j)(2) of this AD, do the detailed inspection of both MLG bogie beams in the bogie stop pad area for damage and corrosion, and all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–32–3248, dated October 5, 2011 (for Model A330–200, –200 Freighter, and –300 series airplanes); or Airbus Mandatory Service Bulletin A340–32–4286, dated October 5, 2011 (for Model A340–200 and –300 series airplanes); except as required by paragraph (k) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the inspection thereafter at intervals not to exceed 2,500 flight cycles or 24 months, whichever is first.

(1) Within 2,500 flight cycles or 24 months, whichever occurs first, accumulated by a MLG bogie beam since its first flight after the most recent accomplishment of Airbus Mandatory Service Bulletin A330–32–3220 or A340–32–4264, as applicable.

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

(k) Service Information Exception

If any cracking of the bogie beam is detected during any inspection or repair required by paragraph (j) of this AD, or any repair required by paragraph (j) of this AD is beyond the maximum repair allowance specified in the service information required by paragraph (j) of this AD: Before further flight, repair using a method approved by either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent).

(l) New Reporting Requirement

Report the results of the initial inspection required by paragraph (j) of this AD, including both positive and negative findings, to Airbus, Customer Services Directorate, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex France; Attn: SEDCC1 Technical Data and Documentation Services; fax (+33) 5 61 93 28 06; email *sb.reporting@airbus.com* at the applicable

time specified in paragraph (l)(1) or (1)(2) of this AD.

(1) If the inspection is done on or after the effective date of this AD: Submit the report within 30 days after doing the inspection.

(2) If the inspection was done prior to the effective date of this AD: Submit the report within 30 days after the effective date 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: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1138; 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. AMOCs approved previously in accordance with AD 2010–02–10, Amendment 39–16181 (75 FR 4477, January 28, 2010), are approved as AMOCs for the corresponding provisions of 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.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing, and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(n) Special Flight Permits

Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), are not allowed if any crack is found during any inspection required by this AD.

(o) Related Information

(1) Refer to MCAI EASA Airworthiness Directive 2011–0211, dated October 1, 2011, and the service information specified in paragraphs (o)(1)(i) through (o)(1)(vi) of this AD, for related information.

(i) Airbus Mandatory Service Bulletin A330–32–3220, dated October 10, 2008.

(ii) Airbus Mandatory Service Bulletin A330–32–3220, Revision 01, dated October 5, 2011.

(iii) Airbus Mandatory Service Bulletin A330–32–3248, dated October 5, 2011.

(iv) Airbus Mandatory Service Bulletin A340–32–4264, dated October 10, 2008.

(v) Airbus Mandatory Service Bulletin A340–32–4286, dated October 5, 2011.

(vi) Airbus Mandatory Service Bulletin A340–32–5087, dated October 10, 2008.

(2) For service information identified in this AD, contact Airbus SAS—Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com*; Internet *http://www.airbus.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on November 8, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–27847 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–1055; Directorate Identifier 2012–NE–33–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Rolls-Royce Deutschland Ltd & Co KG (RRD) BR700–710A1–10 and BR700–710A2–20 turbofan engines, and certain BR700–710C4–11 model engines. This proposed AD was prompted by RRD performing an evaluation that determined that certain high-pressure turbine (HPT) stage 1 and stage 2 discs from a specific supplier may contain steel inclusions that may cause the discs to fail before they reach their current life limits. This proposed AD would require reducing the life limits for certain HPT stage 1 and stage 2 discs. We are proposing this AD to prevent failure of the HPT stage 1 and stage 2 discs, which could result in uncontained failure of the engine and damage to the airplane.

DATES: We must receive comments on this proposed AD by January 15, 2013.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

For service information identified in this proposed AD, contact Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, Dahlewitz, 15827 Blankenfelde-Mahlow, Germany; phone: 49 0 33–7086–1883; fax: 49 0 33–7086–3276. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Robert Morlath, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7154; fax: 781–238–7199; email: *robert.c.morlath@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2012–1055; Directorate Identifier 2012–NE–33–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2012–0166, dated August 30, 2012 (referred to hereinafter as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> The results of a recent quality review of high pressure turbine (HPT) stage 1 and stage 2 discs identified potential for steel inclusions in some production scale parts. Further investigation concluded that all affected parts were manufactured by Udimet 720I and melted by a certain supplier. Subsequent evaluation concluded that the affected parts life limitation values declared in the engine Time Limits Manual cannot be supported for discs with potential steel inclusion.
>
> This condition, if not corrected, could lead to an uncontained HPT disc failure, potentially resulting in damage to, and/or reduced control of the aeroplane.

The FAA has further determined that the risk to the engine is increased by installing an HPT stage 1 disc and an HPT stage 2 disc from the affected population, on the same engine. Therefore the FAA is prohibiting the installation of an HPT stage 1 and HPT stage 2 disc from the affected population in the same engine. You may obtain further information by examining the MCAI in the AD docket.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of Germany, and is approved for operation in the United States. Pursuant to our bilateral agreement with Germany, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require reducing the life limits for certain HPT stage 1 and HPT stage 2 discs that have a serial number listed in this proposed AD.

Costs of Compliance

We estimate that this proposed AD would affect about 10 engines installed on airplanes of U.S. registry. Prorated parts life will cost about $210,000. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $2,100,000. Our cost estimate is exclusive of possible warranty coverage.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Rolls-Royce Deutschland Ltd & Co KG (Formerly Rolls-Royce Deutschland GmbH, formerly BMW Rolls-Royce GmbH): Docket No. FAA–2012–1055; Directorate Identifier 2012–NE–33–AD.

(a) Comments Due Date

We must receive comments by January 15, 2013.

(b) Affected Airworthiness Directives (ADs)

None.

(c) Applicability

This AD applies to the following Rolls-Royce Deutschland Ltd & Co KG (RRD) turbofan engines that have any of the high-pressure turbine (HPT) stage 1 or stage 2 discs with a serial number (S/N) listed in Table 1 to paragraph (c) of this AD, installed:

(1) RRD BR700–710A1–10 and BR700–710A2–20 turbofan engines; and

(2) BR700–710C4–11 model engines that have hardware configuration standard 710C4–11 or 710C4–11/10 engraved on the engine data plate.

TABLE 1 TO PARAGRAPH (C)—AFFECTED HPT STAGE 1 AND STAGE 2 DISCS

S/Ns of HPT Stage 1 discs, Part No. (P/N) BRR23952	S/Ns of HPT Stage 2 discs, P/N BRR22008
LDRQA05719 LDRQA05720 LDRQA05721 LDRQA05722 LDRQA05723 LDRQA05724 LDRQA05726 LDRQA05727 LDRQA05841 LDRQA05842	LDRQA05791 LDRQA05944 LDRQA05945

(d) Reason

This AD was prompted by RRD performing an evaluation that determined that certain HPT stage 1 and stage 2 discs from a specific supplier may contain steel inclusions that may cause the discs to fail before they reach their current life limits. We are issuing this AD to prevent failure of the HPT stage 1 and stage 2 discs, which could result in uncontained failure of the engine and damage to the airplane.

(e) Actions and Compliance

Unless already done, remove from service the HPT stage 1 and stage 2 discs listed by S/N in Table 1 to paragraph (c) of this AD, at the following:

(1) For BR700–710A1–10, BR700–710A2–20, and BR700–710C4–11 engine models (without RRD Mod 72–101466), remove the HPT stage 1 and stage 2 discs from service before accumulating 3,000 cycles-since-new (CSN).

(2) For the BR700–710C4–11 engine model (with RRD Mod 72–101466), remove the HPT stage 1 and stage 2 discs from service before accumulating 2,300 CSN.

(f) Installation Prohibition

After the effective date of this AD, do not install an HPT stage 1 and an HPT stage 2 disc, identified by S/N in Table 1 to paragraph (c) of this AD, in the same engine.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(h) Related Information

(1) For more information about this AD, contact Robert Morlath, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7154; fax: 781–238–7199; email: *robert.c.morlath@faa.gov*.

(2) Refer to European Aviation Safety Agency Airworthiness Directive 2012–0166, dated August 30, 2012, and Rolls-Royce Deutschland Ltd & Co KG Alert Service Bulletin SB–BR700–72–A900508, dated July 26, 2012, for related information. Contact Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, Dahlewitz, 15827 Blankenfelde-Mahlow, Germany; phone: 49 0 33–7086–1883; fax: 49 0 33–7086–3276, for a copy of this service information.

(3) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on November 5, 2012.

Colleen M. D'Alessandro,

Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2012–27824 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0655; Airspace Docket No. 12–AGL–6]

Proposed Amendment of Class E Airspace; Hot Springs, SD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace at Hot Springs, SD. Additional controlled airspace is necessary to accommodate new Standard Instrument Approach Procedures (SIAPs) at Hot Springs Municipal Airport. The FAA is taking this action to enhance the safety and management of Instrument Flight Rules (IFR) operations for SIAPs at the airport. Geographic coordinates of the airport would also be updated.

DATES: 0901 UTC. Comments must be received on or before December 31, 2012.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001. You must identify the docket number FAA–2012–0655/Airspace Docket No. 12–AGL–6, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov*. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527), is on the ground floor of the building at the above address.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2012–0655/Airspace Docket No. 12–AGL–6.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Central Service Center, 2601 Meacham Blvd., Fort Worth, TX 76137.

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

The Proposal

This action proposes to amend Title 14, Code of Federal Regulations (14 CFR), Part 71 by amending Class E airspace extending upward from 700 feet above the surface to accommodate new standard instrument approach procedures at Hot Springs Municipal Airport, Hot Springs, SD. Controlled airspace is needed for the safety and management of IFR operations at the airport. The airport's geographic coordinates also would be updated to coincide with the FAA's aeronautical database.

Class E airspace areas are published in Paragraph 6005 of FAA Order 7400.9W, dated August 8, 2012 and effective September 15, 2012, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

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

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

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

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

* * * * *

AGL SD E5 Hot Springs, SD [Amended]

Hot Springs Municipal Airport, SD
(Lat. 43°22′06″ N., long. 103°23′18″ W.)

That airspace extending upward from 700 feet above the surface within a 7.4-mile radius of Hot Springs Municipal Airport, and within 2 miles each side of the 021° bearing from the airport extending from the 7.4-mile radius to 12.1 miles north of the airport.

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

David P. Melina,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2012–27839 Filed 11–15–12; 8:45 am]

BILLING CODE 4901–13–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

[Docket No. OSH–2011–0184]

RIN 1218–AC65

Updating OSHA Standards Based on National Consensus Standards; Head Protection

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule; withdrawal.

SUMMARY: With this notice, OSHA is withdrawing the proposed rule that accompanied its direct-final rule revising its Head Protection standards for general industry, shipyard employment, marine terminals, longshoring, and construction.

DATES: Effective November 16, 2012, the proposed rule published June 22, 2012 (77 FR 37617), is withdrawn.

FOR FURTHER INFORMATION CONTACT:

General information and press inquiries: Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999.

Technical information: Ken Stevanus, Directorate of Standards and Guidance, Room N–3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2260; fax: (202) 693–1663.

SUPPLEMENTARY INFORMATION:

*Copies of this **Federal Register** notice:* Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This **Federal Register** notice, as well as news releases and other relevant information, is also available at OSHA's Web page at *http://www.osha.gov.*

Withdrawal of the proposal: On June 22, 2012, OSHA published a direct-final rule to update the incorporated references in its Head Protection standards for general industry at 29 CFR 1910.135, shipyard employment at 29 CFR 1915.155, marine terminals at 29 CFR 1917.93, longshoring at 29 CFR 1918.103, and construction at 29 CFR 1926.100 (77 FR 37587). OSHA also published a companion proposed rule along with the direct-final rule (77 FR 37617). In the direct-final rule, OSHA stated that it would withdraw the companion proposed rule and confirm the effective date of the direct-final rule

if it received no significant adverse comments on the direct-final rule by July 23, 2012. OSHA received two comments on the direct-final rule by that date, neither of which were significant adverse comments (see Document IDs OSHA–2011–0184–0003 and –0004). To the contrary, both comments supported the direct final rule.

OSHA is publishing a notice announcing this determination and confirming the effective date of the direct-final rule as September 20, 2012. Accordingly, OSHA is not proceeding with the proposed rule, and is withdrawing it from the rulemaking process.

List of Subjects in 29 CFR Parts 1910, 1915, 1917, 1918, and 1926

Head protection, Occupational safety and health, Safety.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this document. OSHA is issuing this document pursuant to 29 U.S.C. 653, 655, and 657, 5 U.S.C. 553, Secretary of Labor's Order 1–2012 (77 FR 3912), and 29 CFR part 1911.

Signed at Washington, DC on November 8, 2012.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2012–27791 Filed 11–15–12; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0969]

RIN 1625–AA00

Safety Zone for Fireworks Display, Upper Potomac River, Alexandria Channel; Washington, DC

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone encompassing certain waters of the Upper Potomac River. This action is necessary to provide for the safety of life on navigable waters during a fireworks display launched from a barge located within the Alexandria Channel at Washington, DC. This safety zone is intended to protect the maritime public in a portion of the Upper Potomac River.

DATES: Comments and related material must be received by the Coast Guard on or before December 17, 2012. If finalized, this rule would be effective from 10:30 p.m. on December 31, 2012 through 9 p.m. on January 1, 2013.

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

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

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Ronald L. Houck, Sector Baltimore, Waterways Management Division, U.S. Coast Guard; telephone (410) 576–2674, email *Ronald.L.Houck@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking

A. Public Participation and Request for Comments

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

1. Submitting Comments

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

To submit your comment online, go to *http://www.regulations.gov,* type the docket number USCG–2012–0969 in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number (USCG–2012–0969) in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

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

4. Public Meeting

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

B. Regulatory History and Information

This rule involves a New Years Eve fireworks display, an event that takes place in Alexandria, Virginia each year on December 31st and attracts thousands of spectators. This year, the launch site for the annual fireworks display is being moved from land to a discharge barge located on the Upper Potomac River. The permanent safety zone listed as Number 21 in the Table to 33 CFR 165.506 does not apply to this event.

C. Basis and Purpose

First Night Alexandria, of Alexandria, Virginia, will conduct a fireworks display launched from a barge located on the Upper Potomac River, near Alexandria, Virginia, scheduled on December 31, 2012 at approximately 12 a.m. Midnight. If necessary, due to inclement weather, the fireworks display may be re-scheduled to take place on January 1, 2013 at approximately 8 p.m.

Fireworks displays are frequently held from locations on or near the navigable waters of the United States. The potential hazards associated with fireworks displays are a safety concern during such events. The purpose of this rule is to promote public and maritime safety during a fireworks display, and to protect mariners transiting the area from the potential hazards associated with a fireworks display, such as the accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. This rule is needed to ensure safety on the waterway before, during and after the scheduled event.

D. Discussion of Proposed Rule

Through this regulation, the Coast Guard proposes to establish a temporary safety zone. The proposed zone would encompass all waters of the Upper Potomac River, Alexandria Channel, within a 200 yards radius of a fireworks discharge barge in approximate position latitude 38°48′40″ N, longitude 077°02′07″ W, located near the waterfront of Alexandria, Virginia. The temporary safety zone would be enforced from 10:30 p.m. on December 31, 2012 through 1 a.m. on January 1, 2013 and, if necessary due to inclement weather, from 6:30 p.m. through 9 p.m. on January 1, 2013.

The effect of this temporary safety zone would be to restrict navigation in the regulated area during, as well as the set up and take down of, the fireworks display. Vessels would be allowed to transit the waters of the Upper Potomac River outside the safety zone.

This rule would require that entry into or remaining in this safety zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore. Vessels already at berth, mooring, or anchor in the safety zone at the time the safety zone is implemented would not have to depart the zone. All vessels underway within this safety zone at the time it is implemented would have to depart the zone. To seek permission to transit the area of the safety zone, the Captain of the Port Baltimore can be contacted at telephone number 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). Coast Guard vessels enforcing the safety zone can be contacted on Marine Band Radio VHF–FM channel 16 (156.8 MHz). Federal, state, and local agencies may assist the Coast Guard in the enforcement of the safety zone. The Coast Guard will issue notices to the maritime community to further publicize the safety zone and notify the public of changes in the status of the zone. Such notices will continue until the event is complete.

E. Regulatory Analyses

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

1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. There is no vessel traffic associated with recreational boating and commercial fishing expected during the effective period.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to operate or transit through or within the safety zone during the enforcement period. Before the effective period, maritime advisories will be widely available to the maritime community.

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

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the ''For Further Information Contact'' section to coordinate protest activities so that your

message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

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

9. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children From Environmental Health Risks

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

11. Indian Tribal Governments

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

12. Energy Effects

This proposed rule is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

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

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves establishing a temporary safety zone. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T05–0969 to read as follows:

§ 165.0969 Safety Zone, Upper Potomac River, Alexandria Channel; Washington, DC.

(a) *Location.* The following area is a safety zone: All waters of the Upper Potomac River, Alexandria Channel, within a 200 yards radius of a fireworks discharge barge in approximate position latitude 38°48′40″ N, longitude 077°02′07″ W, located near the waterfront of Alexandria, Virginia. All coordinates refer to datum NAD 1983.

(b) *Regulations.* The general safety zone regulations found in 33 CFR 165.23 apply to the safety zone created by this temporary section, § 165.T05.0969.

(1) All persons are required to comply with the general regulations governing safety zones found in 33 CFR 165.23.

(2) Entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore. Vessels already at berth, mooring, or anchor at the time the safety zone is implemented do not have to depart the safety zone. All vessels underway within this safety zone at the time it is implemented are to depart the zone.

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

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

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

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

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

(d) *Effective period.* This section will be enforced from 10:30 p.m. on December 31, 2012 through 1 a.m. on January 1, 2013 and, if necessary due to inclement weather, from 6:30 p.m. through 9 p.m. on January 1, 2013.

Dated: November 2, 2012.

Kevin C. Kiefer,

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

[FR Doc. 2012–27814 Filed 11–15–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 52

[EPA–R03–OAR–2012–0305; FRL–9752–7]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Deferral for CO_2 Emissions From Bioenergy and Other Biogenic Sources Under the Prevention of Significant Deterioration Program; Reopening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: EPA is reopening the comment period for a notice of proposed rulemaking (NPR) published on September 7, 2012. In the NPR, EPA proposed approval of a revision to the Maryland State Implementation Plan (SIP) that would incorporate EPA's ''Biomass Deferral'' into the Maryland SIP. At the request of Community Research, (College Park, Maryland), EPA is reopening the comment period. Comments submitted between the close of the original comment period and the re-opening of this comment period will be accepted and considered.

DATES: The comment period for the proposed rule published on September 7, 2012 (77 FR 55171) is reopened through December 17, 2012. All comments received on or before December 17, 2012 will be entered into the public record and considered by EPA before taking final action on the proposed rule.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2012–0305 by one of the following methods:

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

B. *Email: cox.kathleen@epa.gov.*

C. *Mail:* EPA–R03–OAR–2012–0305, Ms. Kathleen Cox, Associate Director, Office of Permits and Air Toxics, Mailcode 3AP10, 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–2012–0305. 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 Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Mr. David Talley, (215) 814–2117, or by email at *talley.david@epa.gov.*

Dated: October 31, 2012.

W. C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2012–27977 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 95

[ET Docket No. 08–59; Report No. 2966]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: In this document, Petitions for Reconsideration (Petitions) have been filed in the Commission's rulemaking proceeding filed by Dale Woodin, Executive Director of American Society for Healthcare Engineering of American Hospital Association, on behalf of American Society for Healthcare Engineering of the American Hospital Association, and David R. Sidall, Esq., for DS Law PLLC, on behalf of Phillips Healthcare, Ari Q. Fitzgerald, Esq., for Hogan Lovells US LLP, on behalf of GE Healthcare, and William K. Keane, Esq., for Duane Morris LLP, on behalf of AFTRCC.

DATES: Oppositions to the Petitions must be filed on or before December 3, 2012. Replies to an opposition must be filed on or before December 11, 2012.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Brian Butler, Policy and Rules Division, Office of Engineering and Technology, (202) 418–2702, email *brian.butler@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of Commission's document, Report No. 2966, released October 31, 2012. The full text of Report No. 2966 is available for viewing and copying in Room CY–B402, 445 12th Street SW., Washington, DC or may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI) (1–800–378–3160). The Commission will not send a copy of this *Notice* pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this *Notice* does not have an impact on any rules of particular applicability.

Subject: Amendment of the Commission's Rules to Provide

Spectrum for the Operation of Medical Body Area Networks, published at 77 FR 55715, September 11, 2012, in ET Docket No. 08–59, and published pursuant to 47 CFR 1.429(e) of the Commission's rules. *See also* 47 CFR 1.4(b)(1) of the Commission's rules.

Number of Petitions Filed: 2.

Federal Communications Commission.

Marlene H. Dortch,

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

[FR Doc. 2012–27798 Filed 11–15–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket Nos. 11–90 and 10–28; Report No. 2965]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: In this document, Petitions for Reconsideration (Petitions) have been filed in the Commission's rulemaking proceeding by Dennis Farrell, International Sales Manager of Navtech Radar Ltd., on behalf of Navtech Radar Ltd. and Bruce A. Olcott, for Squire Sanders LLP, on behalf of Honeywell International, Inc.

DATES: Oppositions to these Petitions must be filed on or before December 3, 2012. Replies to an opposition must be filed on or before December 11, 2012.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Aamer Zain, Policy and Rules Division, Office of Engineering and Technology, (202) 418–2473, email *aamer.zain@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of Commission's document, Report No. 2965, released October 31, 2012. The full text of Report No. 2965 is available for viewing and copying in Room CY–B402, 445 12th Street SW., Washington, DC or may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI) (1–800–378–3160). The Commission will not send a copy of this *Notice* pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this *Notice* does not have an impact on any rules of particular applicability.

Subject: Amendment of Sections 15.35 and 15.253 of the Commission's Rules Regarding Operation of Radar Systems in the 76–77 GHz Band; Amendment of Section 15.253 of the Commission's Rules to Permit Fixed Use of Radar in the 76–77 GHz Band (ET Docket Nos. 11–90 and 10–28), published at 77 FR 48097, August 13, 2012, in ET Docket Nos. 11–90 and 10–28, and published pursuant to 47 CFR 1.429(e) of the Commission's rules. *See also* 47 CFR 1.4(b)(1) of the Commission's rules.

Number of Petitions Filed: 2.

Federal Communications Commission.

Marlene H. Dortch,

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

[FR Doc. 2012–27797 Filed 11–15–12; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 234

[Docket No. FRA–2011–0007, Notice No. 2]

RIN 2130–AC26

National Highway-Rail Crossing Inventory Reporting Requirements

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

ACTION: Announcement of technical symposium and extension of comment period.

SUMMARY: On October 18, 2012, FRA published a Notice of Proposed Rulemaking (NPRM) on National Highway-Rail Crossing Inventory Reporting Requirements. In the NPRM, FRA announced that it would schedule a technical symposium to give interested parties the opportunity to discuss issues associated with the electronic submission of data to the U.S. DOT National Highway-Rail Crossing Inventory (Crossing Inventory). This notice announces the scheduling of the technical symposium. This notice also extends the NPRM comment period to allow time for interested parties to submit comments after the technical symposium.

DATES: The technical symposium will be held on December 13, 2012 in Washington, DC and will commence at 10 a.m. The comment period in this proceeding is extended to January 31, 2013.

ADDRESSES: (1) *Technical Symposium:* The technical symposium will be held at the Courtyard by Marriott Capitol Hill/Navy Yard, 140 L Street SE., Washington, DC 20003.

(2) *Attendance:* Any person wishing to participate in the technical symposium should notify Michelle Silva in FRA's Office of Chief Counsel by telephone, email, or by mail at least five business days prior to the date of the symposium. Ms. Silva's contact information is as follows: FRA, Office of Chief Counsel, Mail Stop 10, 1200 New Jersey Avenue SE., Washington, DC 20590; *telephone:* 202–493–6030; *email: michelle.silva@dot.gov.*

For information on facilities or services for persons with disabilities or to request special assistance at the meeting, please contact Larry Woolverton in FRA's Office of Railroad Safety, by telephone (202–493–6212) or email (*larry.woolverton@dot.gov*).

SUPPLEMENTARY INFORMATION:

Technical Symposium

The purpose of the technical symposium is to facilitate discussion on technical issues associated with the electronic submission of data to the Crossing Inventory. The meeting is not intended as a forum for discussion or comment on any other aspects of the proposed rule. The proposed topics for discussion include the draft Instructions for Submitting U.S. DOT Crossing Inventory Data by Electronic Methods (Electronic Submission Instructions) referenced in the NPRM (and available in the docket at FRA–2011–0007–0005), proposed options for the submission of electronic crossing data to the Crossing Inventory, data formats that would be accepted for the submission of electronic crossing data to the Crossing Inventory, and the proposed timeframe and related concerns associated with meeting the proposed new requirements for the electronic submission of crossing data to the Crossing Inventory. In order to facilitate discussion at the technical symposium, FRA intends to supplement the docket with revised draft Electronic Submission Instructions prior to the symposium. The revised draft Electronic Submission Instructions will contain information on the proposed file formats and data specifications that would need to be followed when preparing electronic crossing data for submission to the Crossing Inventory. Therefore, interested parties are advised to review, prior to attending the technical symposium, the draft revised Electronic Submission Instructions that will be placed in the docket. Parties are reminded that the docket (No. FRA–2011–0007) can be accessed via the Internet at *www.regulations.gov.*

A transcript of the technical symposium will be taken and placed in the public docket of this proceeding.

Public Participation Procedures

Any person wishing to participate in the technical symposium should notify FRA by telephone, email, or mail as provided in the Attendance section of this notice at least five business days prior to the date of the technical symposium. The notification should identify the docket number of this proceeding (Docket No. FRA–2011–0007), as well as the organization the person represents (if any) and the particular issues associated with electronic data submission that the person plans to address. The notification should also provide a phone number, mailing address, and email address (if applicable) at which the registrant can be reached.

Extension of Comment Period

To afford interested parties the opportunity to submit comments in response to views or information provided at the technical symposium, FRA is extending the comment period in this proceeding to January 31, 2013.

Issued in Washington, DC, on November 9, 2012.

Jo Strang,

Associate Administrator for Railroad Safety/ Chief Safety Officer.

[FR Doc. 2012–27976 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 121009528–2601–01]

RIN 0648–XC287

Fisheries of the Northeastern United States; Summer Flounder, Scup, and Black Sea Bass Fisheries; 2013–2014 Summer Flounder, 2013–2014 Scup, and 2013 Black Sea Bass Specifications; 2013 Research Set-Aside Projects

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

ACTION: Proposed specifications; request for comments.

SUMMARY: NMFS proposes specifications for the 2013 summer flounder, scup, and black sea bass fisheries, and the 2014 summer flounder and scup fisheries, and provides notice of two projects that may be requesting exempted fishing permits as part of the Mid-Atlantic Fishery Management Council's Research Set-Aside Program. The implementing regulations for the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan require NMFS to publish specifications for the upcoming fishing year for each of these species and to provide an opportunity for public comment. Furthermore, regulations under the Magnuson-Stevens Fishery Conservation and Management Act require that NMFS allow the public an opportunity to comment on applications for exempted fishing permits. Accordingly, in addition to proposing catch specifications, NMFS announces exempted fishing permit requests, in accordance with the fishery management plan and Magnuson-Stevens Fishery Conservation and Management Act.

DATES: Comments must be received on or before December 3, 2012.

ADDRESSES: An environmental assessment (EA) was prepared for the specifications and describes the proposed action and other considered alternatives, and provides an analysis of the impacts of the proposed measures and alternatives. Copies of the Specifications Document, including the EA and the Initial Regulatory Flexibility Analysis (IRFA), are available on request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the Internet at *http://www.nero.noaa.gov.*

You may submit comments, identified by NOAA–NMFS–2012–0201, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal at *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2012-0201.* Clicking the preceding link will bring you to the NOAA–NMFS–2012–0201 docket folder for this action. To submit comments once in the docket folder, click the ''Comment Now!'' icon. Fill in the fields on the comment form and enter or attach your comment.
- *Fax:* (978) 281–9135, Attn: Moira Kelly.
- *Mail:* John Bullard, Regional Administrator, NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on FSB Specifications.''

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov.* All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Moira Kelly, Fishery Policy Analyst, (978) 281–9218.

SUPPLEMENTARY INFORMATION:

General Specification Background

The Mid-Atlantic Fishery Management Council (Council) and the Atlantic States Marine Fisheries Commission (Commission) cooperatively manage the summer flounder, scup, and black sea bass fisheries. Fishery specifications in these fisheries include various catch and landing subdivisions, such as the commercial and recreational sector annual catch limits (ACLs), annual catch targets (ACTs), sector-specific landing limits (i.e., the commercial fishery quota and recreational harvest limit (RHL)), and research set-aside (RSA) established for the upcoming fishing year. An explanation of each subdivision appears later in this rule.

Rulemaking for measures used to manage the recreational fisheries for these three species occurs separately and typically takes place in the first quarter of the fishing year. The Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) and its implementing regulations establish the Council's process for establishing specifications. All requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), including the 10 national standards, also apply to specifications.

The management units specified in the FMP include summer flounder (*Paralichthys dentatus*) in U.S. waters of the Atlantic Ocean from the southern border of North Carolina northward to

the U.S./Canada border, and scup (*Stenotomus chrysops*) and black sea bass (*Centropristis striata*) in U.S. waters of the Atlantic Ocean from 35°13.3′ N. lat. (the latitude of Cape Hatteras Lighthouse, Buxton, NC) northward to the U.S./Canada border.

The Council's Scientific and Statistical Committee (SSC) met on July 25 and 26, 2012, to recommend acceptable biological catches (ABC) for the 2013–2015 summer flounder, scup, and black sea bass fisheries. The FMP's implementing regulations require the involvement of a monitoring committee in the specification process for each species. Since the Magnuson-Stevens Act requirements for the SSC to recommend ABC became effective, the monitoring committees' role has largely been to recommend any reduction in catch limits from the SSC-recommended ABCs to offset management uncertainty, and to recommend other management measures (e.g., mesh requirements, minimum commercial fish sizes, gear restrictions, possession restrictions, and area restrictions) needed for the efficient management of these three species' fisheries. The Summer Flounder, Scup, and Black Sea Bass Monitoring Committees met on July 27, 2012, to discuss specification-related recommendations for the three fisheries.

Following the SSC and Monitoring Committee meetings, the Council and the Commission's Summer Flounder, Scup, and Black Sea Bass Management Board (Board) considered the recommendations of the SSC, the three monitoring committees, and public comments, and made their specification recommendations at a meeting held on August 15, 2012. While the Board action was finalized at the August meeting, the Council's recommendations must be reviewed by NMFS to ensure that they comply with the FMP and applicable law. NMFS also must conduct notice-and-comment rulemaking to propose and implement the final specifications.

The FMP also contains formulas to divide the specification catch limits into commercial and recreational fishery allocations, state-by-state quotas, and quota periods, depending on the species in question. The FMP allocation provisions cannot be modified through the specification process. Rather, the Council would be required to develop and recommend allocation changes by amending the FMP. This proposed rule outlines the application of the existing allocation provisions for each species and provides the resulting allocations, by state and sector, as appropriate, for each species.

TABLE 1—SUMMARY OF THE PROPOSED 2013–2014 SPECIFICATIONS

		Summer flounder		Scup		Black sea bass
		2013	2014	2013	2014	2013
ABC	million lb	22.34	22.24	38.71	35.99	4.50
	mt	10,133	10,088	17,557	16,325	2,041
Commercial ACL	million lb	12.11	12.05	30.19	28.07	2.13
	mt	5,491	5,467	13,694	12734	966
Recreational ACL	million lb	10.23	10.19	8.52	7.92	2.37
	mt	4,642	4,621	3,863	3,592	1,075
Commercial ACT	million lb	12.11	12.05	30.19	28.07	2.13
	mt	5,491	5,467	13,694	12734	966
Recreational ACT	million lb	10.23	10.19	8.52	7.92	2.37
	mt	4,642	4,621	3,863	3,592	1,075
Commercial Quota	million lb	11.44	11.39	23.53	21.95	1.78
	mt	5,189	5,166	10,671	9,955	805
RHL	million lb	7.63	7.59	7.55	7.03	1.85
	mt	3,459	3,444	3,425	3,188	838

Note: Commercial Quotas and RHLs include the 3-percent RSA reduction.

Explanation of RSA

In 2001, NMFS implemented regulations under Framework Adjustment 1 to the FMP to allow up to 3 percent of the total allowable landings (TAL) for each species to be set aside each year to support scientific research. NMFS intends to conditionally approve two research projects to harvest a portion of the set-aside quota that has been recommended by the Council and the Commission. In anticipation of receiving applications for exempted fishing permits (EFP) to conduct this research and harvest set-aside quota, the Assistant Regional Administrator for Sustainable Fisheries, Northeast Region, NMFS (Assistant Regional Administrator), has made a preliminary determination that the activities authorized under the EFPs would be consistent with the goals and objectives of the FMP. However, further review and consultation may be necessary before a final determination is made to issue any EFP.

For informational purposes, these proposed specifications include a statement indicating the amount of quota that has been preliminarily set aside for research purposes (a percentage of the TAL for each fishery, not to exceed 3 percent, as recommended by the Council and Board), and a brief description of the likely 2013 Mid-Atlantic RSA projects, including exemptions that will likely be required to conduct the proposed research. The RSA amounts may be adjusted, following consultation with RSA applicants, in the final rule establishing the 2013 specifications for the summer flounder, scup, black sea bass, longfin squid, butterfish, and Atlantic bluefish fisheries. If the total amount of available RSA is not awarded, NMFS will publish a document in the **Federal Register** to restore the unused amount to the applicable TAL.

For 2013, the conditionally approved projects may collectively be awarded up to the following amounts of RSA: 589,880 lb (267.6 mt) of summer flounder; 961,200 lb (436 mt) of scup; 111,900 lb (51 mt) of black sea bass; 1,1453,711 lb of longfin squid; 332,898 lb of butterfish; and 715,830 lb of bluefish. For 2014, projects may collectively be awarded up to 587,100 lb (266 mt) of summer flounder and 896,100 lb (404 mt) of scup. The harvest of RSA quota would occur January 1-December 31, 2013, and January 1-December 31, 2014, by vessels conducting compensation fishing.

Vessels harvesting research quota in support of approved research projects would be issued EFPs authorizing them to exceed Federal possession limits and to fish during Federal quota closures. These exemptions are necessary to facilitate compensation fishing and to allow project investigators to recover research expenses, as well as to adequately compensate fishing industry participants harvesting research quota. Vessels harvesting research quota would operate under all other regulations that govern the fishery, unless specifically exempted in a separate EFP.

2013 RSA Proposal Summaries: Because the research activities of project number one will be analyzed through a separate environmental assessment and a separate consultation process under the Endangered Species Act, only a brief description of the project is included here. A more detailed description will be published in the **Federal Register** at such time as the environmental analysis is completed. For informational purposes, project number one would conduct a spring and fall monitoring (trawl) survey in shallow waters between Martha's Vineyard, MA, and Cape Hatteras, NC. The project investigators plan to provide stock assessment data for Mid-Atlantic RSA species, including summer flounder, scup, black sea bass, longfin squid, butterfish, and Atlantic bluefish, and assessment-quality data for weakfish, Atlantic croaker, spot, several skate and ray species, smooth dogfish, horseshoe crab, and several unmanaged but important forage species.

Project number two is a fishery-independent black sea bass survey of four separate hard bottom sites in Southern New England and Mid-Atlantic waters. Unvented black sea bass pots would be fished on each site for 5 months from June through October in Southern New England, and April through August in the Mid-Atlantic. The project is designed to collect black sea bass from areas un-sampled by current state and Federal finfish bottom trawl surveys. The length frequency distribution of the catch will be compared statistically to each of the other collection sites, and to finfish trawl data collected by NMFS and state agencies. Black sea bass would be collected from four general zones along the coast utilizing black sea bass pots made with coated wire mesh, single mesh entry head, and single mesh inverted parlor nozzle. The four general zones will include one in Massachusetts, one south of Rhode Island, one south of New Jersey, and one south of Virginia. This particular configuration is being proposed as it generally corresponds to the northern and southern core range of the species, and each is an area in which a major black sea bass fishery takes place. In each of these general zones, four individual sampling sites would be selected, each of which would be 1 square mile (2.6 km^2) in size. Each of the individual sampling sites would be separated by at least 4 miles (6.4 km) in order to provide adequate spatial coverage. Specific sampling sites within each square mile sampling site would be randomly selected each month from the sub-blocks. The traps would be set at the center of each sampling site once per month. The sampling protocol would require that a commercial vessel take 30 pots (three 10-pot trawls) to each of the randomly selected hard bottom sampling sites. This procedure would continue each month during the sampling season for 5 months. Thus, 16 locations would be sampled monthly. Pots would be un-baited and allowed to remain in place for a minimum of 4 days. The date, area, depth, set over days, and catch would be recorded and fish measured utilizing the standard NMFS sea sampling protocols. Fish would be measured excluding the tail tendril, which is the NMFS/ASMFC standard. At the conclusion of each sampling cycle, pots would be placed on the vessel for transport back to port.

Research vessels for project number two would require an EFP for exemption from minimum scup and black sea bass pot vent size requirements to ensure that black sea bass length frequency data are representative and not biased. If a participating vessel holds a Federal lobster permit, it would need exemption from lobster pot vent size requirements. Exemption from scup and black sea bass closures and time restrictions would also be needed to ensure the survey is not disrupted by such regulations. Exemption from scup and black sea bass minimum fish sizes and possession limits would also be needed for data collection purposes only. All undersized fish would be discarded as soon as practicable to minimize mortality, and fish in excess of possession limits would either be discarded as soon as practicable or landed as RSA quota.

Summer Flounder

The summer flounder stock was declared rebuilt in 2011. The stock assessment update utilized to derive specification recommendations indicates that summer flounder were not overfished and that overfishing did not occur in 2011, the most recent year of available data. This stock assessment update did, however, indicate that biomass is currently lower than in recent years. This results in catch limits that are lower than 2012 (Table 1).

The overfishing limit (OFL) for 2012 was estimated to be 29.81 million lb (13,523 mt). Based on this information, the SSC recommended to the Council that the 2013 ABC for summer flounder be set no higher than 22.34 million lb (10,133 mt), and, using a strategy of a constant fishing rate, that the 2014 ABC for summer flounder be set no higher than 22.24 million lb (10,088 mt). The SSC did not provide an ABC recommendation for 2015 because it is expected that a benchmark assessment for summer flounder will be conducted in 2013 and it would be more appropriate to wait for that assessment before making a 2015 recommendation.

Consistent with the summer flounder regulations, the sum of the recreational and commercial sector ACLs is equal to ABC. ACL is an expression of total catch (i.e., landings and dead discarded fish). To derive the ACLs, the sum of the sector-specific estimated discards is removed from the ABC to derive the landing allowance. The resulting landing allowance is apportioned to the commercial and recreational sectors by applying the FMP allocation criteria: 60 percent to the commercial fishery and 40 percent to the recreational fishery. Using this method ensures that each sector is accountable for its respective discards, rather than simply apportioning the ABC by the allocation percentages to derive the sector ACLs. Although the derived ACLs are not split exactly at 60/40, the landing portions of the ACLs preserve the 60/40 allocation split, consistent with the FMP. This process results in a commercial ACL of 12.11 million lb (5,491 mt) for 2013 and 12.05 million lb (5,467 mt) for 2014. The recreational ACLs would be 10.23 million lb (4,642 mt) for 2013 and 10.19 million lb (4,621 mt) for 2014.

The Summer Flounder Monitoring Committee met to discuss the SSC's recommendations and to determine if additional reductions in the catch limits were necessary to account for management uncertainty. Because the recreational fishery in recent years has not reached the RHL, discards in the commercial fishery have been relatively low, and the landings monitoring and fishery closure system is timely, the Summer Flounder Monitoring Committee determined that no additional reductions to account for management uncertainty were necessary. Therefore, it was recommended that the ACTs (both commercial and recreational) should be set equal to their respective ACL for both 2013 and 2014. Removing the estimated discards and, as recommended, 3 percent of the TAL for RSA, the commercial summer flounder quotas would be 11.44 million lb (5,189 mt) for 2013 and 11.39 million lb (5,166 mt) for 2014. The RHLs would be 7.63 million lb (3,459 mt) for 2013 and 7.59 million lb (3,444 mt) for 2014.

TABLE 2—PROPOSED SUMMER FLOUNDER SPECIFICATIONS

Year		ABC	Commercial ACL	Recreational ACL	Comm. ACT	Rec. ACT	Comm. Quota (minus 3% RSA)	RHL (minus 3% RSA)
2012	million lb	25.58	14.00	11.56	14.00	11.58	12.73	8.49
	mt	11,603	6,351	5,252	6,351	5,252	5,774	3,850
2013	million lb	22.34	12.11	10.23	12.11	10.23	11.44	7.63
	mt	10,133	5,491	4,624	5,491	4,624	5,189	3,459
2014	million lb	22.24	12.05	10.19	12.05	10.19	11.39	7.59
	mt	10,088	5,467	4,621	5,467	4,621	5,166	3,444

Note: Commercial Quotas and RHLs include the 3-percent RSA reduction.

The Council and Board considered the SSC and Summer Flounder Monitoring Committee recommendations before concurring with the catch recommendations specified in Table 2. Fishing under these catch limits for 2013 and 2014 is not expected to compromise the summer flounder stock, nor will fishing at this level present a high likelihood of overfishing the stock. The Council recommended all other management measures by remain status quo.

Tables 3 and 4 present the proposed allocations for 2013 and 2014, respectively, by state, with and without the commercial portion of the RSA deduction. These state quota allocations are preliminary and are subject to reductions if there are overages of states' quotas carried over from a previous fishing year. Any commercial quota adjustments to account for overages will be included in the final rule implementing these specifications.

TABLE 3—2013 PROPOSED SUMMER FLOUNDER STATE COMMERCIAL QUOTAS

State	Percent share	Initial commercial quota		Commercial quota less RSA [1]	
		lb	kg [2]	lb	kg [2]
ME	0.04756	5,609	2,544	5,441	2,468
NH	0.00046	54	25	53	24
MA	6.82046	804,377	364,859	780,246	353,914
RI	15.68298	1,849,587	838,959	1,794,100	813,790
CT	2.25708	266,191	120,742	258,205	117,120
NY	7.64699	901,855	409,075	874,799	396,802
NJ	16.72499	1,972,478	894,701	1,913,303	867,860
DE	0.01779	2,098	952	2,035	923
MD	2.03910	240,483	109,081	233,269	105,809
VA	21.31676	2,514,012	1,140,337	2,438,592	1,106,127
NC	27.44584	3,236,851	1,468,211	3,139,746	1,424,165
Total [3]	100.00001	11,793,596	5,350,000	11,439,788	5,189,000

[1] Preliminary Research Set-Aside amount is 589,880 lb (267.6 mt).
[2] Kilograms are as converted from pounds and do not sum to the converted total due to rounding.
[3] Rounding of quotas results in totals exceeding 100 percent.

TABLE 4—2014 PROPOSED SUMMER FLOUNDER STATE COMMERCIAL QUOTAS

State	Percent share	Initial commercial quota		Commercial quota less RSA [1]	
		lb	kg [2]	lb	kg [2]
ME	0.04756	5,579	2,533	5,417	2,457
NH	0.00046	54	24	52	24
MA	6.82046	800,091	363,242	776,788	352,345
RI	15.68298	1,839,732	835,240	1,786,147	810,183
CT	2.25708	264,772	120,207	257,061	116,601
NY	7.64699	897,050	407,261	870,922	395,044
NJ	16.72499	1,961,967	890,735	1,904,823	864,013

TABLE 4—2014 PROPOSED SUMMER FLOUNDER STATE COMMERCIAL QUOTAS—Continued

State	Percent share	Initial commercial quota		Commercial quota less RSA [1]	
		lb	kg [2]	lb	kg [2]
DE	0.01779	2,087	947	2,026	919
MD	2.03910	239,202	108,598	232,235	105,340
VA	21.31676	2,500,616	1,135,282	2,427,783	1,101,224
NC	27.44584	3,219,604	1,461,703	3,125,829	1,417,852
Total [3]	100.00001	11,730,754	5,326,000	11,389,082	5,166,000

[1] Preliminary Research Set-Aside amount is 587,100 lb (266 mt).
[2] Kilograms are as converted from pounds and do not sum to the converted total due to rounding.
[3] Rounding of quotas results in totals exceeding 100 percent.

Scup

The OFL for scup is 47.80 million lb (21,680 mt). Using the appropriate control rule and applying the Council's risk policy, the SSC recommended an ABC for scup of 38.71 million lb (17,557 mt) for 2013. The SSC also recommended a constant fishing mortality strategy for scup, using a rate of 0.142, which results in a 2014 ABC of 35.99 million lb (16,325 mt). Similar to summer flounder, the stock assessment update upon which the specifications are based indicates that scup biomass is currently lower than in recent years. Therefore, the proposed catch limits are lower than 2012, but are still relatively high compared to recent landings.

The scup management measures specify that the ABC is equal to the sum of the commercial and recreational sector ACLs. The Scup Monitoring Committee met to discuss the SSC's recommendations and to determine if additional reductions in the catch limits were necessary to account for management uncertainty. Because both the recreational and commercial fisheries have not reached their respective landings limits because of the very high quotas, and the landings monitoring and fishery closure system is timely, the Monitoring Committee determined that no additional reductions to account for management uncertainty were necessary. Therefore, it was recommended that the ACTs (both commercial and recreational) should be set equal to the respective ACL for 2013–2014. Therefore, commercial sector ACL/ACT would be 30.19 million lb (13,694 mt) for 2013 and 28.07 million lb (12,734 mt) for 2014. The recreational sector ACLs/ACTs would be 8.52 million lb (3,863 mt), and 7.92 million lb (3,592 mt) for 2013 and 2014, respectively.

The Council recommended up to 3 percent of the landings for RSA. After RSA is removed, the commercial quotas would be 23.53 million lb (10,671 mt) for 2013 and 21.95 million lb (9,955 mt) for 2014. The recreational harvest limits would be 7.55 million lb (3,425 mt) for 2013 and 7.03 million lb (3,188 mt) for 2014.

TABLE 5—PROPOSED SCUP SPECIFICATIONS

Year		ABC	Commercial ACL	Recreational ACL	Comm. ACT	Rec. ACT	Comm. Quota	RHL
2012	million lb	40.88	31.89	8.99	31.89	8.99	27.91	8.45
	mt	18,543	14,464	4,079	14,464	4,079	12,659	3,831
2013	million lb	38.71	30.19	8.52	30.19	8.52	23.53	7.55
	mt	16,325	13,694	3,863	13,694	3,863	10,671	3,425
2014	million lb	35.99	28.07	7.92	28.07	7.92	21.95	7.03
	mt	16,325	12,734	3,592	12,734	3,592	9,955	3,188

Note: Commercial Quotas and RHLs include the 3-percent RSA reduction.

The scup commercial quota is divided into three commercial fishery quota periods. There are no previous commercial overages applicable to the 2013 scup commercial quota. The period quotas, after deducting for RSA, are detailed in tables 6 and 7. Unused Winter I quota may be carried over for use in the Winter II period. The Council recommended all other management measures remain status quo.

TABLE 6—PROPOSED COMMERCIAL SCUP QUOTA ALLOCATIONS FOR 2013 BY QUOTA PERIOD

Quota period	Percent share	Initial quota		Initial quota less overages (through 10/31/2012)		Adjusted quota less overages and RSA		Federal possession limits (per trip)	
		lb	mt	lb	mt	lb	mt	lb	mt
Winter I	45.11	10,940,583	4,963	N/A	N/A	10,612,366	4,814	50,000	22,680
Summer	38.95	9,446,591	4,285	N/A	N/A	9,163,193	4,156	N/A	N/A
Winter II	15.94	3,865,948	1,754	N/A	N/A	3,749,969	1,701	2,000	907
Total	100.0	24,253,122	11,001	N/A	N/A	23,525,528	10,671	N/A	N/A

Notes: The Winter I possession limit will drop to 1,000 lb (454 kg) upon attainment of 80 percent of that period's allocation. The Winter II possession limit may be adjusted (in association with a transfer of unused Winter I quota to the Winter II period) via notification in the **Federal Register**.

Metric tons are as converted from pounds and may not necessarily total due to rounding.

N/A = Not applicable.

TABLE 7—PROPOSED COMMERCIAL SCUP QUOTA ALLOCATIONS FOR 2014 BY QUOTA PERIOD

Quota period	Percent share	Initial quota		Initial quota less overages (through 10/31/2012)		Adjusted quota less overages and RSA		Federal possession limits (per trip)	
		lb	mt	lb	mt	lb	mt	lb	mt
Winter I ...	45.11	10,206,495	4,630	N/A	N/A	9,900,300	4,491	50,000	22,680
Summer ..	38.95	8,812,746	3,997	N/A	N/A	8,548,364	3,877	N/A	N/A
Winter II ..	15.94	3,606,551	1,636	N/A	N/A	3,498,355	1,587	2,000	907
Total	100.0	22,625,792	10,263	N/A	N/A	21,947,018	9,955	N/A	N/A

Notes: The Winter I possession limit will drop to 1,000 lb (454 kg) upon attainment of 80 percent of that period's allocation. The Winter II possession limit may be adjusted (in association with a transfer of unused Winter I quota to the Winter II period) via notification in the **Federal Register**.

Metric tons are as converted from pounds and may not necessarily add due to rounding.

N/A = Not applicable.

Black Sea Bass

The updated stock assessment indicates that black sea bass were not overfished and overfishing did not occur in 2011. Black sea bass remains a data-poor stock, with relatively high uncertainty for the purposes of calculating ABC. The SSC rejected the OFL estimate provided from the stock assessment, stating that it was highly uncertain and not sufficiently reliable to use as the basis of management advice. The ABC recommendation is the status quo ABC of 4.50 million lb (2,041 mt). The SSC recommended a 3-year specification period, with a constant harvest strategy that would implement the same ABC for 2013–2015. However, the Council only endorsed the ABC for 2013, and recommended the ACL, ACT, and quotas for 2013 only. The Council was concerned with the SSC's determination that black sea bass was a ''Level 4'' fishery under the Council's ABC control rule, despite some data improvements that may have led to a ''Level 3'' determination that could result in higher catch limits. The SSC debated the categorization of black sea bass extensively at its July meeting, but in the end determined that continuing the Level 4 designation was appropriate. The Council decided to recommend specifications for just 2013 in the hope that additional information will be available for the SSC in the coming year.

The Black Sea Bass Monitoring Committee met to discuss the SSC's recommendations and to determine if additional reductions in the catch limits were necessary to account for management uncertainty. The Monitoring Committee determined that no additional reductions to account for management uncertainty were necessary because the constant catch strategy adequately addresses uncertainty. Therefore, it was recommended that the ACTs (both commercial and recreational) should be set equal to their respective ACL for 2013.

The Council and Board considered the SSC and Black Sea Bass Monitoring Committee recommendations at their August meeting. The Council recommends a commercial ACL and ACT of 2.13 million lb (966 mt), a recreational ACL and ACT of 2.37 million lb (1,075 mt), a commercial quota of 1.78 million lb (805 mt), and an RHL of 1.85 million lb (838 mt). The quotas include a reduction of 3 percent, as recommended by the Council, for RSA. While the ABC is the same as last year, the ACL/ACTs and quotas are different from 2012 because the updated discard estimate is higher than the previous year.

Recent data indicate that the 2012 recreational black sea bass ACL has been exceeded, and may be further exceeded, by a significant amount. The regulations require that we deduct the amount of landings that exceeded the RHL from a single subsequent year's ACT. Therefore, the proposed ACT and RHL may be adjusted in the final rule to account for this overage.

TABLE 8—PROPOSED BLACK SEA BASS 2013 SPECIFICATIONS

Year		ABC	Commercial ACL	Recreational ACL	Comm. ACT	Rec. ACT	Comm. quota	RHL
2012	million lb	4.50	1.98	2.52	1.98	1.86	1.71	1.32
	mt	2,041	898	1,143	898	844	774	598
2013	million lb	4.50	2.13	2.37	2.13	2.37	1.78	1.85
	mt	2,041	966	1,075	966	1075	805	838

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Summer Flounder, Scup, and Black Sea Bass FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

These proposed specifications are exempt from review under Executive Order 12866.

An IRFA was prepared by the Council, as required by section 603 of the Regulatory Flexibility Act (RFA), to examine the impacts of these proposed specifications on small business entities, if adopted. A description of the specifications, why they are being considered, and the legal basis for proposing and implementing specifications for the summer flounder, scup, and black sea bass fisheries are contained in the preamble to this proposed rule. A copy of the detailed RFA analysis is available from NMFS or the Council (see ADDRESSES). The Council's analysis made use of quantitative approaches when possible. Where quantitative data on revenues or other business-related metrics that would provide insight to potential impacts were not available to inform the

analyses, qualitative analyses were conducted. A summary of the 2013–2014 specifications RFA analysis follows.

Small businesses operating in commercial and recreational (i.e., party and charter vessel operations) fisheries have been defined by the Small Business Administration as firms with gross revenues of up to $4.0 and $6.5 million, respectively. *See* 13 C.F.R. § 121.201. The categories of small entities likely to be affected by this action include commercial and charter/party vessel owners holding an active Federal permit for summer flounder, scup, or black sea bass, as well as owners of vessels that fish for any of these species in state waters. All federally permitted vessels fall into the definition of small businesses; thus, there would be no disproportionate impacts between large and small entities as a result of the proposed rule.

The Council estimates that the proposed 2013–2014 specifications could affect 2,039 vessels that held a Federal summer flounder, scup, and/or black sea bass permit in 2011 (the most recent year of complete permit data). However, the more immediate impact of this rule will likely be realized by the approximately 870 vessels that actively participated in these fisheries (i.e., landed these species) in 2011. Estimates of costs associated with this rule are discussed further below.

There are no new reporting or recordkeeping requirements contained in any of the alternatives considered for this action. In addition, NMFS is not aware of any relevant Federal rules that may duplicate, overlap, or conflict with this proposed rule.

If the Council took no action regarding the 2013 specifications, several indefinite measures would remain in effect until otherwise changed; however, many components of the 2012 specifications expire on December 31, 2012. These include catch limits for all three species. There are no roll-over provisions for the quotas if the 2013 specifications are not made effective, and so, without specified quotas, NMFS would have no mechanism to close fisheries if management limits were exceeded. This would give rise to a situation in which the goals and objectives of the FMP, its implementing regulations, and the Magnuson-Stevens Act would all be violated. Therefore, the no action alternative is not considered to be a reasonable alternative to the preferred action of developing and implementing 2013 specifications, and it was excluded from detailed analysis in the Council's EA/RFA analyses.

The Council analyzed three sets of combined catch limit alternatives for the 2013–2014 summer flounder, scup, and black sea bass fisheries. Of these, one alternative, labeled Alternative 3 for each species, contained the most restrictive options (i.e., lowest total landing levels). While the Alternative 3 measures would achieve the objectives of the proposed action for each of three species, they have the highest potential adverse economic impacts on small entities in the form of potential foregone fishing opportunities. Alternative 3 was not preferred by the Council because the other alternatives considered are expected have lower adverse impacts on small entities while achieving the stated objectives of sustaining the summer flounder, scup, and black sea bass stocks, consistent with the FMP and Magnuson-Stevens Act.

Alternative 1 (Council's preferred) would implement the following ABCs in 2013: Summer flounder, 22.34 million lb (10,133 mt); scup, 38.71 million lb (17,577 mt); and black sea bass, 4.5 million lb (2,041 mt). Alternative 1 would also implement the following ABCs for 2014: Summer flounder, 22.40 million lb (10,088 mt), and scup, 35.99 million lb (16,325 mt). Alternative 2 (status quo) would implement the following ABCs in 2013 and 2014: Summer flounder, 25.58 million lb (11,603 mt); scup, 40.88 million lb (18,543 mt); and black sea bass (2013 only), 4.5 million lb (2,041 mt).

Commercial Fishery Impacts

As a result of the proposed decrease in commercial and recreational landings from 2012 levels, it is expected that small negative economic impacts on the summer flounder fisheries in 2013 and 2014 may occur. Each state's summer flounder allocation commercial limits will decrease under these adjusted commercial quotas. The proposed scup commercial quota and recreational harvest limits under the proposed alternative are lower than the quotas implemented in 2012; however, they are substantially higher than the 2011 commercial and recreational landings. In 2011, the commercial quota and recreational harvest limit each increased by 91 percent when compared to the limits implemented in 2010. The high 2011 commercial quota and recreational harvest limit values did not constrain the fishery in 2011 as had occurred in previous years when the commercial quota and recreational harvest limits were considerably lower. In fact, the scup fishery did not harvest its full 2011 allocation. Unless market conditions change substantially in 2013, it would be expected that commercial and recreational landings will likely be close to the 2011 landings. There is no indication that the market environment for commercially and recreationally caught scup will change considerably in years 2013 or 2014. Therefore, there are no expected negative impacts from the proposed scup quotas, even though they are lower than the previous year. As a result of the potential increase in landings under the black sea bass commercial quota and recreational harvest limits under preferred alternative 1, it is expected that a small positive economic impacts are likely to occur when compared to 2012.

Recreational Fishery Impacts

While the specifications proposed would establish a 2013 and 2014 recreational harvest limit for summer flounder, scup, and black sea bass, the management measure details for recreational fisheries will be developed by the Council in December 2012, followed by NMFS rulemaking in the first quarter of 2013. A comprehensive analysis of the impacts associated with the recommended recreational management measures will be provided to NMFS from the Council to support these activities. If recreational landings for these three species are the same in 2012 as in 2011 (5.96 million lb for summer flounder, 3.66 million lb for scup, and 1.27 million for black sea bass), the recreational harvest limits proposed for 2013 (7.62 million lb for summer flounder, 7.56 million for scup, and 1.84 million for black sea bass) and 2014 (6.12 million lb for summer flounder and 3.01 million for scup) are not expected to constrain recreational landings in 2013, but may constrain summer flounder recreational landings in 2014. As such, it is unlikely that more restrictive limits (i.e., lower possession limits, higher minimum size limits, and/or shorter open seasons) will be required in 2013 when compared to 2012, but more restrictive recreational harvest measures may be necessary in 2014 for summer flounder. Specific recreational management measures (for all three species) will be determined in December when more complete data regarding 2012 recreational landings are available.

Summary

The Council selected Alternative 1 (preferred) over Alternative 2 (status quo) and Alternative 3 (most restrictive) stating that, while each alternative would provide adequate stock protection, the Alternative 1 measures were expected to result in the least amount of long-term negative economic impact to the summer flounder, scup,

and black sea bass fisheries, and were consistent with the advice provided to the Council from the SSC and its monitoring committees. NMFS agrees with the Council's IRFA analysis and rationale for recommending the catch limits in Alternative 1. As such, NMFS is proposing to implement the Council's preferred ABCs, ACLs, ACTs, Commercial Quotas, and Recreational Harvest Limits for 2013 and 2014:

TABLE 9—SUMMARY OF 2013 AND 2014 CATCH LIMITS

	Summer Flounder		Scup		Black Sea Bass
	2013	2014	2013	2014	2013
ABC (mt)	10,133	10,088	17,557	16,325	2,041
ABC (lb)	22,339,440	22,240,230	38,706,560	35,990,460	4,499,635
Commercial ACL (mt)	5,491	5,467	13,694	12,734	965.6
Commercial ACL (lb)	12,105,580	12,052,670	30,190,100	28,073,660	2,108,942
Recreational ACL (mt)	4,642	4,621	3,863	3,592	1,075.4
Recreational ACL (lb)	10,233,860	10,187,560	8,516,457	7,919,004	2,370,851
Commercial ACT (mt)	5,491	5,467	13,694	12,734	965.6
Commercial ACT (lb)	12,105,580	12,052,670	30,190,100	28,073,660	2,108,942
Recreational ACT (mt)	4,642	4,621	3,863	3,592	1,075.4
Recreational ACT (lb)	10,233,860	10,187,560	8,516,457	7,919,004	2,370,851
Commercial Quota (mt)	5,350	5,326	11,001	10,263	830
Commercial Quota (lb)	11,793,595	11,730,754	24,253,122	22,625,792	1,829,837
RHL (mt)	3,656	3,551	3,531	3,287	864
RHL (lb)	7,861,639	7,827,547	7,784,363	7,245,708	1,904,794
Commercial Quota (mt) less RSA	5,189	5,166	10,671	9,955	805.2
Commercial Quota (lb) less RSA	11,439,790	11,389,080	23,525,530	21,947,020	1,775,162
RHL (mt) less RSA	3,459	3,444	3,425	3,188	838
RHL (lb) less RSA	7,625,790	7,592,720	7,550,832	7,028,337	1,847,474

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

Dated: November 13, 2012.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2012–27973 Filed 11–15–12; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 77, No. 222

Friday, November 16, 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.

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Cold Storage Survey. Revision to burden hours will be needed due to changes in the size of the target population, expected increases in response rates, and modes of data collection. The questionnaires have had some minor modifications to accommodate changes in the products stored by the industry, and to make the questionnaires easier to complete. The target population for cold storage operators (both mandatory and voluntary samples) will be contacted for this data on a monthly basis. Fruit storage operations are contacted on a monthly basis. The capacity survey is conduced once every other year of all operations with refrigerated storage capacity. Most of these surveys are voluntary; the one exception is for operations that store certain manufactured dairy products that are required by Public Law No. 106–532 and 107–171 to respond.

DATES: Comments on this notice must be received by January 15, 2013 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0001, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *Fax:* (202) 720–6396.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Joseph T. Reilly, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333.

SUPPLEMENTARY INFORMATION:

Title: Cold Storage Survey.

OMB Control Number: 0535–0001.

Expiration Date of Approval: March 31, 2013.

Type of Request: To revise and extend a currently approved information collection for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare and issue State and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture and also to conduct the Census of Agriculture.

The monthly Cold Storage Survey provides information on national supplies of food commodities in refrigerated storage facilities. A biennial survey of refrigerated warehouse capacity is also conducted to provide a benchmark of the capacity available for refrigerated storage of the nation's food supply. Information on stocks of food commodities that are in refrigerated facilitates have a major impact on the price, marketing, processing, and distribution of agricultural products.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This notice is submitted in accordance with the Paperwork Reduction Act of 1995, (Pub. L. 104–13) and Office of Management and Budget regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1985).

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Most of these surveys are voluntary; the one exception is for operations that store certain manufactured dairy products that are required by Public Law 106–532 and 107–171 to respond.

Estimate of Burden: Public reporting burden for this information collection is based on 3 individual surveys with expected responses of 10–30 minutes. The Refrigerated Capacity Survey is conducted once every 2 years, the other surveys are conducted monthly.

Respondents: Refrigerated storage facilities.

Estimated Number of Respondents: 1,700.

Estimated Total Annual Burden on Respondents: With an estimated response rate of approximately 85%, we estimate the burden to be 4,400 hours.

Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS Clearance Officer, at (202) 690–2388.

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 will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, October 19, 2012.

Joseph T. Reilly,

Associate Administrator.

[FR Doc. 2012–27632 Filed 11–15–12; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Vegetable Surveys Program. Revision to burden hours will be needed due to changes in the size of the target population, sampling design, and/or questionnaire length. Some of the vegetable production surveys will incorporate sampling of the total population of producers, while the processing surveys will involve a total enumeration of the entire population. Changes are being made to some of the questionnaires to accommodate changes in the industry and to make the questionnaires easier for the respondent to complete. This should help to reduce respondent burden and improve the overall response rates.

DATES: Comments on this notice must be received by January 15, 2013 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0037, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *Fax:* (202) 720–6396.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Joseph T. Reilly, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333.

SUPPLEMENTARY INFORMATION:

Title: Vegetable Surveys Program.

OMB Number: 0535–0037.

Expiration Date of Approval: March 31, 2013.

Type of Request: Intent to Seek Approval to Revise and Extend an Information Collection for 3 years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare, and issue State and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture and also to conduct the Census of Agriculture. The Vegetable Surveys Program obtains basic agricultural statistics for fresh market and processing vegetables in major producing States. Vegetable statistics are used by the U.S. Department of Agriculture to help administer programs and by growers, processors, and marketers in making production and marketing decisions. The fresh market estimating program now consists of 25 selected crops and the processing program consists of 8 principal crops.

Authority: These data will be collected under the authority of 7 U.S.C. 2204g. Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This notice is submitted in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33376.

Estimate of Burden: Public reporting burden for this collection of information is estimated to be between 5 and 20 minutes per respondent per survey.

Respondents: Farms and businesses.

Estimated Number of Respondents: 35,000.

Estimated Total Annual Burden on Respondents: 4,700 hours. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS Clearance Officer, at (202) 690–2388.

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 will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, October 19, 2012.

Joseph T. Reilly,

Associate Administrator.

[FR Doc. 2012–27633 Filed 11–15–12; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Agricultural Prices Surveys. Revision to burden hours will be needed due to changes in the size of the target population, sampling design, and/or questionnaire length.

DATES: Comments on this notice must be received by January 15, 2013 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0003, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *Fax:* (202) 720–6396.

• *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.

• *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Joseph T. Reilly, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333.

SUPPLEMENTARY INFORMATION:

Title: Agricultural Prices.

OMB Control Number: 0535–0003.

Expiration Date of Approval: March 31, 2013.

Type of Request: Intent to Seek Approval to Revise and Extend an Information Collection for 3 years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to prepare and issue State and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture and also to conduct the Census of Agriculture.

The Agricultural Prices surveys provide data on the prices received by farmers and prices paid by them for production goods and services. NASS estimates based on these surveys are used by agencies of the U.S. Department of Agriculture to prepare the economic accounts of the United States. These price estimates are also used to compute Parity Prices in accordance with requirements of the Agricultural Adjustment Act of 1938 as amended (Title III, Subtitle A, Section 301(a)). In addition, price data are used by the Federal Crop Insurance Corporation to help determine payment rates, program option levels, and disaster programs.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–113) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: Public reporting burden for this information collection is based on more than 30 individual surveys with expected responses of 5–20 minutes and frequency of 1–12 times per year. Estimated number of responses per respondent is 1.95.

Respondents: Farmers and farm-related businesses.

Estimated Number of Respondents: 100,000.

Estimated Total Annual Burden on Respondents: 35,000 hours.

Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS Clearance Officer, at (202) 690–2388.

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 will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and will be summarized in the request for OMB approval.

Signed at Washington, DC, October 19, 2012.

Joseph T. Reilly,

Associate Administrator.

[FR Doc. 2012–27634 Filed 11–15–12; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Western and Central Pacific Fisheries Convention Vessel Information Family of Forms.

OMB Control Number: 0648–0595.

Form Number(s): NA.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 63.

Average Hours per Response: Western and Central Pacific Fisheries Convention (WCPFC) Area Endorsement Application, 60 minutes; Foreign Exclusive Economic Zone form, 90 minutes.

Burden Hours: 69.

Needs and Uses: This request is for an extension of a currently approved information collection.

National Marine Fisheries Service (NMFS) has issued regulations under authority of the Western and Central Pacific Fisheries Convention Implementation Act (WCPFCIA; 16 U.S.C. 6901 *et seq.*) to carry out the obligations of the United States under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention), including implementing the decisions of the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Commission). The regulations include requirements for the owners or operators of U.S. vessels to: (1) Apply for and obtain a WCPFC Area Endorsement if the vessel is used for fishing for highly migratory species on the high seas in the Convention Area (50 CFR 300.212), and (2) complete and submit a Foreign Exclusive Economic Zone (EEZ) Form if the vessel is used for fishing for highly migratory species in the Convention Area in areas under the jurisdiction of any nation other than the United States (50 CFR 300.213).

The application for WCPFC Area Endorsements calls for specified information about the vessel and its operator that is not already collected via the application for high seas fishing permits issued under 50 CFR 300.13. The Foreign EEZ Form calls for specified information about the vessel, its owners and operators and any fishing authorizations issued by other nations.

This information collected under the two requirements is used by NOAA, the U.S. Coast Guard, and the Commission to monitor the size and composition of the HMS fleets in the Convention Area for compliance-related and scientific purposes.

Affected Public: Business or other for-profit organizations.

Frequency: Annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing 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 *OIRA_Submission@omb.eop.gov*.

Dated: November 13, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–27916 Filed 11–15–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Alaska Pacific Halibut Fisheries: Subsistence Registration and Marking of Gear.

OMB Control Number: 0648–0460.

Form Number(s): NA.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 8,598.

Average Hours per Response: Registration, 10 minutes; gear marking, 15 minutes.

Burden Hours: 1,709.

Needs and Uses: This request is for extension of information collection requirements that are part of the program for the Pacific halibut subsistence fishery. The program includes requirements for registration to participate in the fishery and the marking of certain types of gear used in this fishery. Eligibility and requirements are codified in 50 CFR 300.65. The registration requirement is intended to allow qualified persons to practice the long-term, customary, and traditional harvest of Pacific halibut for food in a noncommercial manner. The gear-marking requirement aids in enforcement and in actions related to gear damage or loss. The registration information may be submitted by an individual or as a list of multiple individuals from an Alaska Native tribe.

Affected Public: State, local or tribal government.

Frequency: Every two or every four years.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

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 *OIRA_Submission@omb.eop.gov.*

Dated: November 13, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–27940 Filed 11–15–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Minority Business Development Agency

Meeting of the National Advisory Council on Minority Business Enterprise

AGENCY: Minority Business Development Agency, U.S. Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Advisory Council for Minority Business Enterprise (NACMBE) will hold its seventh meeting to discuss final recommendations in support of accelerating the growth of minority-owned businesses. The members of the Council will come to a consensus regarding the final recommendations to fulfill NACMBE's charter mandate in preparation for submission to the Secretary of the U.S. Department of Commerce. The agenda may change to accommodate Council business.

DATES: The meeting will be held on Thursday, December 6, 2012, from 9 a.m. to 5 p.m. Eastern Time (ET).

ADDRESSES: This meeting will be held at the Marriott Wardman Park Hotel, 2660 Woodley Road Northwest, Washington, DC 20008.

FOR FURTHER INFORMATION CONTACT: Demetria Gallagher, National Director's Office, Minority Business Development Agency (MBDA), U.S. Department of Commerce at (202) 482–1624 *email: dgallagher@mbda.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Secretary of Commerce established the NACMBE pursuant to his discretionary authority and in accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2) on April 28, 2010. The NACMBE is to provide the Secretary of Commerce with recommendations from the private sector on a broad range of policy issues that affect minority businesses and their ability to access successfully the domestic and global marketplace.

Topics to be considered: During the meeting the Council will discuss and deliberate on final recommendations to accelerate the growth of minority-owned businesses in domestic and global markets. Recommendations for proposed programs and new policies are centered on the areas of focus of each subcommittee. The subcommittee topics include: (1) Definition of Minority Business Enterprises (MBEs) and MBDA's role, (2) Creation of an MBE Forum, and (3) Strategic Alliances and Exports.

Public Participation: The meeting is open to the public. Public seating is limited and available on a first-come, first-served basis. Members of the public wishing to attend the meeting must notify Demetria Gallagher at the contact information above by 5 p.m. EST on Monday, December 3, 2012, to preregister. Please specify any requests for reasonable accommodation at least ten (10) business days in advance of the meeting. Last minute requests will be accepted, but may not be possible to fulfill.

A limited amount of time, in the afternoon, will be available for pertinent brief oral comments from members of the public attending the meeting. Any member of the public may submit pertinent written comments concerning affairs of the NACMBE at *www.mbda.gov/main/nacmbe-submit-comments.* To be considered during the meeting, comments must be received no later than 5 p.m. ET on Tuesday, December 4, 2012, to ensure transmission to the Council prior to the meeting. Comments received after that date will be distributed to the members but may not be considered at the meeting.

This meeting is physically accessible to people with disabilities. Requests for

sign language interpretation or other auxiliary aids should be directed to Demetria Gallagher, at (202) 482–1624, or *dgallagher@mbda.gov,* at least ten (10) days before the meeting date.

Copies of the NACMBE open meeting minutes will be available to the public upon request.

Dated: November 7, 2012.

David A. Hinson,

National Director, Minority Business Development Agency.

[FR Doc. 2012–27935 Filed 11–15–12; 8:45 am]

BILLING CODE 3510–21–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC355

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Habitat Oversight Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, December 4, 2012 at 9 a.m.

ADDRESSES: The meeting will be held at the Fairfield Inn & Suites, 185 MacArthur Drive, New Bedford, MA 02740; telephone: (774) 634–2000; fax: (774) 634–2001.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The Committee will continue to develop options and alternatives for Omnibus Essential Fish Habitat Amendment 2 (OA2). Specifically, the Committee will review Habitat Advisory Panel and Plan Development Team recommendations about Dedicated Habitat Research Areas and gear modification measures, and select options for inclusion in the OA2 document. In addition, the PDT will provide advice on combining management options into alternatives to meet overall adverse effects minimization requirements. Other area-management options and combined alternatives may also be discussed.

As a reminder, the Habitat Committee's work will feed into a joint process between the Habitat and Groundfish Committees. This joint process will draft combined alternatives that merge habitat options with yet-to-be-developed groundfish productivity-related options. This range of alternatives will be presented to the Council early next year for their approval for analysis in the OA2 Environmental Impact Statement/Magnuson-Stevens Act document.

Bureau of Ocean Energy Management staff will provide a brief status update on the Massachusetts and Rhode Island Wind Energy Areas (WEA) where leasing is under consideration, and will solicit feedback on a recently completed Environmental Assessment for the MA WEA.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: November 13, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–27899 Filed 11–15–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC356

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Monkfish Oversight Committee and Advisory Panel in December, 2012 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Thursday, December 6, 2012 at 10 a.m.

ADDRESSES: This meeting will be held at the Providence Biltmore, 11 Dorrance Street, Providence, RI 02903; telephone: (401) 421–0700; fax: (401) 455–3050.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The Committee and Advisory Panel will continue development of Amendment 6 to the Monkfish Fishery Management Plan, including modifications to the current system, incorporation of monkfish into groundfish sectors, and/or individually transferable quotas (ITQs). This meeting is a continuation of the discussions at the August 8th joint meeting. The Committee will provide further direction to the Plan Development Team in the development of a range of alternatives to be incorporated into a draft amendment document for consideration by the Councils.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: November 13, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–27900 Filed 11–15–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC354

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings of the South Atlantic Fishery Management Council.

SUMMARY: In addition to a Council Member Visioning Workshop, the South Atlantic Fishery Management Council (Council) will hold a joint meeting of its Habitat and Environmental Protection Committee and Ecosystem-Based Management Committee; meetings of its Dolphin Wahoo Committee; Southeast Data, Assessment and Review (SEDAR) Committee; Snapper Grouper Committee; Ad Hoc Data Collection Committee; Personnel Committee (CLOSED SESSION); Executive Finance Committee; and a meeting of the Full Council. The Council will take action as necessary. The Council will also hold an informal public question and answer session regarding agenda items, and a formal public comment session. See **SUPPLEMENTARY INFORMATION** for additional details.

DATES: The Council meeting will be held December 3–7, 2012. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meeting will be held at the Hilton Wilmington Riverside Hotel, 301 North Water Street, Wilmington, NC 28401; telephone: (1–888) 324–8170 or (910) 763–5900; fax: (910) 763–0038.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer; telephone: (843) 571–4366 or toll free at (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION:

Meeting Dates

1. Council Member Visioning Workshop: December 3, 2012, 9 a.m. until 12 noon.

Council members will receive a presentation on the visioning process used by the Mid-Atlantic Fishery Management Council, discuss the visioning process and provide direction to staff.

2. Joint Meeting of the Habitat and Environmental Protection Committee and Ecosystem-Based Management Committee: December 3, 2012, 1:30 p.m. until 3 p.m.

The Habitat and Environmental Protection Committee and the Ecosystem-Based Management Committee will meet jointly and will receive a report from the joint meeting of the respective advisory panels as well as a report from the Habitat and Environmental Protection Advisory Panel (AP). The joint committee will receive: an overview on Coral Amendment 7, pertaining to Coral Habitat Areas of Particular Concern (HAPCs) and transit through the Oculina Bank HAPC; and an update on ecosystem activities. The joint committee will modify Coral Amendment 7 as appropriate and will either recommend an adjustment to the timing of the amendment or recommend the amendment for public hearing.

3. Dolphin Wahoo Committee Meeting: December 3, 2012, 3 p.m. until 4 p.m.

The Dolphin Wahoo Committee will review Dolphin Wahoo Amendment 5, pertaining to bag limit sales of fish and changes to the Allowable Biological Catch (ABC) and the Annual Catch Limit (ACL). The Committee is scheduled to recommend approval of the amendment for the scoping process.

4. SEDAR Committee Meeting: December 3, 2012, 4 p.m. until 5:30 p.m. (**Note:** A portion of the meeting will be closed).

The SEDAR Committee will receive an activities update as well as a report from the Steering Committee. The Committee will discuss SEDAR schedules, terms of reference (TORs) and SEDAR appointments (closed session).

5. Snapper Grouper Committee Meeting: December 4, 2012, 8:30 a.m. until 5 p.m. and December 5, 2012, 8:30 a.m. until 12 noon.

The Snapper Grouper Committee will receive: an update on the status of catches versus quotas for commercial and recreational species under ACLs; an update on the status of amendments under formal review; a report from the Snapper Grouper AP meeting; and a report from the Scientific and Statistical Committee (SSC). The Committee will consider an Emergency Action to increase the commercial ACL for vermilion snapper and will receive overviews of the following amendments: Regulatory Amendment 13, regarding adjustments of snapper grouper ACLs based on Marine Recreational Fishing Statistical Survey (MRFSS)/Marine Recreational Information Program (MRIP) calibration; Regulatory Amendment 15, pertaining to management measures for yellowtail snapper and modifying the Accountability Measure (AM) for gag that currently prohibits the harvest of shallow water grouper species when the gag ACL is met; and Snapper Grouper Amendment 28, addressing framework actions to reopen the red snapper fishery. The Committee will modify these amendments as necessary and is scheduled to recommend approval of these amendments for formal review. The Committee will also receive an overview of Snapper Grouper Amendment 27, which addresses management measures for blue runner and would transfer management responsibility of yellowtail snapper, mutton snapper and Nassau grouper from the Gulf of Mexico Fishery Management Council to the South Atlantic Council. The Committee will modify the amendment as necessary and is scheduled to recommend approval of Amendment 27 for public hearing. The Committee will: discuss the use of Marine Protected Areas (MPAs) and HAPCs for speckled hind and warsaw grouper; receive a presentation on the reorientation of existing MPAs based on occurrence and habitat; and develop guidance on alternatives to be included in Snapper Grouper Regulatory Amendment 17, which involves the use of MPAs for speckled hind and warsaw grouper.

6. Ad Hoc Data Collection Committee Meeting: December 5, 2012, 1:30 p.m. until 5 p.m.

The Ad Hoc Data Collection Committee will receive presentations on: post-stratification methodology used to arrive at recreational landings estimates; and the results of the demonstration of the quota monitoring system. The Committee will receive a status update on the Joint Gulf and South Atlantic Council Generic Dealer Permit and an overview of Comprehensive Ecosystem-Based Amendment 3 (CE–BA 3). The Committee will receive guidance on actions and alternatives in CE–BA 3 and is scheduled to recommend approval of the amendment for formal review.

Note: There will be an informal public question and answer session with the NMFS Regional Administrator and the Council Chairman on December 5, 2012, beginning at 5:30 p.m.

7. Personnel Committee Meeting: December 6, 2012, 8:30 a.m. until 9:30 a.m. (closed session)

The Personnel Committee will discuss the Executive Director's performance review.

8. Executive Finance Committee Meeting: December 6, 2012, 9:30 a.m. until 11 a.m.

The Executive Finance Committee will discuss: the status of calendar year (CY) 2012 budget expenditures; the draft 2013 activities schedules; and the draft 2013 budget. The Committee will also: Discuss joint South Florida management issues and schedule 2013 meetings; develop a position on SSC review responsibilities; address Council follow-up and priorities; and discuss other issues as appropriate.

Council Session: December 6, 2012, 11 a.m. Until 5:30 p.m. and December 7, 2012, 8:30 a.m. Until 12 Noon

Council Session: December 6, 2012, 11 a.m. until 5:30 p.m.

From 11 a.m. until 11:15 a.m., the Council will call the meeting to order, adopt the agenda, and approve the September 2012 meeting minutes.

Note: A formal public comment session will be held on December 6, 2012, beginning at 11:15 a.m., on: Snapper Grouper Regulatory Amendment 13; Snapper Grouper Regulatory Amendment 15; Snapper Grouper Amendment 28; an Emergency Action to increase the commercial ACL for vermilion snapper; and Comprehensive Ecosystem-Based Amendment 3 (CE–BA 3); followed by comment on any other item on the agenda.

From 2:30 p.m. until 4:30 p.m., the Council will receive a report from the Snapper Grouper Committee and approve the following amendments for formal Secretarial review: Snapper Grouper Regulatory Amendment 13; Snapper Grouper Regulatory Amendment 15; and Snapper Grouper Amendment 28. The Council will approve Snapper Grouper Amendment 27 for public hearing and approve an Emergency Action to increase the commercial ACL for vermilion snapper. The Council will consider other Committee recommendations and take action as appropriate.

From 4:30 p.m. until 4:45 p.m., the Council will receive a report from the Ad Hoc Data Collection Committee, approve CE–BA 3 for formal Secretarial review, consider recommendations and take action as appropriate.

From 4:45 p.m. until 5 p.m., the Council will receive a report from the Joint Habitat and Environmental Protection and Ecosystem-Based Management Committees, approve Coral Amendment 7 for public hearing, consider other recommendations and take action as appropriate.

From 5 p.m. until 5:30 p.m., the Council will receive a briefing on Amendment 5 to the Highly Migratory Species (HMS) Fishery Management Plan from HMS staff. The Council will take action as appropriate.

Council Session: December 7, 2012, 8:30 a.m. Until 12 Noon

From 8:30 a.m. until 8:45 a.m., the Council will receive a legal briefing on litigation. (closed session)

From 8:45 a.m. until 9 a.m., the Council will receive a report from the SEDAR Committee, consider other recommendations and take action as appropriate.

From 9 a.m. until 9:15 a.m., the Council will receive a report from the Dolphin Wahoo Committee, approve Dolphin Wahoo Amendment 5 items for scoping, consider other recommendations and take action as appropriate.

From 9:15 a.m. until 9:30 a.m., the Council will receive a report from the Executive Finance Committee, consider other recommendations and take action as appropriate.

From 9:30 a.m. until 12 noon, the Council will receive presentations and status reports from the NOAA Southeast Regional Office (SERO) and the NMFS Southeast Fisheries Science Center (SEFSC), receive an outreach update on the Marine Resource Education Program, review agency and liaison reports, and discuss other business, including upcoming meetings.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal final Council action during these meetings. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Except for advertised (scheduled) public hearings and public comment, the times and sequence specified on this agenda is subject to change.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) by November 26, 2012.

Dated: November 13, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–27946 Filed 11–15–12; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List, Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete services from the Procurement List that were provided by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received On or Before: 12/17/2012.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 USC 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following services are proposed for deletion from the Procurement List:

Services

Service Type/Location: Janitorial/Custodial, Defense Logistics Agency: Point Pleasant Depot, Defense National Stockpile Zone, 2601 Madison Avenue, Point Pleasant, WV.

NPA: Prestera Center for Mental Health Services, Inc., Huntington, WV.

Contracting Activity: Defense Logistics Agency Support Services—DSS, Fort Belvoir, VA.

Service Type/Location: Shelf Stocking & Custodial, Fort Stewart Commissary, Fort Stewart, GA.

NPA: Unknown.
Contracting Activity: Defense Commissary Agency (DECA), Fort Lee, VA.

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2012–27920 Filed 11–15–12; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* 12/17/2012.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION:

Additions

On 9/14/2012 (77 FR 56813–56814) and 9/21/2012 (77 FR 58528–58529), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 USC 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.
2. The action will result in authorizing small entities to furnish the products and services to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 USC 8501–8506) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

NSN: 7045–00–NIB–0392—Blank media discs, DVD–R, Thermal Printable, Silver, 16x Speed, 120Min/4.7GB, 100 PK.
NPA: North Central Sight Services, Inc., Williamsport, PA.
Contracting Activity: General Services Administration, New York, NY.
Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.

NSN: 5120–00–NIB–0029—Digger, Posthole, Industrial Grade, 48'' Fiberglass Handle, Cushioned Grip.
NPA: Keystone Vocational Services, Inc., Sharon, PA.
Contracting Activity: General Services Administration, Tools Acquisitions Division I, Kansas City, MO.
Coverage: B-List for the Broad Government Requirement as aggregated by the General Services Administration.

Services

Service Type/Location: Custodial Services, Customs and Border Protection, Checkpoint 802, S–2 Hwy, MM 56.1, Ocotillo, CA.
NPA: Imperial County Work Training Center, Inc., El Centro, CA.
Contracting Activity: U.S. Customs and Border Protection, Border Enforcement Contracting Division, Washington, DC.
Service Type/Location: Custodial Service, Assistant Special Agent in Charge (ASAC), San Angelo Homeland Security Investigations, 5575 Stewart Lane, San Angelo, TX.
NPA: Enterprise Professional Services, Inc., Austin, TX.
Contracting Activity: DEPT OF HOMELAND SECURITY, U.S. Immigration and Customs ENFORCEMENT, MISSION SUPPORT DALLAS, DALLAS, TX.
Service Type/Location: Custodial & Grounds Maintenance Service, National Oceanic and Atmospheric Administration (NOAA), Air Resources Laboratory, 456 S. Illinois Avenue, Oak Ridge, TN.
NPA: Goodwill Industries—Knoxville, Inc., Knoxville, TN.
Contracting Activity: Department of Commerce, National Oceanic and Atmospheric Administration, Kansas City, MO.

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2012–27921 Filed 11–15–12; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 12–40]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 12–40 with attached transmittal, and policy justification.

Dated: November 13, 2012.

Aaron Siegel,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

NOV 02 2012

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 12-40, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to the United Arab Emirates for defense articles and services estimated to cost $1.135 billion. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

William E. Landay III
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

BILLING CODE 5001–06–C

Transmittal No. 12–40

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, As Amended

(i) *Prospective Purchaser:* United Arab Emirates.

(ii) *Total Estimated Value:*

Major Defense Equipment *	$1.110 billion
Other	$ .025 billion
TOTAL *	$ 1.135 billion

(iii) *Description and Quantity of Articles or Services under Consideration or Purchase:* 48 Terminal High Altitude Area Defense (THAAD) missiles, 9 THAAD launchers; test components, repair and return, support equipment, spare and repair parts, personnel training and training equipment, publications and technical data, U.S. Government and contractor technical assistance, and other related logistics support.

* as defined in Section 47(6) of the Arms Export Control Act.

(iv) *Military Department:* Missile Defense Agency through Army (UAF, Amd #2).

(v) *Prior Related Cases, if any:* FMS case UAF–$3.5M–27Dec11.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* 2 November 2012.

Policy Justification

United Arab Emirates—Terminal High Altitude Area Defense System Missiles (THAAD)

The Government of the United Arab Emirates (UAE) has requested a possible sale of 48 Terminal High Altitude Area Defense (THAAD) missiles, 9 THAAD launchers; test components, repair and return, support equipment, spare and repair parts, personnel training and training equipment, publications and technical data, U.S. Government and contractor technical assistance, and other related logistics support. The estimated cost is $1.135 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country that has been, and continues to be, an important force for political stability and economic progress in the Middle East.

This proposed sale will help strengthen the UAE's capability to counter current and future threats in the region and reduce dependence on U.S. forces.

The proposed sale of these missiles and equipment will not alter the basic military balance in the region.

The principal contractors will be Lockheed Martin Space Systems Corporation in Sunnyvale, CA and Raytheon Corporation in Andover, MA. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to the UAE.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 12–40

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, As Amended

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Terminal High Altitude Area Defense System (THAAD) is the first weapons system with both endo and exo atmospheric capability developed specifically to defend against ballistic missiles. The higher altitude and theater wide protection offered by THAAD provides more protection of larger areas than lower-tier systems alone. THAAD is designed to defend against short, medium, and intermediate range ballistic missiles. The THAAD system consists of four major components: Fire Control/Communications, Radar, Launchers and Interceptors.

2. THAAD contains classified Confidential/Secret components and critical/sensitive technology. This critical/sensitive technology is primarily in the area of design and production know-how and primarily inherent in the design, development and/or manufacturing data related to certain critical components. Information on operational effectiveness with respect to countermeasures, low observable technologies, select software documentation and test data are classified up to and including Secret.

3. If a technologically advanced adversary were to obtain knowledge of specific hardware, the information could be used to develop countermeasures which might reduce weapons system effectiveness or be used in the development of a system with similar or advanced capabilities.

[FR Doc. 2012–27954 Filed 11–15–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 12–49]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 12–49 with attached transmittal, and policy justification.

Dated: November 13, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

NOV 02 2012

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 12-49, concerning the Missile Defense Agency's proposed Letter(s) of Offer and Acceptance to Qatar for defense articles and services estimated to cost $6.5 billion. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

FOR William E. Landay III
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided under Separate Cover)

Transmittal No. 12–49

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Qatar

(ii) *Total Estimated Value:*

Major Defense Equipment * ...	$4.0 billion
Other	$2.5 billion
TOTAL	$6.5 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* 2 Terminal High Altitude Area Defense (THAAD) Fire Units, 12 THAAD Launchers, 150 THAAD Interceptors, 2 THAAD Fire Control and Communications, 2 AN/TPY–2 THAAD Radars, and 1 Early Warning Radars (EWR). Also included are fire unit maintenance equipment, prime movers (trucks), generators, electrical power units, trailers, communications equipment, tools, test and maintenance equipment, repair and return, system integration and checkout, spare/repair parts, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical and logistics personnel support services, and other related support elements.

(iv) *Military Department:* Missile Defense Agency (VAA)

(v) *Prior Related Cases, if any:* None

* as defined in Section 47(6) of the Arms Export Control Act.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* N/A

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 2 November 2012

Policy Justification

Qatar—Terminal High Altitude Area Defense (THAAD)

The Government of Qatar has requested a possible sale of 2 Terminal High Altitude Area Defense (THAAD) Fire Units, 12 THAAD Launchers, 150 THAAD Interceptors, 2 THAAD Fire Control and Communications, 2 AN/TPY–2 THAAD Radars, and 1 Early Warning Radar (EWR). Also included are fire unit maintenance equipment, prime movers (trucks), generators, electrical power units, trailers, communications equipment, tools, test and maintenance equipment, repair and return, system integration and checkout, spare/repair parts, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical and logistics personnel support services, and other related support elements. The estimated cost is $6.5 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country that has been and continues to be an important force for political stability and economic progress in the Middle East.

This proposed sale will help strengthen U.S. efforts to promote regional stability by enhancing regional defense capabilities of a key U.S. partner. The proposed sale will help strengthen Qatar's capability to counter current and future threats in the region and reduce dependence on U.S. forces. Qatar will have no difficulty absorbing this weapon system into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors are Lockheed Martin Space Systems Corporation in Sunnyvale, California, and the sub-contractor is Raytheon Corporation in Andover, Massachusetts.

There are no known offset agreements proposed in connection with this potential sale at this time.

Implementation of this proposed sale will require periodic travel of up to 13 U.S. Government and contractor representatives to Qatar for an undetermined period for delivery, system checkout, and training as determined by the schedule. There is no known adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 12–49

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

Annex

Item No. vii

(vii) *Sensitivity of Technology*

1. The Terminal High Altitude Area Defense System (THAAD) Ballistic Missile Defense System contains classified Confidential/Secret components and critical/sensitive technology. The THAAD Fire Unit is a ground-based, forward deployable terminal missile defense system that represents significant technological advances. The THAAD System continues to hold a technology lead over other terminal ballistic missile systems. THAAD is the first weapon system with both endo- and exo-atmospheric capability developed specifically to defend against ballistic missiles. The higher altitude and theater-wide protection offered by THAAD provides more protection of larger areas than lower-tier systems alone. THAAD is designed to defend against short, medium, and intermediate range ballistic missiles. The THAAD system consists of four major components: Fire Control/Communications, Radar, Launchers, and Interceptors.

2. The THAAD Ballistic Missile Defense System contains sensitive/critical Technology, primarily in the area of design and production know-how and primarily inherent in the design, development and/or manufacturing data related to certain critical components. Information on operational effectiveness with respect to countermeasures and counter-counter measures, low observable technologies, select software documentation and test data are classified up to and including Secret.

3. If a technologically advanced adversary were to obtain knowledge of specific hardware, the information could be used to develop countermeasures which might reduce weapons system effectiveness or be used in the development of a system with similar or advanced capabilities.

[FR Doc. 2012–27956 Filed 11–15–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 12–58]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

SUPPLEMENTARY INFORMATION: The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 12–58 with attached transmittal, policy justification and sensitivity of technology.

Dated: November 13, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

NOV 06 2012

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 12-58, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Qatar for defense articles and services estimated to cost $9.9 billion. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

William E. Landay, III
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided under Separate Cover)

Transmittal No. 12–58

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Qatar

(ii) *Total Estimated Value:*

Major Defense Equipment * ...	$7.2 billion
Other	$2.7 billion
TOTAL	$9.9 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* 11 PATRIOT Configuration-3 Modernized Fire Units, 11 AN/MPQ–65 Radar Sets, 11 AN/MSQ–132 Engagement Control Systems, 30 Antenna Mast Groups, 44 M902 Launching Stations, 246 PATRIOT MIM–104E Guidance Enhanced Missile-TBM (GEM–T) with canisters, 2 PATRIOT MIM–104E GEM–T Test Missiles, 768 PATRIOT Advanced Capability 3 (PAC–3) Missiles with canisters, 10 PAC–3 Test Missiles with canisters, 11 Electrical Power Plants (EPPII), 8 Multifunctional Information Distribution Systems/Low Volume Terminals (MIDS/LVTs), communications equipment, tools and

* as defined in Section 47(6) of the Arms Export Control Act.

test equipment, support equipment, publications and technical documentation, personnel training and training equipment, spare and repair parts, facility design, U.S. Government and contractor technical, engineering, and logistics support services, and other related elements of logistics and program support.

(iv) Military Department: Army (UAP)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 6 November 2012

Policy Justification

Qatar—PATRIOT Missile System and Related Support and Equipment

The Government of Qatar has requested a possible sale of 11 PATRIOT Configuration-3 Modernized Fire Units, 11 AN/MPQ–65 Radar Sets, 11 AN/MSQ–132 Engagement Control Systems, 30 Antenna Mast Groups, 44 M902 Launching Stations, 246 PATRIOT MIM–104E Guidance Enhanced Missile-TBM (GEM–T) with canisters, 2 PATRIOT MIM–104E GEM–T Test Missiles, 768 PATRIOT Advanced Capability 3 (PAC–3) Missiles with canisters, 10 PAC–3 Test Missiles with canisters, 11 Electrical Power Plants (EPPII), 8 Multifunctional Information Distribution Systems/Low Volume Terminals (MIDS/LVTs), communications equipment, tools and test equipment, support equipment, publications and technical documentation, personnel training and training equipment, spare and repair parts, facility design, U.S. Government and contractor technical, engineering, and logistics support services, and other related elements of logistics and program support. The estimated cost is $9.9 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by improving the security of an important ally which has been, and continues to be, a force for political stability and economic progress in the Middle East. This sale is consistent with U.S. initiatives to provide key allies in the region with modern systems that will enhance interoperability with U.S. forces and increase security.

Qatar will use the Patriot Missile System to improve its missile defense capability, strengthen its homeland defense, and deter regional threats. The proposed sale will enhance Qatar's interoperability with the U.S. and its allies, making it a more valuable partner in an increasingly important area of the world. Qatar should have no difficulty absorbing this system into its armed forces.

The proposed sale of these missiles and equipment will not alter the basic military balance in the region.

The prime contractors will be Raytheon Corporation in Andover, Maryland, and Lockheed-Martin in Dallas, Texas. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require approximately 30 U.S. Government and 40 contractor representatives to travel to Qatar for an extended period for equipment de-processing/fielding, system checkout, training and technical and logistics support.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 12–58

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vi

(vi) *Sensitivity of Technology:*

1. The PATRIOT Advanced Capability-3/Configuration-3 Ground Support Equipment (PAC–3/C–3) Air Defense System contains classified Confidential hardware components, Secret tactical software, and critical/sensitive technology. The PAC–3 Missile Four-Pack and Guidance Enhanced Missile (GEM–T) hardware is classified Confidential and the associated launcher hardware is Unclassified. The items requested represent significant technological advances for Qatar. The PAC–3/C–3Air Defense System continues to hold a significant technology lead over other surface-to-air missile systems in the world.

2. The PAC–3/C–3 sensitive/critical technology is primarily in the area of design and production know-how and primarily inherent in the design, development and/or manufacturing data related to the following components:

a. Radar Enhancement Phase III (REP–3) Exciter Assemblies
b. Radar Digital Processor
c. Modern Adjunct Processor
d. REP–3 Traveling Wave Tube
e. Classification, Discrimination, and Identification-3 (CDI–3) Digital Signal Processor
f. CDI–3 Analog/Digital Converters
g. Hardware-in-the-Loop and Digital Simulations
h. Surface Acoustic Wave (SAW) Oscillators
i. PAC–3 Missile Guidance Processor Unit
j. PAC–3 Seeker
k. PAC–3 Missile software
l. GEM–T Fuze
m. GEM–T SAW Oscillator
n. Selected areas of the PATRIOT Ground Equipment software

3. Information on vulnerability to electronic countermeasures and counter-counter measures, system performance capabilities and effectiveness, survivability and vulnerability data, PAC–3 Missile seeker capabilities, non-cooperative target recognition, low observable technologies, select software/software documentation and test data are classified up to and including Secret.

4. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapons systems effectiveness or be used in the development of a system with similar or advanced capabilities.

[FR Doc. 2012–27945 Filed 11–15–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Task Force on the Care, Management, and Transition of Recovering Wounded, Ill, and Injured Members of the Armed Forces; Federal Advisory Committee Meeting

AGENCY: Office of the Assistant Secretary of Defense, Department of Defense.

ACTION: Notice of meeting.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150, the Department of Defense announces that the following Federal Advisory Committee meeting of the Department of Defense Task Force on the Care, Management, and Transition of Recovering Wounded, Ill, and Injured Members of the Armed Forces (subsequently referred to as the Task Force) will take place.

DATES: Tuesday, December 4, 2012–Wednesday, December 5, 2012 from 8:30 a.m. to 5:00 p.m. EDT each day.

ADDRESSES: DoubleTree by Hilton Hotel Washington DC-Crystal City, 300 Army Navy Drive, Arlington, VA 22202 (in the Commonwealth Room).

FOR FURTHER CONTACT INFORMATION: Mail Delivery service through Recovering Warrior Task Force, Hoffman Building II, 200 Stovall St, Alexandria, VA 22332–0021 ''Mark as Time Sensitive for December Meeting''. Emails can be sent to *rwtf@wso.whs.mil.* Denise F. Dailey, Designated Federal Officer; Telephone (703) 325–6640. Fax (703) 325–6710.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: The purpose of the meeting is for the Task Force Members to convene and gather data from panels and briefers on the Task Force's topics of inquiry.

Agenda: (Refer to *http://dtf.defense.gov/rwtf/meetings.html* for most up-to-date meeting information.)

Day One: Tuesday, December 4, 2012

8:30 a.m.–8:45 a.m. Welcome and Member Introductions
8:45 a.m.–9:30 a.m. Walter Reed Installation Visit Review
9:30 a.m.–9:45 a.m. Break
9:45 a.m.–10:45 a.m. Moderator Training
10:45 a.m.–11:00 a.m. Break
11:00 a.m.–12:15 p.m. Institute of Medicine, Committee on the Assessment of Ongoing Effects in the Treatment of Posttraumatic Stress Disorder
12:15 p.m.–1:00 p.m. Break for Lunch
1:00 p.m.–2:00 p.m. National Guard Bureau (NGB) Warrior Support Office
2:00 p.m.–2:15 p.m. Break
2:15 p.m.–3:15 p.m. Army National Guard (ARNG) Medical Management Processing System (MMPS) and Reserve Component Managed Care (RCMC) Pilot
3:15 p.m.–3:30 p.m. Break
3:30 p.m.–4:30 p.m. RC Soldier Medical Support Center (SMSC): Integrated Disability Evaluation System (IDES) for ARNG and USAR
5:00 p.m. Wrap Up

Day Two: Wednesday, December 5, 2012

8:30 a.m.–8:45 a.m. Welcome
8:45 a.m.–9:00 a.m. Public Forum
9:00 a.m.–10:15 a.m. Special Compensation for Activities of Daily Living (SCAADL) Panel
10:15 a.m.–10:30 a.m. Break
10:30 a.m.–11:45 a.m. Physical Disability Board of Review (PDBR)
11:45 a.m.–1:00 p.m. Break for Lunch
1:00 p.m.–2:00 p.m. Task Force Review of Upcoming Installation Visits
2:00 p.m.–2:15 p.m. Break
2:15 p.m.–3:45 p.m. Recovering Warrior Panel
3:45 p.m.–4:00 p.m. Break
4:00 p.m.–5:00 p.m. DoD/VA Employment Task Force
5:00 p.m. Wrap Up

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the Department of Defense Task Force on the Care, Management, and Transition of Recovering Wounded, Ill, and Injured Members of the Armed Forces about its mission and functions. If individuals are interested in making an oral statement during the Public Forum time period, a written statement for a presentation of two minutes must be submitted as below and must identify it is being submitted for an oral presentation by the person making the submission. Identification information must be provided and at a minimum must include a name and a phone number. Individuals may visit the Task Force Web site at *http://dtf.defense.gov/rwtf/* to view the Charter. Individuals making presentations will be notified by Thursday, November 29, 2012. Oral presentations will be permitted only on Wednesday, December 5, 2012 from 8:45 a.m. to 9:00 a.m. EDT before the Task Force. The number of oral presentations will not exceed ten, with one minute of questions available to the Task Force members per presenter. Presenters should not exceed their two minutes.

Written statements in which the author does not wish to present orally may be submitted at any time or in response to the stated agenda of a planned meeting of the Department of Defense Task Force on the Care, Management, and Transition of Recovering Wounded, Ill, and Injured Members of the Armed Forces.

All written statements shall be submitted to the Designated Federal Officer for the Task Force through the contact information in **FOR FURTHER INFORMATION CONTACT**, and this individual will ensure that the written statements are provided to the membership for their consideration.

Statements, either oral or written, being submitted in response to the agenda mentioned in this notice must be received by the Designated Federal Officer at the address listed in **FOR FURTHER INFORMATION CONTACT** no later than 5:00 p.m. EDT, Tuesday, November 27, 2012 which is the subject of this notice. Statements received after this date may not be provided to or considered by the Task Force until its next meeting. Please mark mail correspondence as ''Time Sensitive for June Meeting.''

The Designated Federal Officer will review all timely submissions with the Task Force Co-Chairs and ensure they are provided to all members of the Task Force before the meeting that is the subject of this notice.

Reasonable accommodations will be made for those individuals with disabilities who request them. Requests for additional services should be directed to Heather Jane Moore, (703) 325–6640, by 5:00 p.m. EDT, Tuesday, November 27, 2012.

Dated: November 13, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–27910 Filed 11–15–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notification of an Open Meeting of the National Defense University Board of Visitors (BOV)

AGENCY: National Defense University, DoD.

ACTION: Notice of open meeting.

SUMMARY: The National Defense University (NDU), Designated Federal Officer, has scheduled a meeting of the Board of Visitors. The National Defense University Board of Visitors is a Federal Advisory Board. The Board meets twice each year in proceedings that are open to the public.

DATES: The meeting will be held on December 10–11, 2012, from 9:00 a.m. to 5:30 p.m. on December 10 and continuing on December 11 from 9:00 a.m. to 12:30 p.m.

ADDRESSES: The Board of Visitors meeting will be held at Lincoln Hall, Building 64, Room 1105, the National Defense University, 300 5th Avenue SW., Fort McNair, Washington, DC 20319–5066.

FOR FURTHER INFORMATION CONTACT: The point of contact for this notice of open meeting is Ms. Joycelyn Stevens at (202) 685–0079, Fax (202) 685–3920 or *StevensJ7@ndu.edu.*

SUPPLEMENTARY INFORMATION: The future agenda will include discussion on

accreditation compliance, organizational management, strategic planning, resource management, and other matters of interest to the National Defense University. The meeting is open to the public; limited space made available for observers will be allocated on a first come, first served basis. Written statements to the committee may be submitted to the committee at any time or in response to a stated planned meeting agenda by FAX or email to the point of contact person listed in **FOR FURTHER INFORMATION CONTACT**. (Subject Line: Comment/Statement to the NDU BOV).

Dated: November 13, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–27939 Filed 11–15–12; 8:45 a.m.]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Military Personnel Testing; Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Notice of meeting.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150, the Department of Defense announces that the following Federal advisory committee meeting of the Defense Advisory Committee on Military Personnel Testing will take place.

DATES: Thursday, December 6, 2012, from 8:30 a.m. to 4:00 p.m. and Friday, December 7, 2012, from 8:30 a.m. to 12 p.m.

ADDRESSES: The meeting will be held at the Omni Hotel, 100 South 12th Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Dr. Jane Arabian, (703) 697–9271.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: The purpose of the meeting is to review planned changes and progress in developing computerized tests for military enlistment.

Agenda: The agenda includes an overview of current enlistment test development timelines and planned research for the next 3 years.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. § 552b and 41 CFR §§ 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public.

Committee's Designated Federal Officer or Point of Contact: Dr. Jane M. Arabian, Assistant Director, Accession Policy, Office of the Under Secretary of Defense (Personnel and Readiness), Room 3D1066, The Pentagon, Washington, DC 20301–4000, telephone (703) 697–9271. Persons desiring to make oral presentations or submit written statements for consideration at the Committee meeting must contact Dr. Jane M. Arabian at the address or telephone number above no later than November 28, 2012.

Dated: November 13, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–27913 Filed 11–15–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2012–OS–0135]

Privacy Act of 1974; System of Records

AGENCY: Defense Information Systems Agency, DoD.

ACTION: Notice to add a new system of records.

SUMMARY: The Defense Information Systems Agency proposes to add a new system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on December 17, 2012 unless comments are received which result in a contrary determination. Comments will be accepted on or before December 17, 2012.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Jeanette Weathers-Jenkins, 6916 Cooper Avenue, Fort Meade, MD 20755–7901, or (301) 225–8158.

SUPPLEMENTARY INFORMATION: The Defense Information Systems Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on October 31, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 13, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

K890.21 DoD

SYSTEM NAME:

DoD Enterprise Portal Service (DEPS).

SYSTEM LOCATION:

Defense Enterprise Computing Centers (DECC), 5450 Carlisle Pike Mechanicsburg, PA 17055–0975.

Defense Enterprise Computing Centers (DECC), 8705 Industrial Blvd., Bldg 3900, Tinker AFB, Oklahoma 73145–3009.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Department of Defense civilian employees, military personnel, and contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Full name, DoD ID Number, birth date, email address, organizational address, telephone, and fax number, military rank/grade, military branch, and current DoD identification badge for registration and access management.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; Pub. L. 106–229, Electronic Signatures in Global and National Commerce; OASD (C3I) Policy Memorandum, subject: Department of Defense (DoD) Public Key Infrastructure (PKI); and OASD (C3I) Memorandum, subject: Common Access Card (CAC).

PURPOSE(S):

DEPS will utilize Microsoft Office SharePoint Server as an integrated suite of server capabilities that will improve organizational effectiveness by providing comprehensive content management and enterprise search, accelerating shared business processes, and facilitating information-sharing across boundaries for better business insight. Additionally, this collaboration and content management server provides information technology (IT) professionals and developers with the platform and tools they need for server administration, application extensibility, and interoperability.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974 as amended, these records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD Blanket Routine Uses set forth at the beginning of the DISA's compilation of systems of records notices may apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Retrieved by full name.

SAFEGUARDS:

Records are maintained in a controlled facility. Physical entry is restricted by the use of locks, guards, password protection, and encryption and is accessible only to authorized personnel. Access to records is limited to person(s) responsible for servicing the record in performance of their official duties and who are properly screened and cleared for need-to-know. Access to computerized data is restricted by Common Access Card (CAC) and/or password which are changed periodically. Additionally, users receive training and awareness notices on the proper marking of sensitive information. Host Based Security System (HBSS) is operational and provides mechanisms to protect, detect, track, and report malicious computer-related activities in near real-time.

RETENTION AND DISPOSAL:

Disposition pending (until the National Archives and Records Administration approves retention and disposal schedule, records will be treated as permanent).

SYSTEM MANAGER(S) AND ADDRESS:

DEPS Program Manager, Enterprise Services Division, Defense Information Systems Agency, Acquisition Building, 6914 Cooper Ave, Ft. Meade, MD 20755–7088.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Defense Information Systems Agency (DISA), Defense Enterprise Service Directorate (ESD), 6914 Cooper Ave, Fort Meade, MD 20755–7088.

Written requests should contain the full name of the requesting individual, current DoD identification badge or a copy of driver's license as proof of identity. The requester may also visit the system manager listed above.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Defense Information Systems Agency, Defense Enterprise Service Directorate (ESD), 6914 Cooper Ave, Fort Meade, MD 20755–7088.

Written requests should contain the full name of the requesting individual, current DoD identification badge or a copy of driver's license as proof of identity. The requester may also visit the system manager listed above.

CONTESTING RECORD PROCEDURES:

DISA's rules for accessing records, for contesting content and appealing initial agency determinations are published in DISA Instruction 210–225–2; 32 CFR part 316; or may be obtained from the systems manager at the Defense Information Systems Agency (DISA), Defense Enterprise Service Directorate (ESD), 6914 Cooper Ave, Fort Meade, MD 20755–7088.

RECORD SOURCE CATEGORIES:

Data obtained and manually entered by system administrators.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2012–27915 Filed 11–15–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Reestablishment of Department of Defense Federal Advisory Committees

AGENCY: DoD.

ACTION: Notice to reestablish Federal Advisory Committee.

SUMMARY: Under the provisions of 5 CFR 532, Federal Wage System (Pub. L. 92–392), the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b), and 41 CFR 102–3.50(c), the Department of Defense (DoD) gives notice that it is reestablishing the charter for the Department of Defense Wage Committee (hereafter referred to as ''the Committee'').

The Committee is a discretionary federal advisory committee that shall provide the Secretary and the Deputy Secretary of Defense, through the Under Secretary of Defense for Personnel and Readiness (USD(P&R)), independent advice and recommendations on all matters relating to the conduct of wage surveys and the establishment of wage schedules for all appropriated fund and non-appropriated fund wage areas of blue-collar employees within the DoD.

The Committee shall report to the Secretary and Deputy Secretary of Defense, through the USD(P&R). The USD(P&R) may act upon the Committee's advice and recommendations.

The Committee, consistent with 5 CFR 532.227, shall be comprised of seven members—a chairperson and six additional members. Committee members shall be appointed by the Secretary of Defense and their appointments will be renewed on an annual basis. Those members, who are not full-time or permanent part-time Federal officers or employees, shall be appointed to serve as experts and consultants under the authority of 5 U.S.C. § 3109 and serve as special government employees. Each Committee member is appointed to provide advice on behalf of the government on the basis of his or her best judgment without representing any particular point of view and in a manner that is free from conflict of interest. With the exception of travel and per diem for official Committee related travel, Committee members shall serve without compensation, unless authorized by the Secretary of Defense.

The Secretary of Defense may approve the appointment of Committee members for one-to-two year terms of service,

with annual renewals; however, no member, unless authorized, by the Secretary of Defense, may serve more than two consecutive terms of service.

The Department, when necessary, and consistent with the Committee's mission and DoD policies/procedures, may establish subcommittees to support the Committee. Establishment of subcommittees will be based upon a written determination, to include terms of reference, by the Secretary of Defense, or the Committee's sponsor.

These Subcommittees shall not work independently of the chartered Committee, and shall report all their recommendations and advice to the Committee for full deliberation and discussion. Subcommittees have no authority to make decisions on behalf of the chartered Committee; nor can any subcommittee or its members update or report directly to the DoD or any Federal officers or employees.

All subcommittee members shall be appointed in the same manner as the Committee members; that is, the Secretary of Defense shall appoint subcommittee members even if the member in question is already a Committee member. Subcommittee members, with the approval of the Secretary of Defense, may serve a term of service on the Subcommittee of one to four years; however, no member shall serve more than two consecutive terms of service on the Subcommittee, unless authorized by the Secretary of Defense.

Subcommittee members, if not full-time or part-time government employees, shall be appointed to serve as experts and consultants under the authority of 5 U.S.C. § 3109, and shall serve as special government employees, whose appointments must be renewed by the Secretary of Defense on an annual basis. With the exception of travel and per diem for official Committee-related travel, Subcommittee members shall serve without compensation.

All subcommittees operate under the provisions of FACA, the Government in the Sunshine Act, governing Federal statutes and regulations, and governing DoD policies/procedures.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Committee shall meet at the call of the Committee's Designated Federal Officer, in consultation with Committee's Chairperson. The estimated number of Committee meetings is twenty-six per year.

In addition, the Designated Federal Officer is required to be in attendance at all Committee and subcommittee meetings for the entire duration of each and every meeting; however, in the absence of the Designated Federal Officer, a properly approved Alternate Designated Federal Officer shall attend the entire duration of the Committee or subcommittee meeting.

The Designated Federal Officer, or the Alternate Designated Federal Officer, shall call all of the Committee's and Subcommittee's meetings; prepare and approve all meeting agendas; adjourn any meeting when the Designated Federal Officer, or the Alternate Designated Federal Officer, determines adjournment to be in the public interest or required by governing regulations or DoD policies/procedures; and chair meetings when directed to do so by the official to whom the Committee reports.

Pursuant to 41 CFR §§ 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to Department of Defense Wage Committee membership about the Committee's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of Department of Defense Wage Committee.

All written statements shall be submitted to the Designated Federal Officer for the Department of Defense Wage Committee, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Department of Defense Wage Committee's Designated Federal Officer can be obtained from the GSA's FACA Database—*https://www.fido.gov/facadatabase/public.asp.*

The Designated Federal Officer, pursuant to 41 CFR § 102–3.150, will announce planned meetings of the Department of Defense Wage Committee. The Designated Federal Officer, at that time, may provide additional guidance on the submission of written statements that are in response to the stated agenda for the planned meeting in question.

Dated: November 13, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–27923 Filed 11–15–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Intent To Prepare a Draft Environmental Impact Statement and Feasibility Report for the Caño Martín Peña Ecosystem Restoration, San Juan, PR

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent.

SUMMARY: The Jacksonville District, U.S. Army Corps of Engineers (Corps) intends to prepare a Draft Environmental Impact Statement (DEIS) and Feasibility Report (FR) for the ecosystem restoration of the Caño Martín Peña (CMP) within the San Juan Bay National Estuary (SJBE), San Juan, Puerto Rico. The CMP Ecosystem Restoration Project consists of (a) dredging approximately 825,200 cubic yards of sediments and debris in 2.2 miles of the eastern segment of the CMP, from the San José Lagoon westbound to the Enrique Martí Coll Linal Park pedestrian bridge; and, (b) installing sheet piles along north and south of the CMP. Additional features include, among others, a mangrove restoration project along the CMP, formal public spaces for recreation and interaction between the communities, visitors and the CMP identified as water plazas, and a mangrove restoration project at the Suárez Canal. The project is a cooperative effort between the Corps and the non-Federal sponsor Corporación del Proyecto ENLACE del Caño Martín Peña (ENLACE).

ADDRESSES: U.S. Army Corps of Engineers, Jacksonville District, Planning Division, Environmental Branch, P.O. Box 4970, Jacksonville, FL 32232–0019.

FOR FURTHER INFORMATION CONTACT: Wilberto Cubero by email at *martinpena@usace.army.mil* or by telephone at (904) 232–2050.

SUPPLEMENTARY INFORMATION: These DEIS and FR will be prepared under the provisions of the Memorandum for Commander, South Atlantic Division (CESAD–PM) Implementation Guidance for Section 5127 of the Water Resources Development Act of 2007 (WRDA 2007)—Caño Martín Peña, San Juan, Puerto Rico dated October 27, 2008. A Reconnaissance Report completed in June 2004 by the Corps, concluded that there is justification to continue into more detailed investigation and that there was strong Federal interest in proceeding to the feasibility phase.

Background: The CMP is a tidal channel 3.75 miles long in metropolitan San Juan, Puerto Rico and one of eight interconnected bodies of water within the SJBE, the only tropical estuary in the U.S. Environmental Protection Agency (EPA) National Estuary Program (NEP). The SJBE interior coastal lagoons and tidal channels are connected to the Atlantic Ocean at both ends. Extending from east to west through eight densely populated impoverished communities in San Juan, the CMP connects the San Juan Bay with the San José and Los Corozos Lagoons, which are further connected by the Suárez Canal to La Torrecilla Lagoon and the Atlantic Ocean. The drainage area of the CMP comprises about 2,500 acres. Historically, the CMP had an average width of approximately 200 feet and a depth between 6 to 8 feet and provided tidal exchange between San Juan Bay and San José Lagoon. The CMP's ability to convey flows has been almost completely blocked as a result of siltation, accumulation of household and construction debris, and encroachment of housing and other structures, thus affecting the habitat functional value and water quality in both the CMP and San José Lagoon. Water quality has been affected by the lack of sewer systems and proper trash collection in neighboring areas. The study area is the SJBE and the detailed project area is the eastern half of the CMP from the Enrique Martí Coll pedestrian bridge eastward, the San José and Los Corozos Lagoons, and the western half of the Suárez Canal.

Purpose: The purpose of this project is to restore the hydraulic connection and tidal exchange between the San José Lagoon and the San Juan Bay, and thus, in the SJBE. The dredging of 2.2 miles of the CMP will restore and improve habitat functional value and water quality in both the CMP and San José Lagoon, and significantly enhance the fish and wildlife habitats and water quality of the entire SJBE, thus achieving ecological uplift. The tidal restoration will achieve viable, healthy, diverse, and sustainable conditions that are necessary to support life. The project will also improve the quality of life of approximately 26,000 residents along the CMP, addressing health and safety concerns. As ancillary benefits, the project will reduce the risk of flooding, and promote recreation and tourism, with minimal temporary negative impact on the ecosystem and the adjacent communities. It will create new economic development opportunities for the San Juan Metropolitan Area and Puerto Rico, while contributing to the protection of crucial port and airport facilities. The Project responds to one of the most significant ecosystem restoration and environmental justice efforts in Puerto Rico.

Alternatives: The restoration of the CMP will occur within the Public Domain lands associated with the CMP Maritime Terrestrial Zone, as per Commonwealth Law 489 of September 24, 2004. The alternative interventions within the restoration area include no action, rectangular section 100 feet wide x 10 feet deep channel width with earth bottom and sheet piles; hybrid section 100 feet x 10 feet channel width with earth bottom and sheet piles in some areas and slopes in others; rectangular section 75 feet wide x 10 feet deep channel with articulated cement bottom and sheet piles; and hybrid section 75 feet wide x 10 feet deep canal with articulated cement bottom and sheet piles in some areas and slopes in others.

All the alternatives may restore open water resources and improve the wetland and benthic habitat functional value. The Corps will consider other project measures such as in-bay sediment disposal and the relocation of infrastructure.

Issues: The DEIS will consider impacts on benthic communities, protected species, public health and safety, water quality, aesthetics and recreation, fish and wildlife resources, cultural resources, conservation resources, environmental justice, and other impacts identified through scoping, public involvement and interagency coordination.

Scoping: Scoping has been conducted by ENLACE, the non-Federal sponsor and leading local expert, over the past 10 years. ENLACE conducted a scoping meeting and interagency review in 2003, and created varied mechanisms to ensure continued participation of all concerned parties. The scoping process has involved federal, state, and municipal agencies, residents along the CMP, as well as other interested persons and organizations.

Public Involvement: We invite the participation of affected federal, state and local agencies, and other interested private organizations and individuals. There will be a public meeting on the DEIS following its preparation. The exact location, date, and time of the public meeting will be announced in a public notice and local newspapers.

Coordination: The proposed action is being coordinated with the U.S. Fish and Wildlife Service (FWS) [under Section 7 of the Endangered Species Act and the Fish and Wildlife Coordination Act] and with the National Marine Fisheries Service [under Magnuson-Stevens Fishery Conservation and Management Act (on Essential Fish Habitat)] and Section 7 of the Endangered Species Act. The proposed action is also being coordinated with the Puerto Rico State Historic Preservation Office and the U.S. Environmental Protection Agency.

Other Environmental Review and Consultation: The proposed action would involve evaluation for compliance with guidelines pursuant to Section 404(b)(1) of the Clean Water Act, water quality certification (application to the Puerto Rico Environmental Quality Board) pursuant to Section 401 of the Clean Water Act, certification of state lands, easements, and rights-of-way, and determination of Coastal Zone Management Act Consistency.

Agency Role: As the cooperating agency, non-Federal sponsor and leading local expert, ENLACE will provide information and assistance on the resources to be impacted and construction mitigation measures and alternatives. Additionally, other agencies with either regulatory authority or special expertise have been incorporated and are participating in an interagency Technical Dredge Committee coordinated by ENLACE. These agencies may be called upon in preparation of the DEIS.

DEIS Preparation: It is anticipated that the DEIS will be available for public review in the 3rd quarter of 2013.

Dated: November 2, 2012.

Eric P. Summa,

Chief, Environmental Branch.

[FR Doc. 2012–27752 Filed 11–15–12; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Intent To Prepare a Draft Environment Impact Statement for the Proposed Prado Basin, California Feasibility Study, City of Corona, Riverside County, CA

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent.

SUMMARY: The Los Angeles District of the U.S. Army Corps of Engineers (Corps) and Orange County Water District (OCWD), the non-Federal sponsor for the project, intend to jointly prepare an Environmental Impact Statement/Environmental Impact Report (EIS/EIR) to study, plan, and implement a multifaceted project to restore

environmental resources and conserve water within Prado Basin and downstream of the Prado Dam, within the Santa Ana River. This effort will focus on restoring aquatic, wetland, and riparian habitats for endangered and otherwise associated native species, conserving water and resolving issues related to the alteration of the natural sediment transport regime.

ADDRESSES: Christopher T. Jones, U.S. Army Corps of Engineers, Los Angeles District, Ecosystem Planning Section, CESPL–PD–RN, P.O. Box 532711, Los Angeles, CA 90053–2325.

FOR FURTHER INFORMATION CONTACT: Christopher T. Jones, Biologist, *Christopher.T.Jones@usace.army.mil,* 213–304–6234.

SUPPLEMENTARY INFORMATION: The Prado Basin, California study was authorized by a study resolution dated May 8, 1964, the Committee on Public Works, U.S. House of Representatives (House Document No. 135, 81st Congress, 1st Session). It was additionally authorized by Section 401(a) of the Water Resources Development Act of 1986.

The U.S. Army Corps of Engineers (USACE) previously conducted a Reconnaissance Phase Study of the Santa Ana River Basin and Orange County Streams, California. Ecosystem restoration and water conservation problems were identified as having a Federal interest. The study did not identify sediment management as a Federal interest to address at that time. However, sediment management has been determined to contribute to ecosystem restoration goals and is a planning objective of the study.

1. Project Description. The proposed feasibility study will investigate alternatives to restore environmental resources, conserve water and resolve issues related to alterations to the natural sediment transport regime in the Santa Ana River.

Preliminary objectives for this study were based on identification and consideration of problems, needs and opportunities in the areas associated with ecosystem restoration and watershed development. The establishment of these objectives focused primarily on the authorized study purpose of determining the Federal interest in ecosystem restoration in Prado Basin. However, related problems and needs in the study area were also given consideration.

The first objective is to restore environmental resources in the study area, which would contribute to the National Ecosystem Restoration (NER) Federal objective. The efficiency of the restoration would be measured in the increases in the net quantity and/or quality of desired ecosystem resources.

A second objective is to provide a more efficient means of meeting the study area's water demands. The efficiency of meeting these water demands is measured in the cost of providing the needed water supplies. A reduced cost in providing water supply as compared to the without project condition would result in savings to the nation's economic development (NED).

A third objective is to improve sediment management and sediment transport in the study area. Improvements to sediment management and transport could result in habitat, water supply and flood risk reduction benefits.

2. Alternatives. Several potential measures have been discussed that may meet the objectives of this study. Measures will be grouped into discrete alternatives and analyzed in the EIS/EIR. These potential measures include, but are not limited to, wetland and riparian habitat creation, restoration of stream banks through bio-engineering, creation of perennial stream habitat for the Santa Ana sucker, removal of non-native vegetation, eradication of non-native fish species, enhancement of habitats and structures to facilitate wildlife movement, dredging sediment, sluicing sediment past Prado Dam, fish passage structures, passage of sediment through the dam's spillway via various means, re-operate dam for water conservation year-round at 505 feet in elevation, and to re-operate the dam for water conservation at a level higher than 498 feet elevation, but lower than 505 feet in elevation. This initial list of potential measures may be enhanced by input received at public meetings.

3. Scoping. a. The Corps intends to hold a public scoping meeting(s) for the EIS/EIR to aid in the determination of significant environmental issues associated with the proposed project. Affected federal, state and local resource agencies, Native American groups and concerned interest groups/individuals are encouraged to participate in the scoping process. Public participation is critical in defining the scope of analysis in the Draft EIS/EIR, identifying significant environmental issues in the Draft EIS/EIR, providing useful information such as published and unpublished data, and knowledge of relevant issues and recommending mitigation measures to offset potential impacts from proposed actions. The time and location of the public scoping meeting will be advertised in letters, public announcements and news releases.

b. Potential impacts associated with the proposed project will be fully evaluated. Resource categories that will be analyzed include: physical environment, geology, biological resources, air quality, water quality, recreational usage, aesthetics, cultural resources, transportation, noise, hazardous waste, socioeconomics and safety.

c. Individuals and agencies may offer information or data relevant to the environmental or socioeconomic impacts of the proposed project by submitting comments, suggestions, and requests to be placed on the mailing list for announcements by sending correspondence to the address listed above, or to the following email address: *christopher.t.jones@usace.army.mil.*

d. The project will require certification under Section 401 of the Clean Water Act from the Regional Water Quality Control Board. Depending upon the recommended alternative, the project may also require additional real property rights for construction and operation of a facility, compliance with Federal and State Endangered Species Acts, and relevant Department of California Fish and Game Code.

4. Public Scoping Meeting: A public scoping meeting will be held at the Inland Empire Utilities Agency (IEUA) Events Center on Wednesday, November 28, 2012, from 2:00 p.m. to 8:00 p.m. The project will be presented twice during this open house style meeting. The address for the IEUA Events Center is: Inland Empire Utilities Agency, 6075 Kimball Avenue, Chino, CA 91708, Phone: (909) 993–1600.

5. The Draft EIS/EIR is scheduled to be published and circulated for public review in May 2014.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2012–27756 Filed 11–15–12; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2012–0019]

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to amend a System of Records.

SUMMARY: The Department of the Navy is amending a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on December 17, 2012 unless comments are received which result in a contrary determination. Comments will be accepted on or before December 17, 2012.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Patterson, at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed changes to the record systems being amended are set forth below. The proposed amendment is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: November 13, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

NM01650–1

SYSTEM NAME:

Department of the Navy (DON) Military Awards System (May 5, 2010, 75 FR 24667).

CHANGES:

* * * * *

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should contact their local Personnel Support Activity or Personnel Support Detachment for a search of their Navy military personnel record or go to the Navy awards Web site at *Awards.navy.mil* and conduct a personal awards query.

Marine Corps personnel seeking to determine whether information about themselves is contained in this system of records should contact their unit administrative officer (G–1/S–1) for a search of their Service Record Book/Officer Qualification Record or write to Headquarters U.S. Marine Corps, Manpower and Reserve Affairs Department, Personnel Management Division, Military Awards Branch (MMMA), 3280 Russell Road, MCB Quantico, Virginia 22134–5103.

All other individuals seeking to determine whether information about themselves is contained in this system of records should contact either the Chief of Naval Operations, Navy Awards Branch (DNS–35), 2000 Navy Pentagon, Washington, DC 20350–2000 (for U.S. Navy awards) or Headquarters U.S. Marine Corps, Manpower and Reserve Affairs Department, Personnel Management Division, Military Awards Branch (MMMA), MCB Quantico, Virginia 22134–5103 (for U.S. Marine Corps awards).

Written requests should include full name, SSN, time period of award, and must be signed. The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.''

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Navy Department Awards Web Service; OPNAV Form 1650/3, Personal Award Recommendation Form, OPNAV 1650/14, Unit Award Recommendation Form, general orders; military personnel file, medical file, deck logs, command histories, award letter 1650.

Marine Corps Awards histories, Marine Corps Awards Processing System, Personal Award Recommendation (OPNAV 1650/3), Marine Corps orders, official military records, command histories, historical paper copies of personal award citations, and microfilm copies of Navy and Marine Corps 3 x 5 award cards.''

* * * * *

[FR Doc. 2012–27917 Filed 11–15–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Privacy Act of 1974; System of Records—Impact Evaluation of Race to the Top and School Improvement Grants

AGENCY: Institute of Education Sciences, Department of Education.

ACTION: Notice; correction.

SUMMARY: On October 12, 2012, the Institute of Education Sciences in the U.S. Department of Education (Department) published in the **Federal Register** (77 FR 62228) a new system of records notice (SORN) entitled ''Impact Evaluation of Race to the Top and School Improvement Grants'' (18–13–32) (RTT–SIG). This notice corrects one error in terminology in the RTT–SIG SORN.

DATES: Effective November 16, 2012.

SUPPLEMENTARY INFORMATION: On page 62230 of the RTT–SIG SORN, in the second column, under the heading the ROUTINE USES OF RECORDS MAINTAINTED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES, in the last sentence of the introductory paragraph, we correct the phrase ''individually identifying information'' to read ''personally identifiable information''.

FOR FURTHER INFORMATION CONTACT: Dr. Audrey Pendleton, Associate Commissioner, Evaluation Division, National Center for Education Evaluation and Regional Assistance, Institute of Education Sciences, U.S. Department of Education, 555 New Jersey Avenue NW., Room 502D, Washington, DC 20208–0001. Telephone: (202) 208–7078.

If you use a telecommunications device for the deaf (TDD) or text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Accessible format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document

Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: November 9, 2012.

John Q. Easton,

Director, Institute of Education Sciences.

[FR Doc. 2012–27845 Filed 11–15–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Intent To Grant Exclusive License Between National Energy Technology Laboratory and Corrosion Solutions

AGENCY: National Energy Technology Laboratory, Department of Energy.

ACTION: Notice of Intent To Grant Exclusive License.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i). The National Energy Technology Laboratory (NETL) hereby gives notice of its intent to grant an exclusive license to practice the inventions described and claimed in U.S. Patent No 7,553,517, issued June 30, 2009, entitled ''Method of applying a cerium diffusion coating to a metallic alloy,'' to Corrosion Solutions having its principal place of business in Eugene, Oregon. The inventions are owned by the United States of America as represented by the Department of Energy (DOE). The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

DATES: Written comments or nonexclusive license applications are to be received at the address listed below no later than December 3, 2012. Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

ADDRESSES: Objections relating to the prospective exclusive license may be submitted to the Office of Chief Counsel, National Energy Technology Laboratory, P.O. Box 10940, Pittsburgh, PA 15236, or via facsimile at (412) 386–5949.

FOR FURTHER INFORMATION CONTACT: Jessica Sosenko, Technology Transfer Program Manager, U.S. Department of Energy, National Energy Technology Laboratory, P.O. Box 10940, Pittsburgh, PA 15236; Telephone (412) 386–7417; Email: *jessica.sosenko@netl.doe.gov*.

SUPPLEMENTARY INFORMATION: Section 209(c) gives DOE with authority to grant exclusive or partially exclusive licenses in department-owned inventions, where a determination can be made, among other things, that the desired practical application of the invention has not been achieved, or is not likely expeditiously to be achieved, under a nonexclusive license. The statute and implementing regulations (37 CFR 404) require that the necessary determinations be made after public notice and opportunity for filing written objections.

Corrosion Solutions, a new small business, has applied for an exclusive license to practice the inventions and has a plan for commercialization of the invention. DOE intends to grant the license, upon a final determination in accordance with 35 U.S.C. 209(c), unless, within 15 days of publication of this notice, NETL's Office of Chief Counsel (contact information listed above) receives in writing any of the following, together with the supporting documents:

(i) A statement from any person setting forth reasons why it would not be in the best interest of the United States to grant the proposed license; or

(ii) An application for a nonexclusive license to the invention, in which the applicant states that it already has brought the invention to practical application or is likely to bring the invention to practical application expeditiously.

The proposed license would be exclusive, subject to a license and other rights retained by the U.S. Government, and subject to a negotiated royalty. DOE will review all timely written responses to this notice and will grant the license if, after expiration of the 15-day notice period and after consideration of any written responses to this notice, a determination is made in accordance with Section 209(c) that the license is in the public interest.

Dated: October 26, 2012.

Anthony V. Cugini,

Director, National Energy Technology Laboratory.

[FR Doc. 2012–27928 Filed 11–15–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

[Case No. CAC–039]

Decision and Order Granting a Waiver Granted to Fujitsu General Limited From the Department of Energy Commercial Package Air Conditioner and Heat Pump Test Procedures

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

ACTION: Decision and Order.

SUMMARY: The U.S. Department of Energy (DOE) gives notice of the decision and order (Case No. CAC–039) that grants Fujitsu General Limited (Fujitsu) a waiver from the DOE commercial package air-source central air conditioners and heat pumps test procedures for determining the energy consumption set forth in its petition for waiver. Under today's decision and order, Fujitsu shall be required to test and rate its AIRSTAGE V–II multi-split heat pump with a capacity of 264,000 Btu/h, and specified compatible indoor units using American National Standards Institute (ANSI)/Air-conditioning, Heating and Refrigeration Institute (AHRI) Standard 1230, as adopted in DOE's final rule dated May 16, 2012.

DATES: This Decision and Order is effective November 16, 2012 through May 12, 2013.

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Berringer, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–0371. Email: *Bryan.Berringer@ee.doe.gov*.

Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–71, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585–0103. Telephone: (202) 586–7796. Email: *mailto:Elizabeth.Kohl@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: DOE issues notice of this Decision and Order in accordance with Title 10 of the Code of Federal Regulations (10 CFR) 431.401(f)(4). In this Decision and Order, DOE grants Fujitsu a waiver for the Airstage V–II multi-split equipment specified in its waiver submitted on December 16, 2011. Fujitsu must test and rate this equipment using ANSI/AHRI 1230, as adopted in DOE's final rule dated May 16, 2012 (77 FR 28928), as the alternative test procedure. DOE's

final rule specifies use of ANSI/AHRI 1230, but omits sections 5.1.2 and 6.6.

Today's decision requires Fujitsu to make representations concerning the energy efficiency of this equipment consistent with the provisions and restrictions of the alternate test procedure in the Decision and Order below, and the representations must fairly disclose the test results. (42 U.S.C. 6314(d)) The same standard applies to distributors, retailers, and private labelers when making representations of the energy efficiency of this equipment.

Issued in Washington, DC, on November 9, 2012.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

Decision and Order

In the Matter of: Fujitsu General Limited (Fujitsu) (Case No. CAC–039).

I. Background and Authority

Title III, Part C of the Energy Policy and Conservation Act of 1975 (EPCA), Pub. L. 94–163 (42 U.S.C. 6311–6317), established the Energy Conservation Program for certain industrial equipment, which includes commercial air conditioning equipment, the focus of this decision and order.[1] Part C specifically includes definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6316). With respect to test procedures, Part C authorizes the Secretary of Energy (the Secretary) to prescribe test procedures that are reasonably designed to produce results that measure energy efficiency, energy use, and estimated annual operating costs, and that are not unduly burdensome to conduct. (42 U.S.C. 6314(a)(2))

For commercial package air-conditioning and heating equipment, EPCA provides that ''the test procedures shall be those generally accepted industry testing procedures or rating procedures developed or recognized by the Air-Conditioning and Refrigeration Institute [ARI] or by the American Society of Heating, Refrigerating and Air-Conditioning Engineers [ASHRAE], as referenced in ASHRAE/IES Standard 90.1 and in effect on June 30, 1992.'' (42 U.S.C. 6314(a)(4)(A)) If the industry test procedure for commercial package air-conditioning and heating equipment is amended, EPCA directs the Secretary to amend the corresponding DOE test procedure unless the Secretary determines, by rule and based on clear and convincing evidence, that such a modified test procedure does not meet the statutory criteria set forth in 42 U.S.C. 6314(a)(2) and (3). (42 U.S.C. 6314(a)(4)(B))

On December 8, 2006, DOE published a final rule adopting test procedures for commercial package air-conditioning and heating equipment, effective January 8, 2007. 71 FR 71340. Table 1 to Title 10 of the Code of Federal Regulations (10 CFR) 431.96 directs manufacturers of commercial package air conditioning and heating equipment to use the appropriate procedure when measuring energy efficiency of this equipment. For commercial package air-source equipment with capacities between 65,000 and 760,000 Btu/h, ARI Standard 340/360–2004 is the applicable test procedure.

DOE's regulations for covered products and equipment permit a person to seek a waiver from the test procedure requirements for covered commercial equipment if at least one of the following conditions is met: (1) The petitioner's basic model contains one or more design characteristics that prevent testing according to the prescribed test procedures; or (2) the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. 10 CFR 431.401(a)(1). Petitioners must include in their petition any alternate test procedures known to the petitioner to evaluate the basic model in a manner representative of its energy consumption. 10 CFR 431.401(b)(1)(iii). The Assistant Secretary for Energy Efficiency and Renewable Energy (Assistant Secretary) may grant a waiver subject to conditions, including adherence to alternate test procedures. 10 CFR 431.401(f)(4). Waivers remain in effect according to the provisions of 10 CFR 431.401(g).

On December 16, 2011, Fujitsu submitted a petition for waiver from the DOE test procedure applicable to commercial package air-source and water-source central air conditioners and heat pumps set forth in 10 CFR 431.96. Fujitsu requested the waiver for specified basic model of Fujitsu AIRSTAGE V–II multi-split heat pump with a capacity of 264,000 Btu/h, and specified compatible indoor units. The applicable test procedure for these heat pumps is ARI 340/360–2004. Manufacturers are directed to use these test procedures pursuant to Table 1 of 10 CFR 431.96. Fujitsu seeks a waiver from the applicable test procedures under 10 CFR 431.96 on the grounds that its AIRSTAGE V–II multi-split heat pumps contain design characteristics that prevent testing according to the current DOE test procedures. Fujitsu requested that DOE allow it to test and rate its Airstage V–II multi-split heat pump with a capacity of 264,000 Btu/h, and specified compatible indoor units according to the American National Standards Institute (ANSI)/Air-conditioning, Heating and Refrigeration Institute (AHRI) Standard 1230–2010: Performance Rating of Variable Refrigerant Flow (VRF) Multi-Split Air-Conditioning and Heat Pump Equipment (AHRI 1230).

On May 16, 2012, DOE published a final rule (77 FR 28928) adopting American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 90.1–2010 (ASHRAE final rule). The ASHRAE final rule incorporated by reference ANSI/AHRI 1230–2010 but omits sections 5.1.2 and 6.6 for the products addressed in this waiver request. The rule was effective on July 16, 2012 and requires use of the test procedure on or after May 13, 2013. This decision and order (D&O) requires Fujitsu to use ANSI/AHRI 1230–2010 as addressed in the DOE's May 16, 2012 final rule (77 FR 28928) to test and rate specified models in order to be consistent with future test procedure requirements.

II. Fujitsu's Petition for Waiver: Assertions and Determinations

In its December 16, 2011 petition, Fujitsu seeks a waiver from the applicable test procedures under 10 CFR 431.96 on the grounds that its AIRSTAGE V–II multi-split heat pumps contain design characteristics that prevent testing according to the current DOE test procedures. Specifically, Fujitsu asserts that the two primary factors that prevent testing of its AIRSTAGE V–II multi-split variable speed products are the same factors stated in the waivers that DOE granted to Mitsubishi Electric & Electronics America USA, Inc. (Mitsubishi) and other manufacturers for similar lines of commercial multi-split air-conditioning systems:

- Testing laboratories cannot test products with so many indoor units; and
- There are too many possible combinations of indoor and outdoor units to test. See, e.g., 72 FR 17528 (April 9, 2007) (Mitsubishi); 76 FR 19069 (April 6, 2011) (Daikin); 76 FR 19078 (April 6, 2011) (Mitsubishi); 76 FR 31951 (June 2, 2011) (Carrier); 76 FR

[1] For editorial reasons, upon codification in the U.S. Code, Part C was re-designated Part A–1.

50204 (August 12, 2011) (Fujitsu General Limited); 76 FR 65710 (October 24, 2011) (Mitsubishi).

The AIRSTAGE V–II systems have operational characteristics similar to the commercial multi-split products manufactured by other manufacturers. As indicated above, DOE has already granted waivers for these products. The AIRSTAGE V–II system consists of multiple indoor units connected to an air-cooled outdoor unit. These multi-splits are used in zoned systems where an outdoor or water-source unit can be connected with up to 45 separate indoor units, which need not be the same models. According to Fujitsu, the various indoor and outdoor models can be connected in a multitude of configurations, with many thousands of possible combinations. Consequently, Fujitsu requested that DOE grant a waiver from the applicable test procedures for its AIRSTAGE V–II product designs until a suitable test method is prescribed.

For the reasons discussed above, and because DOE prescribed ANSI/AHRI 1230 as the alternate test procedure in waivers granted to other manufacturers (including the grant of Fujitsu's interim waiver request (77 FR 13107, Mar. 5, 2012)), DOE determined that the equipment specified in Fujitsu's December 16, 2011 petition contains design characteristics that prevent testing according to the DOE test procedure, and that allowing Fujitsu to use as an alternate test procedure ANSI/AHRI 1230, as adopted in DOE's final rule dated May 16, 2012 (77 FR 28928), addresses these testing difficulties.

Consultations With Other Agencies

DOE consulted with the Federal Trade Commission (FTC) staff concerning the Fujitsu petition for waiver. The FTC staff did not have any objections to granting a waiver to Fujitsu.

III. Conclusion

After careful consideration of all the material that was submitted by Fujitsu and consultation with the FTC staff, it is ordered that:

(1) The petition for waiver submitted by Fujitsu (Case No. CAC–039) is hereby granted as set forth in the following paragraphs.

(2) Fujitsu shall be required to test and rate the following basic model groups according to the alternate test procedure set forth in paragraph (3) of this section.

Add-on system models	(Module models)
AOUA264RLBVG	(AOUA72RLBV + AOUA96RLBV + AOUA96RLBV)

With nominal cooling capacity of 264,000 Btu/h.

Compatible indoor units for the above listed outdoor units:

Compact cassette:
AUUA7RLAV, AUUA9RLAV, AUUA12RLAV, AUUA14RLAV, AUUA18RLAV and AUUA24RLAV with nominal cooling capacities of 7,500, 9,500, 12,000, 14,000, 18,000 and 24,000 Btu/hr respectively

Cassette:
AUUB30RLAV and AUUB36RLAV with nominal cooling capacities of 30,000 and 36,000 Btu/hr respectively

Slim cassette:
AUUB18RLAV and AUUB24RLAV with nominal cooling capacities of 18,000 and 24,000 Btu/hr respectively

Compact wall mounted:
ASUA7RLAV, ASUE7RLAV, ASUA9RLAV, ASUE9RLAV, ASUA12RLAV, ASUE12RLAV, ASUA14RLAV and ASUE14RLAV with nominal cooling capacities of 7,500, 7,500, 9,500, 9,500, 12,000, 12,000, 14,000 and 14,000 Btu/hr respectively

Wall mounted:
ASUB18RLAV and ASUB24RLAV with nominal cooling capacities of 18,000 and 24,000 Btu/hr respectively

Floor/Ceiling (Universal):
ABUA12RLAV, ABUA14RLAV, ABUA18RLAV and ABUA24RLAV with nominal cooling capacities of 12,000, 14,000, 18,000, 24,000 Btu/hr respectively

Ceiling:
ABUA30RLAV and ABUA36RLAV with nominal cooling capacities of 30,000 and 36,000 Btu/hr respectively

Slim duct:
ARUL7RLAV, ARUL9RLAV, ARUL12RLAV, ARUL14RLAV and ARUL18RLAV with nominal cooling capacities of 7,500, 9,500, 12,000, 14,000 and 18,000 Btu/hr respectively

Middle static pressure duct:
ARUM24RLAV, ARUM30RLAV, ARUM36RLAV, ARUM48RLAV and ARUM54RLAV with nominal cooling capacities of 24,000, 30,000, 36,000, 48,000 and 54,000 Btu/hr respectively

High static pressure duct:
ARUH36RLAV, ARUH48RLAV, ARUH54RLAV, ARUH60RLAV, ARUH72RLAV, ARUH90RLAV and ARUH96RLAV with nominal cooling capacities of 36,000, 48,000, 60,000, 72,000, 90,000 and 96,000 Btu/hr respectively

(3) Fujitsu shall not be required to test the products listed in paragraph (2) of this section according to the test procedure for commercial package air conditioners and heat pumps prescribed by DOE at 10 CFR 431.96 (ARI Standard 340/360–2004 (incorporated by reference in 10 CFR 431.95(b)(2)–(3)), but instead shall use as the alternate test procedure ANSI/AHRI 1230–2010 as adopted in DOE's final rule dated May 16, 2012 (77 FR 28928).

(4) *Representations.* In making representations about the energy efficiency of its Airstage V–II multi-split equipment, for compliance, marketing, or other purposes, Fujitsu must fairly disclose the results of testing under the DOE test procedure in a manner consistent with the provisions outlined below:

(i) For multi-split combinations tested in accordance with this alternate test procedure, Fujitsu may make representations based on those test results.

(ii) For multi-split combinations that are not tested, Fujitsu may make representations based on the testing results for the tested combination and that are consistent with one of the following methods:

(a) Rating of non-tested combinations according to an alternative rating method approved by DOE; or

(b) Rating of non-tested combinations having the same outdoor unit and all non-ducted indoor units shall be set equal to the rating of the tested system having all non-ducted indoor units.

(c) Rating of non-tested combinations having the same outdoor unit and all ducted indoor units shall be set equal to the rating of the tested system having all ducted indoor units. To be considered a ducted unit, the indoor unit must be intended to be connected with ductwork and have a rated external static pressure capability greater than zero (0).

(d) Rating of non-tested combinations having the same outdoor unit and a mix of non-ducted and ducted indoor units shall be set equal to the average of the ratings for the two required tested combinations.

(5) This waiver amendment shall remain in effect from the date this Decision and Order is issued, consistent with the provisions of 10 CFR 431.401(g). Compliance with the ASHRAE final rule, (77 FR 28928, May 16, 2012), is required as of May 13, 2013. Therefore, this Decision and Order is valid through May 12, 2013. Beginning on May 13, 2013, all manufacturers must use the ASHRAE procedures to determine the energy use of this type of equipment.

Issued in Washington, DC, on November 9, 2012.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2012–27927 Filed 11–15–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

[Case No. CAC–038]

Decision and Order Granting a Waiver Granted to Samsung Electronics America, Inc. From the Department of Energy Commercial Package Air Conditioner and Heat Pump Test Procedures

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

ACTION: Decision and Order.

SUMMARY: The U.S. Department of Energy (DOE) gives notice of the decision and order (Case No. CAC–038) that grants Samsung Electronics America, Inc. (Samsung) a waiver from the DOE commercial package air-source central air conditioners and heat pumps test procedures for determining the energy consumption set forth in its petition for waiver. Under today's decision and order, Samsung shall be required to test and rate its variable capacity Digital Variable Multi (DVM) (commercial) multi-split heat pumps with cooling capacities ranging from 72,000 Btu/h to 120,000 Btu/h, as specified in its petition using American National Standards Institute (ANSI)/Air-conditioning, Heating and Refrigeration Institute (AHRI) Standard 1230, as adopted in DOE's final rule dated May 16, 2012.

DATES: This Decision and Order is effective November 16, 2012 through May 12, 2013.

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Berringer, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–0371. Email: *Bryan.Berringer@ee.doe.gov*.

Ms. Jennifer Tiedeman, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–71, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585–0103. Telephone: (202) 287–6111. Email: *Jennifer.Tiedeman@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: DOE issues notice of this Decision and Order in accordance with Title 10 of the Code of Federal Regulations (10 CFR) 431.401(f)(4). In this Decision and Order, DOE grants Samsung a waiver for the variable capacity DVM (commercial) multi-split heat pump equipment specified in its waiver submitted on October 17, 2011. Samsung must test and rate this equipment using ANSI/AHRI 1230, as adopted in DOE's final rule dated May 16, 2012 (77 FR 28928), as the alternative test procedure. DOE's final rule specifies use of ANSI/AHRI 1230, but omits sections 5.1.2 and 6.6.

Today's decision requires Samsung to make representations concerning the energy efficiency of this equipment consistent with the provisions and restrictions of the alternate test procedure in the Decision and Order below, and the representations must fairly disclose the test results. (42 U.S.C. 6314(d)) The same standard applies to distributors, retailers, and private labelers when making representations of the energy efficiency of this equipment.

Issued in Washington, DC, on November 9, 2012.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

Decision and Order

In the Matter of: Samsung Electronics America, Inc. (Samsung) (Case No. CAC–038).

I. Background and Authority

Title III, Part C of the Energy Policy and Conservation Act of 1975 (EPCA), Public Law 94–163 (42 U.S.C. 6311–6317), established the Energy Conservation Program for certain industrial equipment, which includes commercial air conditioning equipment, the focus of this decision and order.[1] Part C specifically includes definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6316). With respect to test procedures, Part C authorizes the Secretary of Energy (the Secretary) to prescribe test procedures that are reasonably designed to produce results that measure energy efficiency, energy use, and estimated annual operating costs, and that are not unduly burdensome to conduct. (42 U.S.C. 6314(a)(2))

For commercial package air-conditioning and heating equipment, EPCA provides that ''the test procedures shall be those generally accepted industry testing procedures or rating procedures developed or recognized by the Air-Conditioning and Refrigeration Institute [ARI] or by the American Society of Heating, Refrigerating and Air-Conditioning Engineers [ASHRAE], as referenced in ASHRAE/IES Standard 90.1 and in effect on June 30, 1992.'' (42 U.S.C. 6314(a)(4)(A)) If the industry test procedure for commercial package air-conditioning and heating equipment is amended, EPCA directs the Secretary to amend the corresponding DOE test procedure unless the Secretary determines, by rule and based on clear and convincing evidence, that such a modified test procedure does not meet the statutory criteria set forth in 42 U.S.C. 6314(a)(2) and (3). (42 U.S.C. 6314(a)(4)(B))

On December 8, 2006, DOE published a final rule adopting test procedures for commercial package air-conditioning and heating equipment, effective January 8, 2007. 71 FR 71340. Table 1 to Title 10 of the Code of Federal Regulations (10 CFR) 431.96 directs manufacturers of commercial package air conditioning and heating equipment to use the appropriate procedure when measuring energy efficiency of this equipment. For commercial package air-source equipment with capacities between 65,000 and 760,000 Btu/h, ARI Standard 340/360–2004 is the applicable test procedure.

DOE's regulations for covered products and equipment permit a person to seek a waiver from the test procedure requirements for covered commercial equipment if at least one of the following conditions is met: (1) The petitioner's basic model contains one or more design characteristics that prevent testing according to the prescribed test procedures; or (2) the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. 10 CFR 431.401(a)(1). Petitioners must include in their petition any alternate test procedures known to the petitioner to evaluate the basic model in a manner representative of its energy consumption. 10 CFR 431.401(b)(1)(iii). The Assistant Secretary for Energy Efficiency and Renewable Energy (Assistant Secretary) may grant a waiver subject to conditions, including adherence to alternate test procedures. 10 CFR 431.401(f)(4). Waivers remain in effect according to the provisions of 10 CFR 431.401(g).

On October 17, 2011, Samsung submitted a petition for waiver from the DOE test procedure applicable to commercial package air-source and water-source central air conditioners and heat pumps set forth in 10 CFR 431.96. Samsung requested the waiver for the specified basic model of Samsung's variable capacity Digital Variable Multi (DVM) (commercial) multi-split heat pumps with cooling capacities ranging from 72,000 Btu/h to

[1] For editorial reasons, upon codification in the U.S. Code, Part C was re-designated Part A–1.

120,000 Btu/h. The applicable test procedure for these heat pumps is ARI 340/360–2004. Manufacturers are directed to use these test procedures pursuant to Table 1 of 10 CFR 431.96. Samsung seeks a waiver from the applicable test procedures under 10 CFR 431.96 on the grounds that its DVM multi-split heat pumps contain design characteristics that prevent testing according to the current DOE test procedures. Samsung requested that DOE allow it to test and rate its DVM multi-split heat pumps with cooling capacities ranging from 72,000 Btu/h to 120,000 Btu/h according to the American National Standards Institute (ANSI)/Air-conditioning, Heating and Refrigeration Institute (AHRI) Standard 1230–2010: Performance Rating of Variable Refrigerant Flow (VRF) Multi-Split Air-Conditioning and Heat Pump Equipment (AHRI 1230).

On May 16, 2012, DOE published a final rule (77 FR 28928) adopting certain revised efficiency standards and test procedures provided in American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 90.1–2010 (ASHRAE final rule). The ASHRAE final rule incorporated by reference ANSI/AHRI 1230–2010 but it omits sections 5.1.2 and 6.6 for the products addressed in this waiver request. The rule was effective on July 16, 2012 and requires use of the test procedure on or after May 13, 2013. This decision and order (D&O) requires Samsung to use ANSI/AHRI 1230–2010 as addressed in the DOE's May 16, 2012 final rule (77 FR 28928) to test and rate specified models in order to be consistent with future test procedure requirements.

II. Samsung's Petition for Waiver: Assertions and Determinations

In its October 17, 2011 petition, Samsung seeks a waiver from the applicable test procedures under 10 CFR 431.96 on the grounds that its DVM multi-split heat pumps contain design characteristics that prevent testing according to the current DOE test procedures. Specifically, Samsung asserts that the two primary factors that prevent testing of its DVM multi-split variable speed products are the same factors stated in the waivers that DOE granted to Mitsubishi Electric & Electronics America USA, Inc. (Mitsubishi) and other manufacturers for similar lines of commercial multi-split air-conditioning systems:

- Testing laboratories cannot test products with so many indoor units; and
- There are too many possible combinations of indoor and outdoor units to test.

See, e.g., 72 FR 17528 (April 9, 2007) (Mitsubishi); 76 FR 19069 (April 6, 2011) (Daikin); 76 FR 19078 (April 6, 2011) (Mitsubishi); 76 FR 31951 (June 2, 2011) (Carrier); 76 FR 50204 (August 12, 2011) (Fujitsu General Limited); 76 FR 65710 (October 24, 2011) (Mitsubishi).

The DVM systems have operational characteristics similar to the commercial multi-split products manufactured by other manufacturers. As indicated above, DOE has already granted waivers for these products. The DVM system consists of multiple indoor units connected to an air-cooled outdoor unit. These multi-splits are used in zoned systems where an outdoor or water-source unit can be connected with up to 10 separate indoor units, which need not be the same models. According to Samsung, the various indoor and outdoor models can be connected in a multitude of configurations, with many thousands of possible combinations. Consequently, Samsung requested that DOE grant a waiver from the applicable test procedures for its DVM product designs until a suitable test method can be prescribed.

For the reasons discussed above, and because DOE prescribed ANSI/AHRI 1230 as the alternate test procedure in waivers granted to other manufacturers (including the grant of Samsung's interim waiver request (76 FR 80916, Dec. 27, 2011), DOE determined that the equipment specified in Samsung's October 17, 2011 petition contains design characteristics that prevent testing according to the DOE test procedure, and that allowing Samsung to use as an alternate test procedure ANSI/AHRI 1230, as adopted in DOE's final rule dated May 16, 2012 (77 FR 28928), addresses these testing difficulties.

Consultations With Other Agencies

DOE consulted with the Federal Trade Commission (FTC) staff concerning the Samsung petition for waiver. The FTC staff did not have any objections to granting a waiver to Samsung.

III. Conclusion

After careful consideration of all the material that was submitted by Samsung and consultation with the FTC staff, it is ordered that:

(1) The petition for waiver submitted by the Samsung (Case No. CAC–038) is hereby granted as set forth in the paragraphs below.

(2) Samsung shall be required to test and rate the following basic model groups according to the alternate test procedure set forth in paragraph (3) of this section.

Type	Model	Description	Cooling/heating [Btu/h]
Outdoor Unit	RVXVHT075FE	Condensing unit heat pump	72,000/81,000
	RVXVHT100FE	Condensing unit heat pump	96,000/108,000
	RVXVHT125FE	Condensing unit heat pump	120,000/135,000
	RD075VRXFA	Condensing unit heat pump	72,000/81,000
	RD100VRXFA	Condensing unit heat pump	96,000/108,000
	RD125VRXFA	Condensing unit heat pump	120,000/135,000
Indoor Unit	AVXCMH032CE	4-Way Ceiling Cassette Heat pump	9,500/10,500
	AVXCMH040CE	4-Way Ceiling Cassette Heat pump	12,000/13,500
	AVXCMH052CE	4-Way Ceiling Cassette Heat pump	18,000/20,000
	AVXCMH060CE	4-Way Ceiling Cassette Heat pump	20,000/23,000
	AVXC4H052CE	4-Way Ceiling Cassette Heat pump	18,000/20,000
	AVXC4H072CE	4-Way Ceiling Cassette Heat pump	24,000/27,000
	AVXC4H100CE	4-Way Ceiling Cassette Heat pump	30,000/34,000
	AVXC4H110CE	4-Way Ceiling Cassette Heat pump	36,000/40,000
	AVXC4H145CE	4-Way Ceiling Cassette Heat pump	48,000/54,000
	AVXDSH020CE	Built-in Slim Duct (Low pressure)	6,000/7,000
	AVXDSH032CE	Built-in Slim Duct (Low pressure)	9,500/10,500
	AVXDSH040CE	Built-in Slim Duct (Low pressure)	12,000/13,500
	AVXDSH052CE	Built-in Slim Duct (Low pressure)	18,000/20,000
	AVXDSH072CE	Built-in Slim Duct (Low pressure)	24,000/27,000

Type	Model	Description	Cooling/heating [Btu/h]
	AVXDSH100CE	Built-in Slim Duct (Low pressure)	30,000/34,000
	AVXDSH110CE	Built-in Slim Duct (Low pressure)	36,000/40,000
	AVXDSH145CE	Built-in Slim Duct (Low pressure)	48,000/54,000
	AVXDUH100CE	Built-in Duct (Mid pressure)	30,000/34,000
	AVXDUH110CE	Built-in Duct (Mid pressure)	36,000/40,000
	AVXDUH145CE	Built-in Duct (Mid pressure)	48,000/54,000
	AVXWVH020CE	High Wall Mount Heat Pump	6,000/7,000
	AVXWVH032CE	High Wall Mount Heat Pump	9,500/10,500
	AVXWVH040CE	High Wall Mount Heat Pump	12,000/13,500
	AVXWVH052CE	High Wall Mount Heat Pump	18,000/20,000
	AVXWVH060CE	High Wall Mount Heat Pump	20,000/23,000
	AVXWNH020CE	High Wall Mount Heat Pump	6,000/7,000
	AVXWNH032CE	High Wall Mount Heat Pump	9,500/10,500
	AVXWNH040CE	High Wall Mount Heat Pump	12,000/13,500
	AVXWNH052CE	High Wall Mount Heat Pump	18,000/20,000
	AVXWNH060CE	High Wall Mount Heat Pump	20,000/23,000
	AVXCSH023CE	1-Way Ceiling Cassette Heat pump	7,500/8,500
	AVXCSH032CE	1-Way Ceiling Cassette Heat pump	9,500/10,500
	AVXCSH040CE	1-Way Ceiling Cassette Heat pump	12,000/13,500

(3) Samsung shall not be required to test the products listed in paragraph (2) of this section according to the test procedure for commercial package air conditioners and heat pumps prescribed by DOE at 10 CFR 431.96 (ARI Standard 340/360–2004 (incorporated by reference in 10 CFR 431.95(b)(2)–(3)), but instead shall use as the alternate test procedure ANSI/AHRI 1230–2010 as adopted in DOE's final rule dated May 16, 2012 (77 FR 28928).

(4) *Representations.* In making representations about the energy efficiency of its DVM multi-split equipment, for compliance, marketing, or other purposes, Samsung must fairly disclose the results of testing under the DOE test procedure in a manner consistent with the provisions outlined below:

(i) For multi-split combinations tested in accordance with this alternate test procedure, Samsung may make representations based on those test results.

(ii) For multi-split combinations that are not tested, Samsung may make representations based on the testing results for the tested combination and that are consistent with one of the following methods:

(a) Rating of non-tested combinations according to an alternative rating method approved by DOE; or

(b) Rating of non-tested combinations having the same outdoor unit and all non-ducted indoor units shall be set equal to the rating of the tested system having all non-ducted indoor units.

(c) Rating of non-tested combinations having the same outdoor unit and all ducted indoor units shall be set equal to the rating of the tested system having all ducted indoor units. To be considered a ducted unit, the indoor unit must be intended to be connected with ductwork and have a rated external static pressure capability greater than zero (0).

(d) Rating of non-tested combinations having the same outdoor unit and a mix of non-ducted and ducted indoor units shall be set equal to the average of the ratings for the two required tested combinations.

(5) This waiver amendment shall remain in effect from the date this Decision and Order is issued, consistent with the provisions of 10 CFR 431.401(g). Compliance with the ASHRAE final rule, (77 FR 28928, May 16, 2012), is required beginning on May 13, 2013. Therefore, this D&O is valid through May 12, 2013. Beginning on May 13, 2013, all manufacturers must use the amended DOE test procedures to determine the energy use of this type of equipment.

Issued in Washington, DC, on November 9, 2012.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2012–27919 Filed 11–15–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. P–13404–002, P–13405–002, P–13406–002, P–13407–002, P–13408–002, P–13411–002, and P–13412–002]

Clean River Power MR–1, LLC; Clean River Power MR–2, LLC; Clean River Power MR–3, LLC; Clean River Power MR–5, LLC; Clean River Power MR–6, LLC; Clean River Power MR–7, LLC; Clean River Power MR–8, LLC; Notice of Applications Tendered for Filing With the Commission and Soliciting Additional Study Requests

a. *Type of Applications:* Original Major Licenses.

b. *Project Nos.:* 13404–002, 13405–002, 13406–002, 13407–002, 13408–002, 13411–002, and 13412–002.

c. *Dated Filed:* October 31, 2012.

d. *Applicants:* Clean River Power MR–1, LLC; Clean River Power MR–2, LLC; Clean River Power MR–3, LLC; Clean River Power MR–5, LLC; Clean River Power MR–6, LLC; Clean River Power MR–7, LLC; and Clean River Power MR–8, LLC (Clean River Power), subsidiaries of Free Flow Power Corporation.

e. *Names of Projects:* Beverly Lock and Dam Project, P–13404–002; Devola Lock and Dam Project, P–13405–002; Malta/McConnelsville Lock and Dam Project, P–13406–002; Lowell Lock and Dam Project, P–13407–002; Philo Lock and Dam Project, P–13408–002; Rokeby Lock and Dam Project, P–13411–002; and Zanesville Lock and Dam Project, P–13412–002.

f. *Location:* At existing locks and dams formally owned and operated by the U.S. Army Corps of Engineers but now owned and operated by the State of

Ohio on the Muskingum River in Washington, Morgan, and Muskingum counties, Ohio (see table below for specific project locations).

Project No.	Projects	County(s)	City/town
P–13404	Beverly Lock and Dam	Washington	Upstream of the city of Beverly.
P–13405	Devola Lock and Dam	Washington	Near the city of Devola.
P–13406	Malta/McConnelsville Lock and Dam	Morgan	Southern shore of the town of McConnelsville.
P–13407	Lowell Lock and Dam	Washington	West of the city of Lowell.
P–13408	Philo Lock and Dam	Muskingum	North of the city of Philo.
P–13411	Rokeby Lock and Dam	Morgan	Near the city of Rokeby.
P–13412	Zanesville Lock and Dam	Muskingum	Near the center of the city of Zanesville.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contacts:* Ramya Swaminathan, Chief Operating Officer, Free Flow Power Corporation, 239 Causeway Street, Suite 300, Boston, MA 02114; or at (978) 283–2822.

Daniel Lissner, General Counsel, Free Flow Power Corporation, 239 Causeway Street, Suite 300, Boston, MA 02114; or at (978) 283–2822.

Alan Topalian, Regulatory Attorney, Free Flow Power Corporation, 239 Causeway Street, Suite 300, Boston, MA 02114; or at (978) 283–2822.

i. *FERC Contact:* Aaron Liberty at (202) 502–6862; or email at *aaron.liberty@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* December 31, 2012.

All documents 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 at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. 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.

m. The applications are not ready for environmental analysis at this time.

n. The proposed Beverly Lock and Dam Water Power Project would be located on the Muskingum River at river mile (RM) 24.6, and consist of the following new facilities: (1) A 37-foot-long, 52-foot-high, 75-foot-wide intake structure with 2-inch clear bar spacing trash racks; (2) a 160-foot by 75-foot powerhouse located downstream of the dam on the left bank of the Muskingum River; (3) two turbine-generator units providing a combined installed capacity of 3.0 megawatts (MW); (4) a 65-foot-long, 75-foot-wide draft tube section; (5) a 40-foot by 40-foot substation; (6) a 970-foot-long, three-phase, overhead 69-kilovolt (kV) transmission line to connect the project substation to the local utility distribution lines; and (7) appurtenant facilities. The average annual generation would be about 17,853 megawatt-hours (MWh).

The proposed Devola Lock and Dam Water Power Project would be located at RM 5.8, and consist of the following new facilities: (1) A 160-foot-long, 66-foot-high, 80-foot-wide intake structure with 2-inch clear bar spacing trash racks; (2) a 160-foot by 80-foot powerhouse located on the bank of the Muskingum River opposite the existing lock; (3) two turbine-generator units providing a combined installed capacity of 4.0 MW; (4) a 65-foot-long, 80-foot-wide draft tube section; (5) a 40-foot by 40-foot substation; (6) a 3,600-foot-long, three-phase, overhead 69-kV transmission line to connect the project substation to the local utility distribution lines; and (7) appurtenant facilities. The average annual generation would be about 20,760 MWh.

The proposed Malta Lock and Dam Water Power Project would be located at RM 49.4, and consist of the following new facilities: (1) A 37-foot-long, 52-foot-high, 80-foot-wide intake structure with 2-inch clear bar spacing trash racks; (2) a 160-foot by 80-foot powerhouse located adjacent to the right bank of the dam; (3) two turbine-generator units providing a combined installed capacity of 4.0 MW; (4) a 65-foot-long, 80-foot-wide draft tube section; (5) a 40-foot by 40-foot substation; (6) a 1,500-foot-long, three-phase, overhead 69-kV transmission line to connect the project substation to the local utility distribution lines; and (7) appurtenant facilities. The average annual generation would be about 21,895 MWh.

The proposed Lowell Lock and Dam Water Power Project would be located at RM 13.6, and consist of the following new facilities: (1) A 37-foot-long, 52-foot-high, 80-foot-wide intake structure with 2-inch clear bar spacing trash racks; (2) a 160-foot by 75-foot powerhouse located adjacent to the left bank of the dam; (3) two turbine-generator units providing a combined installed capacity of 5 MW; (4) a 65-foot-long, 75-foot-wide draft tube section; (5) a 40-foot by 40-foot substation; (6) a 1,200-foot-long, three-phase, overhead 69-kV transmission line to connect the project substation to the local utility distribution lines; and (7) appurtenant facilities. The average annual generation would be about 30,996 MWh.

The proposed Philo Lock and Dam Water Power Project would be located at RM 68.6, and consist of the following new facilities: (1) A 40-foot-long, 20-foot-high flap gate bay; (2) a 37-foot-long, 52-foot-high, 80-foot-wide intake structure with 2-inch clear bar spacing trash racks; (3) a 160-foot by 75-foot

powerhouse located on the bank of the Muskingum River opposite the existing lock; (4) two turbine-generator units providing a combined installed capacity of 3 MW; (5) a 65-foot-long, 80-foot-wide draft tube section; (6) a 40-foot by 40-foot substation; (7) a 1,600-foot-long, three-phase, overhead 69-kV transmission line to connect the project substation to the local utility distribution lines; and (8) appurtenant facilities. The average annual generation would be about 15,957 MWh.

The proposed Rokeby Lock and Dam Water Power Project would be located at RM 57.4, and consist of the following new facilities: (1) A 37-foot-long, 52-foot-high, 80-foot-wide intake structure with 2-inch clear bar spacing trash racks; (2) a 160-foot by 75-foot powerhouse located on the bank of the Muskingum River opposite the existing lock; (3) two turbine-generator units providing a combined installed capacity of 4 MW; (4) a 65-foot-long, 75-foot-wide draft tube section; (5) a 40-foot by 40-foot substation; (6) a 490-foot-long, three-phase, overhead 69-kV transmission line to connect the project substation to the local utility distribution lines; and (7) appurtenant facilities. The average annual generation would be about 17,182 MWh.

The proposed Zanesville Lock and Dam Water Power Project would be located at RM 77.4, and consist of the following new facilities: (1) A 135-foot-long, 16-foot-high, 30-foot-wide intake structure with 2-inch clear bar spacing trash racks; (2) two 10-foot diameter, 62-foot-long buried steel penstocks; (3) a 45-foot by 37-foot powerhouse located approximately 2,750 feet downstream of the dam; (4) two turbine-generator units providing a combined installed capacity of 2 MW; (5) a 31-foot-long, 37-foot-wide draft tube; (6) a 40-foot by 40-foot substation; (7) a 400-foot-long, three-phase, overhead 69-kV transmission line to connect the project substation to the local utility distribution lines; and (8) appurtenant facilities. The average annual generation would be about 12,295 MWh.

The applicant proposes to operate all seven projects in a run-of-river mode, such that the water surface elevations within each project impoundment would be maintained at the crest of each respective dam spillway.

o. A copy of the applications are available for review at the Commission in the Public Reference Room or may 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, contact FERC Online Support. Copies are also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. Procedural schedule: The applications will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Issue Notice of Acceptance	January 2013.
Issue Scoping Document 1 for comments.	February 2013.
Comments on Scoping Document 1.	April 2013.
Issue Scoping Document 2	April 2013.
Issue notice of ready for environmental analysis.	July 2013.
Commission staff issues EA.	January 2014.
Comments due on EA	February 2014.

Final amendments to the applications must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: November 9, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27961 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1821–003.
Applicants: Goshen Phase II LLC.
Description: Notification of Non-Material Change in Status of Goshen Phase II LLC.
Filed Date: 11/7/12.
Accession Number: 20121107–5061.
Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER10–2331–012; ER10–2343–012; ER10–2319–011; ER10–2320–0011; ER10–2317–010; ER10–2322–012; ER10–2324–011; ER10–2325–010; ER10–2332–011; ER10–2326–012; ER10–2327–013; ER10–2328–011; ER11–4609–010; ER10–2330–012.
Applicants: J.P. Morgan Ventures Energy Corporation, J.P. Morgan Commodities Canada Corporation, BE Alabama LLC, BE Allegheny LLC, BE CA LLC, BE Ironwood LLC, BE KJ LLC, BE Louisiana LLC, BE Rayle LLC, Cedar Brakes I, L.L.C., Cedar Brakes II, L.L.C., Central Power & Lime LLC, Triton Power Michigan LLC, Utility Contract Funding, L.L.C.
Description: JPMorgan Sellers' Notice of Non-Material Change in Status re: Minonk.
Filed Date: 11/7/12.
Accession Number: 20121107–5079.
Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER10–2460–001; ER10–2461–001; ER12–682–002; ER10–2463–001; ER11–2201–005; ER12–1311–001; ER10–2466–002; ER11–4029–001.
Applicants: Evergreen Wind Power, LLC, Canandaigua Power Partners, LLC, Evergreen Wind Power V, LLC, Evergreen Wind Power III, LLC, Stetson Wind II, LLC, Vermont Wind, LLC, Stetson Holdings, LLC, Erie Wind, LLC, Canandaigua Power Partners II, LLC.
Description: Supplement to Notice of Change in Status of Canandaigua Power Partners LLC, *et al.*
Filed Date: 10/15/12.
Accession Number: 20121015–5168.
Comments Due: 5 p.m. ET 11/19/12.

Docket Numbers: ER10–2460–003; ER10–2461–003; ER12–682–004; ER10–2463–003; ER11–2201–007; ER12–1311–003; ER10–2466–004; ER11–4029–003.
Applicants: Canandaigua Power Partners, LLC, Canandaigua Power Partners II, LLC, Erie Wind, LLC, Evergreen Wind Power, LLC, Evergreen Wind Power III, LLC, Stetson Holdings, LLC, Stetson Wind II, LLC, Vermont Wind, LLC.
Description: Notice of Change in Status of Canandaigua Power Partners, LLC, *et al.*
Filed Date: 11/7/12.
Accession Number: 20121107–5082.
Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER12–162–005; ER11–3876–007; ER11–2044–008; ER10–2611–005.
Applicants: Bishop Hill Energy II LLC, Cordova Energy Company LLC, MidAmerican Energy Company, Saranac Power Partners, L.P.
Description: Notice of Change in Status of Bishop Hill Energy II LLC, *et al.*
Filed Date: 11/7/12.
Accession Number: 20121107–5081.
Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER12–2145–002; ER10–2834–002; ER11–2905–001; ER11–2904–001; ER10–2821–002.
Applicants: Munnsville Wind Farm, LLC, Pioneer Trail Wind Farm, LLC, Settlers Trail Wind Farm, LLC, Stony Creek Wind Farm, LLC, EC&R O&M, LLC.

Description: EC&R O&M, LLC, *et al.* submits Notice of Change in Status.

Filed Date: 11/6/12.

Accession Number: 20121106–5171.

Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–321–001.

Applicants: Fairless Energy, LLC.

Description: Fairless Energy, LLC submits tariff filing per 35: Amended Baseline Single Market-Based Rate Tariff to be effective 11/8/2012.

Filed Date: 11/7/12.

Accession Number: 20121107–5044.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER13–336–000.

Applicants: PJM Interconnection, L.L.C.

Description: Original Service Agreement No. 3416; Queue No. X2–085 to be effective 10/24/2012.

Filed Date: 11/7/12.

Accession Number: 20121107–5033.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER13–337–000.

Applicants: Florida Power Corporation.

Description: Florida Power Corporation submits Notice of Cancellation of Rate Schedule No. 207, Power Sales Agreement with Gainesville Regional Utilities.

Filed Date: 11/7/12.

Accession Number: 20121107–5076.

Comments Due: 5 p.m. ET 11/28/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR § 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 7, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27893 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP13–260–000.

Applicants: High Point Gas Transmission, LLC.

Description: High Point Gas Transmission, LLC submits tariff filing per 154.203: NAESB Compliance Filing to be effective 12/1/2012.

Filed Date: 11/5/12.

Accession Number: 20121105–5104.

Comments Due: 5 p.m. ET 11/19/12.

Docket Numbers: RP13–261–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Algonquin Gas Transmission, LLC submits tariff filing per 154.204: Con Ed Releases November 2012 Ramapo to be effective 11/3/2012.

Filed Date: 11/5/12.

Accession Number: 20121105–5106.

Comments Due: 5 p.m. ET 11/19/12.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR § 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP13–172–001.

Applicants: Questar Southern Trails Pipeline Company.

Description: Questar Southern Trails Pipeline Company submits tariff filing per 154.205(b): Section 35, Segmentation of Capacity, Amended to be effective 12/1/2012.

Filed Date: 11/5/12.

Accession Number: 20121105–5128.

Comments Due: 5 p.m. ET 11/19/12.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR § 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 6, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27891 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP13–262–000.

Applicants: Rockies Express Pipeline LLC.

Description: NAESB 2.0 Compliance to be effective 12/1/2012.

Filed Date: 11/7/12.

Accession Number: 20121107–5051.

Comments Due: 5 p.m. ET 11/19/12.

Docket Numbers: RP13–263–000.

Applicants: Questar Southern Trails Pipeline Company.

Description: Order 587–V revised section 28 to be effective 12/1/2012.

Filed Date: 11/7/12.

Accession Number: 20121107–5084.

Comments Due: 5 p.m. ET 11/19/12.

Docket Numbers: RP13–265–000.

Applicants: Gulf South Pipeline Company, LP.

Description: Revise Destin Fuel Rate Reference filing to be effective 12/1/2012.

Filed Date: 11/8/12.

Accession Number: 20121108–5019.

Comments Due: 5 p.m. ET 11/20/12.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP13–102–002.

Applicants: Northwest Pipeline GP.

Description: NWP NAESB 2.0 Compliance Filing—Second Substitute Sheet to be effective 12/1/2012.

Filed Date: 11/6/12.

Accession Number: 20121106–5132.

Comments Due: 5 p.m. ET 11/14/12.

Docket Numbers: RP13–169–001.

Applicants: El Paso Natural Gas Company, L.L.C.
Description: Non-Conforming Agreement Amendment to be effective 10/25/2012.
Filed Date: 11/6/12.
Accession Number: 20121106–5066.
Comments Due: 5 p.m. ET 11/19/12.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR § 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 8, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27890 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC13–33–000.
Applicants: Mesquite Power, LLC.
Description: Section 203 Application for Authorization of Transfer of Jurisdictional Assets of Mesquite Power, LLC.
Filed Date: 11/6/12.
Accession Number: 20121106–5169.
Comments Due: 5 p.m. ET 11/27/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2431–002; ER10–2434–002; ER10–2467–002; ER11–3731–002; ER10–2436–002.
Applicants: Wapsipinicon Wind Project, LLC, Hoosier Wind Project, LLC, Chanarambie Power Partners, LLC, Fenton Power Partners I, LLC, LWP Lessee, LLC.
Description: Supplement to Triennial Market Power Analysis Update of enXco Central Region Companies.
Filed Date: 08/17/2012.
Accession Number: 20120817–5172.
Comments Due: 5 p.m. ET 11/19/12.

Docket Numbers: ER10–2985–003; ER10–3049–004; ER10–3051–004.
Applicants: Champion Energy Marketing LLC, Champion Energy Services, LLC, Champion Energy, LLC.
Description: Supplement to Updated Market Power Analysis for the Central Region of Champion Energy Marketing LLC, *et al.*
Filed Date: 8/22/12.
Accession Number: 20120822–5118.
Comments Due: 5 p.m. ET 11/19/12.

Docket Numbers: ER11–4633–001.
Applicants: Madison Gas and Electric Company.
Description: Madison Gas and Electric Company submits an Updated Market Power Analysis.
Filed Date: 11/2/12.
Accession Number: 20121106–0203.
Comments Due: 5 p.m. ET 11/23/12.

Docket Numbers: ER12–2695–002.
Applicants: Public Service Company of Colorado.
Description: Public Service Company of Colorado submits tariff filing per 35.17(b): 2012_11_06 PSCo MBR Filing to be effective 1/6/2013.
Filed Date: 11/6/12.
Accession Number: 20121106–5134.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–41–000.
Applicants: Dynasty Power Inc.
Description: Dynasty Power Inc. submits Supplement to Notice of Change in Status.
Filed Date: 11/6/12.
Accession Number: 20121106–5137.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–322–000.
Applicants: PJM Interconnection, L.L.C.
Description: Queue Position W4–025; Original Service Agreement No. 3429 to be effective 10/17/2012.
Filed Date: 11/6/12.
Accession Number: 20121106–5080.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–323–000.
Applicants: New England Power Pool Participants Committee, ISO New England Inc.
Description: New England Power Pool Participants Committee submits tariff filing per 35.13(a)(2)(ii: MR1 Revisions Rel. to Auditing of Gener. Resources to be effective 12/31/9998.
Filed Date: 11/6/12.
Accession Number: 20121106–5091.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–324–000.
Applicants: Entergy Arkansas, Inc.
Description: Entergy Arkansas, Inc. submits tariff filing per 35: EAI Compliance Filing in ER10–1676 to be effective 4/29/2011.
Filed Date: 11/6/12.
Accession Number: 20121106–5094.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–325–000.
Applicants: Entergy Gulf States Louisiana, L.L.C.
Description: Entergy Gulf States Louisiana, L.L.C. submits tariff filing per 35: EGSL Compliance Filing Docket No. ER10–1676 to be effective 4/29/2011.
Filed Date: 11/6/12.
Accession Number: 20121106–5098.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–326–000.
Applicants: Entergy Louisiana, LLC.
Description: Entergy Louisiana, LLC submits tariff filing per 35: ELL Compliance Filing Docket No. ER10–1676 to be effective 4/29/2011.
Filed Date: 11/6/12.
Accession Number: 20121106–5101.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–327–000.
Applicants: Porter-Walker LLC.
Description: Porter-Walker LLC submits tariff filing per 35.12: FERC Electric Tariff, Volume No. 1 to be effective 11/6/2012.
Filed Date: 11/6/12.
Accession Number: 20121106–5105.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–328–000.
Applicants: Entergy Mississippi, Inc.
Description: Entergy Mississippi, Inc. submits tariff filing per 35: EMI Compliance Filing Docket No. ER10–1676 to be effective 4/29/2011.
Filed Date: 11/6/12.
Accession Number: 20121106–5106.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–329–000.
Applicants: Entergy New Orleans, Inc.
Description: Entergy New Orleans, Inc. submits tariff filing per 35: ENOI Compliance Filing Docket No. ER10–1676 to be effective 4/29/2011.
Filed Date: 11/6/12.
Accession Number: 20121106–5107.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–330–000.
Applicants: Entergy Texas, Inc.
Description: Entergy Texas, Inc. submits tariff filing per 35: ETI Compliance Filing Docket No. ER10–1676 to be effective 4/29/2011.
Filed Date: 11/6/12.
Accession Number: 20121106–5109.
Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–331–000.
Applicants: Nevada Power Company.
Description: Nevada Power Company submits tariff filing per 35: Rate Schedule No. 30 Amended & Restated Transmission Facilities Agmt-PacifiCorp to be effective 6/20/2011.
Filed Date: 11/6/12.
Accession Number: 20121106–5118.

Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–332–000.

Applicants: DeSoto County Generating Company, LLC.

Description: DeSoto County Generating Company, LLC submits tariff filing per 35.13(a)(2)(iii: Rate Schedule FERC No. 1 to be effective 1/1/2013.

Filed Date: 11/6/12.

Accession Number: 20121106–5133.

Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–333–000.

Applicants: PacifiCorp.

Description: PacifiCorp submits tariff filing per 35: Nevada Power Transmission Facilities Agreement Compliance Filing to be effective 6/20/2011.

Filed Date: 11/7/12.

Accession Number: 20121107–5000.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER13–334–000.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: ISO New England Inc. and New England Power Pool Participants Committee submit Installed Capacity Requirement, Hydro Quebec Interconnection Capability Credits and Related Values for the 2016/2017 Capability Year.

Filed Date: 11/6/12.

Accession Number: 20121106–5165.

Comments Due: 5 p.m. ET 11/27/12.

Docket Numbers: ER13–335–000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. submits 7th Forward Capacity Auction Informational Filing.

Filed Date: 11/6/12.

Accession Number: 20121106–5167.

Comments Due: 5 p.m. ET 11/21/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR § 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 7, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27892 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG13–9–000.

Applicants: Shiloh IV Lessee, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Shiloh IV Lessee, LLC.

Filed Date: 11/7/12.

Accession Number: 20121107–5107.

Comments Due: 5 p.m. ET 11/28/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4267–003; ER11–4270–003; ER11–4269–004; ER11–4268–003; ER11–113–004; ER10–2682–003; ER12–1680–001.

Applicants: Algonquin Energy Services Inc., Algonquin Power Windsor Locks LLC, Algonquin Tinker Gen Co., Algonquin Northern Maine Gen Co., Sandy Ridge Wind, LLC, Granite State Electric Company, Minonk Wind, LLC.

Description: Notice of Change in Status of Algonquin Energy Services Inc., *et al.*

Filed Date: 11/7/12.

Accession Number: 20121107–5137.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER12–2654–002.

Applicants: Netsales & Arts, Inc.

Description: mbr_tar to be effective 9/30/2012.

Filed Date: 11/7/12.

Accession Number: 20121107–5118.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER13–214–001.

Applicants: Middletown Cogeneration Company LLC.

Description: Middletown Cogen Supplemental Tariff to be effective 12/1/2012.

Filed Date: 11/7/12.

Accession Number: 20121107–5126.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER13–215–001.

Applicants: Haverhill Cogeneration Company LLC.

Description: Haverhill Cogen Supplemental Filing to be effective 12/1/2012.

Filed Date: 11/7/12.

Accession Number: 20121107–5125.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER13–338–000.

Applicants: Shiloh IV Lessee, LLC.

Description: Shiloh IV Lessee MBR Application Filing to be effective 12/15/2012.

Filed Date: 11/7/12.

Accession Number: 20121107–5099.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER13–339–000.

Applicants: Entergy Arkansas, Inc.

Description: Service Agreement 670 to be effective 1/1/2013.

Filed Date: 11/7/12.

Accession Number: 20121107–5101.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER13–340–000.

Applicants: PacifiCorp.

Description: Construction Agreement to Move Chehalis into PacifiCorp's BA to be effective 11/8/2012.

Filed Date: 11/7/12.

Accession Number: 20121107–5122.

Comments Due: 5 p.m. ET 11/28/12.

Docket Numbers: ER13–341–000.

Applicants: Southwest Power Pool, Inc.

Description: Energy Imbalance Market Offer Cap Update—2013 to be effective 1/1/2013.

Filed Date: 11/7/12.

Accession Number: 20121107–5123.

Comments Due: 5 p.m. ET 11/28/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 8, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27894 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP13–3–000]

Tennessee Gas Pipeline Company, L.L.C.; Notice of Intent To Prepare an Environmental Assessment for the Proposed Rose Lake Expansion Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Rose Lake Expansion Project involving the modification of compression facilities by Tennessee Gas Pipeline Company, L.L.C. (TGP) in Bradford and Tioga Counties, Pennsylvania. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Please note that the scoping period will close on December 10, 2012.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

TGP provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?''. This fact sheet addresses a number of typically-asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*www.ferc.gov*).

Summary of the Proposed Project

TGP proposes to construct, abandon, and replace certain compression facilities at three existing compressor stations on its 300 Line in northeastern Pennsylvania. The proposed Rose Lake Expansion Project includes the following:

- Installation of a new 12,630 horsepower (hp) compressor unit, ancillary equipment, and station piping modifications at Station 315 in Tioga County, Pennsylvania;
- Abandonment in place of two 4,500 hp compressor units and replacing these with the installation of a new 12,661 hp compressor unit, ancillary equipment, and station piping modifications at Station 319 in Bradford County, Pennsylvania; and
- Abandonment by removal of an existing gear box and compressor unit and replacement with a new gear box and compressor unit, ancillary equipment, and station piping modifications at Station 317 in Bradford County, Pennsylvania.

Construction of the project would disturb about 70 acres of land, of which approximately 5.4 acres would be permanently impacted. All land disturbance would occur on land owned by TGP adjacent to its existing facilities. The general location of the project facilities is shown in appendix 1.[1]

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- Land use;
- Water resources, fisheries, and wetlands;
- Cultural resources;
- Vegetation and wildlife;
- Air quality and noise;
- Endangered and threatened species; and
- Public safety.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section beginning on page 4.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the Pennsylvania State Historic Preservation Office (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, § 1501.6.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register for Historic Places.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before December 10, 2012.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the project docket number (CP13–3–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You can file your comments electronically using the eComment feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the eFiling feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are current right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''e-filing'' link on the Commission's Web site.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site at *www.ferc.gov* using the ''eLibrary'' link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (i.e., CP13–3). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/esubscribenow.htm.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: November 9, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27958 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13239–002]

Parker Knoll Hydro, LLC; Notice of Intent To Prepare An Environmental Impact Statement and Notice of Scoping Meetings and Soliciting Scoping Comments

Take notice that the following hydroelectric applications have been filed with Commission and are available for public inspection:

a. *Type of Application:* New Major License.

b. *Project No.:* 13239.

c. *Date filed:* November 30, 2011.

d. *Applicant:* Parker Knoll Hydro, LLC.

e. *Name of Project:* Parker Knoll Pumped Storage Hydroelectric Project.

f. *Location:* At Parker Mountain, near the Town of Richfield, Piute County, Utah. The project would occupy 458.7 acres of federal land administered by the U.S. Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Justin Barker, Parker Knoll Hydro, LLC., 975 South State Highway, Logan, UT 84321; (435) 752–2580.

i. *FERC Contact:* Matt Buhyoff, *matt.buhyoff@ferc.gov,* (202) 502–6824.

j. *Deadline for filing scoping comments:* January 10, 2013.

All documents 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 at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. 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.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener 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.

k. This application is not ready for environmental analysis at this time.

l. The proposed project would be a closed-loop pumped storage system, with an initial fill from the existing Otter Creek reservoir. Parker Knoll would include the following new facilities: (1) An approximately 175-feet-high upper main dam with a crest length of approximately 1,650 feet and one saddle dam; (2) an upper reservoir with a storage capacity of approximately 6,780 acre-feet and a surface area of approximately 110 acres; (3) an approximately 100-feet-high lower dam with a crest length of approximately 1,750 feet and two saddle dams; (4) a lower reservoir with storage capacity of approximately 6,760 acre-feet and a surface area of approximately 130 acres; (5) a 2,390-feet-long and 27-feet-diameter headrace tunnel; (6) a 2,200-feet-long and 27-feet-diameter vertical shaft; (7) a 1,000-feet-long and 27-feet-diameter steel-lined penstock tunnel; (8) a 7,126-feet-long and 35-feet-diameter tailrace tunnel; (9) a powerhouse containing four variable speed, reversible pump-turbine units with a minimum rating of 250 megawatt (MW); (10) an approximately 585-feet by 340-feet substation; (11) a 16-inch diameter and 68,000-feet-long fill pipeline and system; (12) approximately one mile of 345-kV transmission line; and (13) appurtenant facilities. The project would occupy 458.7 acres of federal land and would have an estimated annual generation of 2,630 gigawatt hours.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may 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, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Scoping Process:* The Commission intends to prepare an Environmental Impact Statement (EIS) on the project in accordance with the National Environmental Policy Act. The EIS will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

Scoping Meetings

FERC staff will conduct one agency scoping meeting and one public meeting. The agency scoping meeting will focus on resource agency and non-governmental organization (NGO) concerns, while the public scoping meeting is primarily for public input. All interested individuals, organizations, and agencies are invited to attend one or both of the meetings, and to assist the staff in identifying the scope of the environmental issues that should be analyzed in the EIS. The times and locations of these meetings are as follows:

Agency Scoping Meeting

Date: December 11, 2012.
Time: 10:00 a.m. (MST).
Place: Holiday Inn Express.
Address: 20 West 1400 North, Richfield, Utah.

Public Scoping Meeting

Date: December 11, 2012.
Time: 6:00 p.m. (MST).
Place: Holiday Inn Express.
Address: 20 West 1400 North, Richfield, Utah.

Copies of the Scoping Document (SD1) outlining the subject areas to be addressed in the EIS were distributed to the parties on the Commission's mailing list. Copies of the SD1 will be available at the scoping meeting or may be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link (see item m above).

Objectives

At the scoping meetings, the staff will: (1) Summarize the environmental issues tentatively identified for analysis in the EIS; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue; (3) encourage statements from experts and the public on issues that should be analyzed in the EIS, including viewpoints in opposition to, or in support of, the staff's preliminary views; (4) determine the resource issues to be addressed in the EIS; and (5) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis.

Procedures

The meetings are recorded by a court reporter and become part of the formal record of the Commission proceeding on the project.

Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meeting and to assist the staff in defining and clarifying the issues to be addressed in the EIS.

Dated: November 9, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27960 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13739–002]

Lock+ Hydro Friends Fund XLII, LLC; Notice of Scoping Meetings and Environmental Site Review and Soliciting Scoping Comments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Major Original License.

b. *Project No.:* 13739–002.

c. *Date filed:* September 17, 2012.

d. *Applicant:* Lock+ Hydro Friends Fund XLII, LLC.

e. *Name of Project:* Braddock Locks and Dam Hydroelectric Project.

f. *Location:* At the existing U.S. Army Corps of Engineers' Braddock Locks and Dam on the Monongahela River, in Allegheny County, Pennsylvania. The project would occupy about 0.19 acre of federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Mark R. Stover, Lock+™ Hydro Friends Fund XLII, LLC, c/o Hydro Green Energy, LLC, 900 Oakmont Lane, Suite 310, Westmont, IL 60559; (877) 556–6566 ext. 711; email—*mark@hgenergy.com.*

i. *FERC Contact:* John Mudre at (202) 502–8902; or email at *john.mudre@ferc.gov.*

j. *Deadline for filing scoping comments:* January 4, 2013.

All documents 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 at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. 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.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on 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.

k. This application is not ready for environmental analysis at this time.

l. The proposed project would utilize the existing U.S. Army Corps of Engineers' Braddock Locks and Dam and the Braddock Pool, and would consist of the following new facilities: (1) A new powerhouse with five turbine-generators having a total installed capacity of 3,750 kilowatts; (2) a new approximately 3,450-foot-long, 23-kilovolt electric distribution line; (3) a switchyard and control room; and (4) appurtenant facilities. The average annual generation is estimated to be 25,020 megawatt-hours.

The proposed project would deploy hydropower turbines within a patented ''Large Frame Module'' (LFM) that would be deployed on the south (river left) side of the dam, opposite the location of the existing navigational locks and at the upstream face of the existing left closure weir. The proposed modular, low environmental impact powerhouse would be approximately 60.4 feet long, 16.6 feet wide, and 40 feet high, and constructed of structural-grade steel. The powerhouse will bear on a concrete foundation on rock that is anchored to the existing left closure weir. A trash rack with 6-inch openings would be placed at the powerhouse intake to increase safety and protect the turbines from large debris.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may 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, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Scoping Process

The Commission intends to prepare an Environmental Assessment (EA) on the project in accordance with the National Environmental Policy Act. The EA will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

Scoping Meetings

FERC staff will conduct one daytime scoping meeting and one evening meeting. The daytime scoping meeting will focus on resource agency and non-governmental organization (NGO) concerns, while the evening scoping meeting is primarily for public input. All interested individuals, organizations, and agencies are invited to attend one or both of the meetings, and to assist the staff in identifying the scope of the environmental issues that should be analyzed in the EA. The times and locations of these meetings are as follows:

Daytime Scoping Meeting

Date: Wednesday, December 5, 2012.
Time: 1:00 p.m.
Place: Allegheny Conference Room, 8th floor of the Brunner Building.
Address: 11 Stanwix Street, Pittsburgh, Pennsylvania.

Evening Scoping Meeting

Date: Wednesday December 5, 2012.
Time: 7:00 p.m.
Place: Doubletree Hotel.
Address: 101 Mall Blvd., Monroeville, Pennsylvania.

Copies of the Scoping Document (SD1) outlining the subject areas to be addressed in the EA are being distributed to the parties on the Commission's mailing list and the applicant's distribution list. Copies of the SD1 will be available at the scoping meeting or may be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link (see item m above).

Environmental Site Review

The Applicant and FERC staff will conduct a project Environmental Site Review beginning at 10:00 a.m. on Wednesday December 5, 2012. All interested individuals, organizations, and agencies are invited to attend. All participants should meet in the parking lot at the Great Allegheny Passage Trailhead, Pump House, 880 East Waterfront Drive, Munhall, Pennsylvania at 10:00 a.m. All participants are responsible for their own transportation to the site.

Objectives

At the scoping meetings, the staff will: (1) Summarize the environmental issues tentatively identified for analysis in the EA; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue; (3) encourage statements from experts and the public on issues that should be analyzed in the EA, including viewpoints in opposition to, or in support of, the staff's preliminary views; (4) determine the resource issues to be addressed in the EA; and (5) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis.

Procedures

The meetings are recorded by a stenographer and become part of the formal record of the Commission proceeding on the project.

Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meetings and to assist the staff in defining and clarifying the issues to be addressed in the EA.

Dated: November 5, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27959 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–342–000]

CPV Shore, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of CPV Shore, LLC's application for market-

based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is November 29, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: November 9, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27965 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–338–000]

Shiloh IV Lessee, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Shiloh IV Lessee, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is November 29, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: November 9, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27964 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–2448–000]

Chisholm View Wind Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Chisholm View Wind Project, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is November 19, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: November 9, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27963 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–343–000]

CPV Maryland, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of CPV Maryland, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is November 29, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: November 9, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27957 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM10–12–000]

Electricity Market Transparency Provisions of Section 220 of the Federal Power Act; Notice of Technical Conference

The Federal Energy Regulatory Commission staff will hold a one-day conference on Order No. 768.[1] The conference will be held on December 12, 2012, in the Commission Meeting Room at 888 First Street NE., Washington, DC 20426.

There will be a morning session and an afternoon session. The public may attend. The conference will principally address satisfying the Electric Quarterly Reports (EQRs) reporting requirements. The conference will not address the merits of issues raised on rehearing of Order No. 768. Advance registration is not required but is encouraged. Please register at *https://www.ferc.gov/whats-new/registration/eqr-12-12-12-form.asp*.

The morning session will begin at 9:00 a.m. (EST) and is intended for new EQR filers who are not currently filing EQR reports. However, anyone may attend. FERC staff will provide introductory and background information about the EQR, including data fields that existed prior to Order No. 768. These data fields include information on seller names, customer names, contract data, transaction data, product type, quantity, and rate, among others.

The afternoon session will begin at 1:00 p.m. (EST). This session is intended for all EQR filers, including new filers, and will focus on refinements to the existing filing requirements as set forth in Order No. 768, including the new data fields. The requirements for these data fields will include (1) reporting the trade date and type of rate; (2) identifying the exchange used for a sales transaction, if applicable; (3) reporting whether a broker was used to consummate a transaction; (4) reporting electronic tag ID data; and (5) reporting standardized prices and quantities for energy, capacity, and booked out power transactions, among others.

A free webcast of the conference will be available through *www.ferc.gov*. Anyone with Internet access interested in viewing this conference can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The event will contain a link to the webcast. Capitol Connection provides technical support for the webcasts and offers the option of listening to the conferences via phone-bridge for a fee. If you need technical support, please visit *www.CapitolConnections.org* or call (703) 993–3100.

Commission staff encourages participants to email questions in advance to *eqr@ferc.gov*. When emailing questions, please include ''EQR Conference'' in the subject line.

The conference will be transcribed and the transcript placed in the record in Docket No. RM 10–12.

FERC conferences and meetings are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or 202–502–8659 (TTY), or send a fax to 202–208–2106 with the required accommodations.

For more information on this conference, please contact Sarah McKinley at *sarah.mckinley@ferc.gov* or (202) 502–8004 or Connie Caldwell at

[1] *Electricity Market Transparency Provisions of Section 220 of the Federal Power Act,* Order No. 768, 77 FR 61896 (Oct. 11, 2012), FERC Stats. & Regs. ¶ 31,336 (2012). The Office of Management and Budget (OMB) has yet to act upon the information collection requirements adopted in Order No. 768.

connie.caldwell@ferc.gov or (202) 502–6055.

Dated: November 9, 2012.

Kimberly D. Bose,

Secretary.

Agenda for the EQR Conference

RM10–12–000

(December 12, 2012)

9:00 a.m.–9:15 a.m. Greeting and Opening Remarks
9:15 a.m.–12:00 p.m. Presentation on EQR, including Pre-Order No. 768 Data Fields
12:00 p.m.–1:00 p.m. Break
1:00 p.m.–4:30 p.m. Presentation on Order No. 768, including New Data Fields
4:30 p.m.–4:45 p.m. Closing Remarks

[FR Doc. 2012–27962 Filed 11–15–12; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2003–0004; FRL–9367–8]

Access to Confidential Business Information by Abt Associates, Inc.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has authorized its contractor, Abt Associates, Inc. (Abt) of Cambridge, MA, to access information which has been submitted to EPA under section 8 of the Toxic Substances Control Act (TSCA). Some of the information may be claimed or determined to be Confidential Business Information (CBI).

DATES: Access to the confidential data occurred on or about October 11, 2012.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Timothy Kiely, Office of Chemical Safety & Pollution Prevention, Office of Pesticide Programs (7503P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8112; fax number: (703) 308–8189; email address: *kiely.timothy@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to me?

This action is directed to the public in general. This action may, however, be of interest to all who manufacture, process, or distribute industrial chemicals. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2003–0004. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

II. What action is the agency taking?

Under EPA Contract Number EP–W–12–001, contractor Abt of 55 Wheeler Street, Cambridge, MA is assisting the EPA in developing public information products for the 2012 Chemical Data Reporting (CDR) data. These products shall include individual fact sheets; a natural report with various descriptions of the data resulting from data queries and associated program analyses; trend analysis and other items.

In accordance with 40 CFR 2.306(j), EPA has determined that under EPA Contract Number EP–W–12–001, Abt requires access to CBI submitted to EPA under section 8 of TSCA to perform successfully the duties specified under the contract. Abt's personnel were given access to information submitted to EPA under section 8 of TSCA. Some of the information may be claimed or determined to be CBI.

EPA is issuing this notice to inform all submitters of information under section 8 of TSCA that EPA is providing Abt access to these CBI materials on a need-to-know basis only. All access to TSCA CBI under this contract will take place at EPA Headquarters and Abt's Bethesda, MD and Cambridge, MA sites, in accordance with EPA's *TSCA CBI Protection Manual.*

Access to TSCA data, including CBI, will continue until November 30, 2016. If the contract is extended, this access will also continue for the duration of the extended contract without further notice.

Abt's personnel were required to sign nondisclosure agreements and were briefed on appropriate security procedures before they were permitted access to TSCA CBI.

List of Subjects

Environmental protection, Confidential business information.

Dated: October 24, 2012.

Matthew G. Leopard,

Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2012–27861 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2003–0004; FRL–9365–8]

Access to Confidential Business Information by Eastern Research Group

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has authorized its contractor, Eastern Research Group (ERG) of Chantilly, VA, to access information which has been submitted to EPA under all sections of the Toxic Substances Control Act (TSCA). Some of the information may be claimed or determined to be Confidential Business Information (CBI).

DATES: Access to the confidential data occurred on or about September 26, 2012.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Leigh DeHaven, Office of Research and Development (8104R), Office of Science Policy, Environmental Protection Agency, 1200 Pennsylvania Ave. NW.,

Washington, DC 20460–0001; telephone number: (202) 564–1974; fax number: (202) 565–2911; email address: *dehaven.leigh@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to me?

This action is directed to the public in general. This action may, however, be of interest to all who manufacture, process, or distribute industrial chemicals. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2003–0004. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

II. What action is the agency taking?

Under EPA Contract Number EP–C–12–021, contractor ERG of 14555 Avion Parkway, Suite 200, Chantilly, VA, will assist the EPA in data analysis of data and reports provided by industry on hydraulic fracturing. The work includes preparation of technical analysis and technical information; and report preparation.

In accordance with 40 CFR 2.306(j), EPA has determined that under EPA Contract Number EP–C–12–021, ERG will require access to CBI submitted to EPA under all sections of TSCA to perform successfully the duties specified under the contract. ERG's personnel will be given access to information submitted to EPA under all sections of TSCA. Some of the information may be claimed or determined to be CBI.

EPA is issuing this notice to inform all submitters of information under all sections of TSCA that EPA may provide ERG access to these CBI materials on a need-to-know basis only. All access to TSCA CBI under this contract will take place at EPA Headquarters and ERG's Chantilly, VA site, in accordance with EPA's *TSCA CBI Protection Manual.* Notice was also sent to each affected company by email on September 18, 2012, and receipt of this email has been confirmed by representatives of each company.

Access to TSCA data, including CBI, will continue until September 26, 2017. If the contract is extended, this access will also continue for the duration of the extended contract without further notice.

ERG's personnel will be required to sign nondisclosure agreements and will be briefed on appropriate security procedures before they are permitted access to TSCA CBI.

List of Subjects

Environmental protection, Confidential business information.

Dated: October 24, 2012.

Matthew G. Leopard,

Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2012–27854 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL9752–3]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Vermont

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of Vermont's request to revise/modify certain of its EPA-authorized programs to allow electronic reporting.

DATES: EPA's approval is effective December 17, 2012 for the State of Vermont's National Primary Drinking Water Regulations Implementation program if no timely request for a public hearing is received and accepted by the Agency; and on November 16, 2012 for the State of Vermont's other authorized programs.

FOR FURTHER INFORMATION CONTACT: Evi Huffer, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 566–1697, *huffer.evi@epa.gov,* or Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribal, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribal or local

government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribal or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On December 5, 2011, the Vermont Department of Environmental Conservation (VT DEC) submitted an application titled ''Online Report Submittal System Electronic Document Receiving System'' for revisions/modifications of its EPA-authorized programs under title 40 CFR. EPA reviewed VT DEC's request to revise/modify its EPA-authorized programs and, based on this review, EPA determined that the application met the standards for approval of authorized program revisions/modifications set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Vermont's request to revise/modify its following EPA-authorized programs to allow electronic reporting under 40 CFR parts 51, 60–63, 70, 141, 144–148, 262–265, 266, 268, 270–271, and 403 is being published in the **Federal Register**:

Part 52—Approval and Promulgation of Implementation Plans;

Part 61—National Emission Standards for Hazardous Air Pollutants;

Part 62—Approval and Promulgation of State Plans for Designated Facilities and Pollutants;

Part 63—National Emission Standards for Hazardous Air Pollutants for Source Categories;

Part 70—State Operating Permit Programs;

Part 142—National Primary Drinking Water Regulations Implementation;

Part 147—State Underground Injection Control Programs;

Part 272—Approved State Hazardous Waste Management Programs; and

Part 403—General Pretreatment Regulations for Existing and New Sources of Pollution.

VT DEC was notified of EPA's determination to approve its application with respect to the authorized program listed above.

Also, in today's notice, EPA is informing interested persons that they may request a public hearing on EPA's action to approve the State of Vermont's request to revise its authorized public water system program under 40 CFR part 142, in accordance with 40 CFR 3.1000(f). Requests for a hearing must be submitted to EPA within 30 days of publication of today's **Federal Register** notice. Such requests should include the following information:

(1) The name, address and telephone number of the individual, organization or other entity requesting a hearing;

(2) A brief statement of the requesting person's interest in EPA's determination, a brief explanation as to why EPA should hold a hearing, and any other information that the requesting person wants EPA to consider when determining whether to grant the request; and

(3) The signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

In the event a hearing is requested and granted, EPA will provide notice of the hearing in the **Federal Register** not less than 15 days prior to the scheduled hearing date. Frivolous or insubstantial requests for hearing may be denied by EPA. Following such a public hearing, EPA will review the record of the hearing and issue an order either affirming today's determination or rescinding such determination. If no timely request for a hearing is received and granted, EPA's approval of the State of Vermont's request to revise its Part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting will become effective 30 days after today's notice is published, pursuant to CROMERR section 3.1000(f)(4).

Dated: November 6, 2012.

Andrew Battin,

Director, Office of Information Collection.

[FR Doc. 2012–27972 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9006–1]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 11/05/2012 Through 11/09/2012

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

SUPPLEMENTARY INFORMATION: As of October 1, 2012, EPA will not accept paper copies or CDs of EISs for filing purposes; all submissions on or after October 1, 2012 must be made through e-NEPA.

While this system eliminates the need to submit paper or CD copies to EPA to meet filing requirements, electronic submission does not change requirements for distribution of EISs for public review and comment. To begin using e-NEPA, you must first register with EPA's electronic reporting site—*https://cdx.epa.gov/epa_home.asp*

EIS No. 20120361, Final EIS, BR, UT, Narrows Project, Development of a Supplemental Water Supply for Agricultural and Municipal Water Use, Sanpete County, UT, Review Period Ends: 12/17/2012, Contact: Peter Crookston 801–379–1152.

EIS No. 20120362, Draft EIS, BLM, CA, Casa Diablo IV Geothermal Development Project, Mono County, CA, Comment Period Ends: 01/15/2013, Contact: Collin Reinhardt 760–872–5024.

EIS No. 20120364, Draft EIS, BLM, WY, Gas Hills In-Situ Recovery Uranium Project, Fremont and Natrona Counties, WY, Comment Period Ends: 12/31/2012, Contact: Kristin Yannone 307–332–8400.

EIS No. 20120365, Final EIS, USACE, CA, Pier S Marine Terminal Development and Back Channel Improvements, Los Angeles County, CA, Review Period Ends: 12/17/2012, Contact: John W. Markham 805–585–2150.

Dated: November 13, 2012.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2012–27979 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2012–0873; FRL–9369–6]

Pesticide Program Dialogue Committee; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Environmental Protection Agency's (EPA's) Office of Pesticide Programs is

giving notice that a public meeting of the Pesticide Program Dialogue Committee (PPDC) is scheduled for November 29–30, 2012. A draft agenda is under development and will be posted by November 16, 2012. Three PPDC workgroup meetings are scheduled to meet on November 28, 2012, as follows: PPDC Work Group on Integrated Pest Management; PPDC Work Group on Comparative Safety Statements; and PPDC Work Group on Pollinator Protection. The PPDC Work Group on 21st Century Toxicology/Integrated Testing Strategies will meet on November 29, 2012. All meetings are free, open to the public, and no advance registration is required.

DATES: The PPDC meeting will be held on Thursday, November 29, 2012, from 9 a.m. to 5 p.m., and Friday, November 30, 2012, from 9 a.m. to noon. On Wednesday, November 28, 2012, PPDC work group meetings are scheduled as follows: Integrated Pest Management from 1 p.m. to 4 p.m.; Comparative Safety Statements from 1 p.m. to 4 p.m.; and Pollinator Protection from 1 p.m. to 4 p.m.; and on Thursday, November 29, 2012, the PPDC Work Group on 21st Century Toxicology/Integrated Testing Strategies will meet from noon to 1:15 p.m. in N–4850–70 Potomac Yards North. Information regarding PPDC Work Groups is available on EPA's Web site at *http://www.epa.gov/pesticides/ppdc/*.

To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATON CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

ADDRESSES: The PPDC and Work Group meetings will be held at EPA's location at 1 Potomac Yard South, 2777 S. Crystal Drive, Arlington, VA. The PPDC meeting will be held in the lobby-level Conference Center. The PPDC Work Group on Pollinator Protection will meet on November 28, 2012, in the lobby-level Conference Center. The PPDC Work Group on Integrated Pest Management will meet on November 28, 2012, in room S–4850–70 Potomac Yards South. The PPDC Work Group on Comparative Safety Statements will meet on November 28, 2012, in S–4370–80 Potomac Yards South. On November 29, 2012, the PPDC Work Group on 21st Century Toxicology/Integrated Testing Strategies will meet in N–4850–70 Potomac Yards North. EPA's Potomac Yard South building is approximately one mile from the Crystal City Metro Station.

FOR FURTHER INFORMATION CONTACT: Margie Fehrenbach, Office of Pesticide Programs (7501P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–4775; fax number: (703) 308–4776; email address: *fehrenbach.margie@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of particular interest to persons who work in agricultural settings or persons who are concerned about implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food, Drug, and Cosmetic Act (FFDCA); and the amendments to both of these major pesticide laws by the Food Quality Protection Act (FQPA) of 1996; and the Pesticide Registration Improvement Act. Potentially affected entities may include, but are not limited to: Agricultural workers and farmers; pesticide industry and trade associations; environmental, consumer, and farm worker groups; pesticide users and growers; animal rights groups; pest consultants; State, local, and tribal governments; academia; public health organizations; and the public. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0873, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The 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 Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

II. Background

The Office of Pesticide Programs (OPP) is entrusted with the responsibility to help ensure the safety of the American food supply, the education and protection from unreasonable risk of those who apply or are exposed to pesticides occupationally or through use of products, and general protection of the environment and special ecosystems from potential risks posed by pesticides.

The Charter for EPA's PPDC was established under the Federal Advisory Committee Act (FACA), Public Law 92–463, in September 1995, and has been renewed every 2 years since that time. PPDC's Charter was renewed October 28, 2011, for another 2-year period. The purpose of PPDC is to provide advice and recommendations to the EPA Administrator on issues associated with pesticide regulatory development and reform initiatives, evolving public policy and program implementation issues, and science issues associated with evaluating and reducing risks from use of pesticides. It is determined that PPDC is in the public interest in connection with the performance of duties imposed on the Agency by law. The following sectors are represented on the current PPDC: Environmental/public interest and animal rights groups; farm worker organizations; pesticide industry and trade associations; pesticide user, grower, and commodity groups; Federal and State/local/tribal governments; the general public; academia; and public health organizations.

Copies of the PPDC Charter are filed with appropriate committees of Congress and the Library of Congress and are available upon request.

III. How can I request to participate in this meeting?

PPDC meetings are open to the public and seating is available on a first-come basis. Persons interested in attending do not need to register in advance of the meeting. Comments may be made during the public comment session of each meeting or in writing to the address listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Agricultural workers, Agriculture, Chemicals, Endangered species, Foods, Integrated pest management, Pesticide labels, Pesticides and pests, Public health, Spray drift, 21st Century toxicology.

Dated: November 9, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2012–27975 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2012–0818; FRL–9367–9]

FIFRA Scientific Advisory Panel; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 4-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review scientific issues associated with Prioritizing the Universe of Endocrine Disruptor Screening Program (EDSP) Chemicals Using Computational Toxicology Tools.

DATES: The meeting will be held on January 29–February 1, 2013, from approximately 9 a.m. to 5:30 p.m.

Comments. The Agency encourages that written comments be submitted by January 15, 2013 and requests for oral comments be submitted by January 22, 2013. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after January 15, 2013 should contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

Nominations. Nominations of candidates to serve as ad hoc members of FIFRA SAP for this meeting should be provided on or before November 30, 2012.

Webcast. This meeting may be webcast. Please refer to the FIFRA SAP's Web site, *http://www.epa.gov/scipoly/sap* for information on how to access the webcast. Please note that the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

ADDRESSES: The meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202.

Comments: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2012–0818, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

Nominations, requests to present oral comments, and requests for special accommodations: Submit nominations to serve as ad hoc members of FIFRA SAP, requests for special seating accommodations, or requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Sharlene Matten, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–0130; fax number: (202) 564–8382; email address: *matten.sharlene@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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

When submitting comments, remember to:

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

C. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA–HQ–OPP–2012–0818 in the subject line on the first page of your request.

1. *Written comments.* The Agency encourages that written comments be submitted, using the instructions in **ADDRESSES**, no later than January 15, 2013, to provide FIFRA SAP the time necessary to consider and review the written comments. Written comments are accepted until the date of the meeting, but anyone submitting written comments after January 15, 2013 should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Anyone submitting written comments at the meeting should bring 30 copies for distribution to FIFRA SAP.

2. *Oral comments.* The Agency encourages that each individual or group wishing to make brief oral comments to FIFRA SAP submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** no later than January 22, 2013, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting and, to the extent that time permits, the Chair of FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. The request should identify the name of the

individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment (e.g., overhead projector, 35 mm projector). Oral comments before FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 30 copies of his or her comments and presentation slides for distribution to the FIFRA SAP at the meeting.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc members of FIFRA SAP for this meeting.* As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas:

- Organic and analytical chemistry (expertise focused on developing criteria for physical chemical properties that cannot be easily tested in *in vitro* systems or stable enough for human exposure potential).
- *In vitro* models of receptor binding (e.g., estrogen) and gene activation.
- Quantitative structural-activity relationship (QSAR) models and estrogen receptor (ER) expert systems development.
- High-throughput data generation and analysis (expertise focused on how this methodology can be applied to assess toxicity potential of environmental compounds with a range of potency).
- Application of QSAR models and expert systems in prioritization processes for regulatory toxicity testing programs.

Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before November 30, 2012. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before this date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the panel and the expertise needed to address the Agency's charge to the panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency except the EPA. Other factors considered during the selection process include availability of the potential panel member to fully participate in the panel's reviews, absence of any conflicts of interest or appearance of lack of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of lack of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on FIFRA SAP. Numerous qualified candidates are identified for each panel. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the panel. In order to have the collective breadth of experience needed to address the Agency's charge for this meeting, the Agency anticipates selecting approximately 12–15 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on the FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. The EPA will evaluate the candidates financial disclosure form to assess whether there are financial conflicts of interest, appearance of a lack of impartiality or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on FIFRA SAP. Those who are selected from the pool of prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP Web site at *http://www.epa.gov/scipoly/sap* or may be obtained from the OPP Docket or at *http://www.regulations.gov.*

II. Background

A. Purpose of FIFRA SAP

FIFRA SAP serves as the primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act. FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. FIFRA established a Science Review Board consisting of at least 60 scientists who are available to the SAP on an ad hoc basis to assist in reviews conducted by the SAP. As a peer review mechanism, FIFRA SAP provides comments, evaluations and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

B. Public Meeting

Under the 1996 FFDCA, section 408(p), and Safe Drinking Water Act, section 1457, EPA is required to screen all pesticide chemicals (active and inert ingredients) and only those drinking water contaminants to which a ''substantial population'' is exposed for the *potential* to interact with the endocrine system. The combination of both pesticide and drinking water chemicals amounts to a universe of over 10,000 chemicals. The Agency must therefore prioritize which chemicals are listed for screening and testing in multiple biologically complex and resource intensive assays. The Agency is developing the use of structure-activity relationships (SARs) and high-throughput (HTP) assay data as cost effective prioritization tools that can help focus the generation of new data on chemicals that are more likely to have the potential to interact with the

estrogen, androgen, or thyroid pathways.

In 2009, EPA developed the Estrogen Receptor (ER) Expert System (ERES) to help prioritize candidate chemicals specific to an estrogen receptor (ER) mediated pathway for testing in the Tier 1 Endocrine Disruptor Screening Program. The ERES was initially developed for pesticide, food use inert ingredients and antimicrobial pesticides and predicts ER binding affinity based on data derived from two types of *in vitro* assays: ER binding and ER transcriptional assays. The FIFRA SAP reviewed the initial ERES approach including the transparency of the approach, biological endpoint definition, mechanistic interpretation, and model's applicability domain (*http://www.epa.gov/scipoly/sap/meetings/2009/august/082509minutes.pdf*).

EPA incorporated the 2009 SAP's recommendations and is expanding the ERES training set through the use of chemical read across techniques (i.e., using data from a tested chemical for a particular property or effect to a similar untested chemical) and *in vitro* HTP assay data. This SAP review will seek comment on the expansion of the ERES training set to cover a larger chemical universe and the approach to interpreting the HTP data to inform the ERES. The SAP will also be asked to comment on various aspects of the HTP data including transparency of how the data were generated, processed, and analyzed.

While this SAP is focused on the estrogenic toxicity pathway, the recommendations may be more broadly applied for additional toxicity pathways (e.g., androgen and thyroid). In addition, this SAP review will establish a solid foundation upon which the agency seeks to build upon as we advance the use of these computational toxicology tools beyond EDSP chemical prioritization and into Tier 1 data replacement.

C. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, related supporting materials, charge/questions to FIFRA SAP, FIFRA SAP composition (i.e., members and ad hoc members for this meeting), and the meeting agenda will be available at least 15 days prior to the meeting. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, at *http://www.regulations.gov* and the FIFRA SAP homepage at *http://www.epa.gov/scipoly/sap.*

FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes will be posted on the FIFRA SAP Web site or may be obtained from the OPP Docket or at *http://www.regulations.gov.*

List of Subjects

Environmental protection, Pesticides and pests.

Dated: November 7, 2012.

Frank Sanders,

Director, Office of Science Coordination and Policy.

[FR Doc. 2012–27816 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9752–4]

Notice of Proposed Administrative Settlement Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with Section 122 (i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), notice is hereby given of a proposed administrative settlement concerning the Agrifos Phosphoric Acid Release Superfund Site in Pasadena, Harris County, Texas.

The settlement requires the settling party to pay a total of $385,000 as payment of response costs to the Hazardous Substances Superfund. The settlement includes a covenant not to sue pursuant to Section 107 of CERCLA.

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to this notice and will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at 1445 Ross Avenue, Dallas, Texas 75202–2733.

DATES: Comments must be submitted on or before December 17, 2012.

ADDRESSES: The proposed settlement and additional background information relating to the settlement are available for public inspection at 1445 Ross Avenue, Dallas, Texas 75202–2733. A copy of the proposed settlement may be obtained from Robert Werner at 1445 Ross Avenue, Dallas, Texas 75202–2733 or by calling (214) 665–6724. Comments should reference the Agrifos Phosphoric Acid Release Site, Pasadena, Harris County, Texas and EPA Docket Number 06–01–13, and should be addressed to Robert Werner at the address listed above.

FOR FURTHER INFORMATION CONTACT: Elizabeth Pletan, Assistant Regional Counsel, 1445 Ross Avenue, Dallas, Texas 75202–2733 or call (214) 665–8525.

Dated: November 7, 2012.

Samuel Coleman,

Acting Regional Administrator (6RA).

[FR Doc. 2012–27968 Filed 11–15–12; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

[Public Notice 2012–0541]

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: AP085833XX.

Purpose and Use: Brief description of the purpose of the transaction:

To support the export of U.S. services and equipment for the construction of a liquefied natural gas (LNG) plant in Australia.

Brief non-proprietary description of the anticipated use of the items being exported:

Production of LNG.

To the extent that Ex-Im Bank is reasonably aware, the item(s) being exported are not likely 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: Bechtel International.

Obligor: BG Energy Holdings Limited.

Guarantor(s): N/A.

Description of Items Being Exported: Engineering, procurement and constructions services, various chiller systems, valves, pumps, vessel, compressors and monitoring equipment.

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 11, 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. 2012–27911 Filed 11–15–12; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank of the United States has received an application for a $135 million direct loan to support the export of approximately $103 million in U.S. aluminum manufacturing equipment and services to a smelter in the United Arab Emirates. The U.S. exports will enable the foreign buyer to increase its production capacity of aluminum by about 574,000 metric tons of aluminum per year. Available information indicates that the majority of this new foreign production will be sold in the following markets: Netherlands, Japan, United Arab Emirates, United States, South Korea, and Thailand. The balance of the foreign production will be sold to China, Cyprus, Egypt, France, Germany, Greece, Hungary, Indonesia, Italy, Kenya, Malaysia, Philippines, Poland, Romania, Slovakia, South Africa, Spain, Sri Lanka, Taiwan, Turkey, and United Kingdom. Interested parties may submit comments on this transaction by email to *economic.impact@exim.gov* or by mail to 811 Vermont Avenue NW., Room 442, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Angela Mariana Freyre,

Senior Vice President and General Counsel.

[FR Doc. 2012–27909 Filed 11–15–12; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB)

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3502–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimates; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before December 17, 2012. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Nicholas A. Fraser, Office of Management and Budget (OMB), via fax at 202–395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to Judith B. Herman, Federal Communications Commission, via the Internet at *Judith-b.herman@fcc.gov.* To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, FCC, at 202–418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1031.

Title: Commission's Initiative to Implement Enhanced 911 (E911) Emergency Services.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 858 respondents; 1,992 responses.

Estimated Time per Response: 3.3012048 hours.

Frequency of Response: On occasion and one time reporting requirements, recordkeeping requirements and third party disclosure requirements.

Obligation to Respond: Voluntary. Statutory authority for this information collection is contained in 47 U.S.C. sections 154(i), 160, 201, 251–254, 303 and 332 of the Communications Act of 1934, as amended.

Total Annual Burden: 10,168 hours.

Total Annual Cost: N/A.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: Although the Commission does not believe that any confidential information will need to be disclosed in order to comply with the certification and notification requirements and the corresponding PSAP response provisions, covered carriers or PSAPs are free to request that materials or information submitted to the Commission be withheld from public inspection and from the E911 Web site. Entities wishing to submit confidential information may do so under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission is now submitting this collection to the Office of Management and Budget (OMB) for approval of an extension of this information collection. There is no change to the reporting, recordkeeping and/or third party disclosure requirements. The Commission's previous burden estimates (2009) have not changed.

Under the Commission's E911 rules, a wireless carrier must provide E911 service to a particular Public Safety Answering Point (PSAP) within six months only if that PSAP makes a request for the service and is capable of receiving and utilizing the information provided. In the City of Richardson, TX Order, the Commission's actions were intended to facilitate the E911 implementation process by encouraging parties to communicate with each other earl in the implementation process, and to maintain a constructive, on-going dialog throughout the implementation process. See the 60 day notice for more details on the specific information collection requirements in this information collection which was published in the **Federal Register** on August 28, 2012 (77 FR 52028).

Federal Communications Commission.

Marlene H. Dortch,

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

[FR Doc. 2012–27795 Filed 11–15–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before January 15, 2013. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Judith B. Herman, Federal Communications Commission, via the Internet at *Judith-b.herman@fcc.gov.* To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0270.

Title: Section 90.443, Content of Station Records.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households, business or other for-profit entities, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 65,295 respondents; 65,295 responses.

Estimated Time per Response: .25 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. section 309(j) of the Communications Act of 1934, as amended.

Total Annual Burden: 16,324 hours.

Total Annual Cost: N/A.

Privacy Impact Assessment: Yes. Records of the Wireless Radio Services may include information about individuals or households, and the use(s) and disclosure of this information is governed by the requirements of a system of records, FCC/WTB–1, ''Wireless Services Licensing Records''.

Nature and Extent of Confidentiality: Respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of their rules. Information within Wireless Radio Services is maintained in the Commission's system or records notice or 'SORN', FCC/WTB–1, ''Wireless Services Licensing Records''.

Information on private land mobile licensees is maintained in the Commission's system of records. The licensee records will be publicly available and routinely used in accordance with subsection b of the Privacy Act.

Needs and Uses: Each licensee in the private land mobile radio service must comply with the recordkeeping requirement in 47 CFR section 90.443 of the Commission's rules. Specifically, paragraph (b) of this section requires that the dates and pertinent details of any maintenance performed on station equipment, and the name and address of the service technician who did the work be entered in the station records. These records will reflect whether or not maintenance of the licensee's equipment has been performed.

OMB Control Number: 3060–XXXX.

Title: Annual Report for Mobility Fund Phase I Support, FCC Form 690 and Record Retention Requirements.

Form Number: FCC Form 690.

Type of Review: New collection.

Respondents: Business or other for-profit entities, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 70 respondents; 890 responses.

Estimated Time per Response: 18 hours.

Frequency of Response: On occasion reporting requirement and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 154, 254 and 303(r) of the Communications Act of 1934, as amended.

Total Annual Burden: 14,830 hours.

Total Annual Cost: N/A.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality. The information to be collected will be made available for public inspection. Applicants may request materials or information submitted to the Commission be given confidential treatment under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: On November 18, 2011, the Federal Communications

Commission released a Report and Order, FCC 11–161, in the Universal Service Fund and Intercarrier Compensation Transformation Order (USF/ICC) proceeding; and a Bureau Order, DA 12–147, in the same proceeding, on February 3, 2012, which adopted rules to govern the Connect America Fund Mobility Fund. On May 14, 2012, the Commission released the Third Order on Reconsideration of the USF/ICC Report and Order, FCC 12–52, which revised certain Mobility Fund Phase I rules. In adopting the rules, the Commission provided for one-time support to immediately accelerate deployment of networks for mobile broadband services in unserved areas. Thus, the information being collected is being used to meet the objectives of the Universal Service Fund program. The Commission will also use this information to ensure that each winning bidder is meeting its obligations for receiving Mobility Fund Phase I support.

Federal Communications Commission.

Marlene H. Dortch,

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

[FR Doc. 2012–27796 Filed 11–15–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before January 15, 2013. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to Judith B. Herman, Federal Communications Commission, via the Internet at *Judith-b.herman@fcc.gov.* To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0307.

Title: Parts 1, 22 and 90 of the Commission's Rules to Facilitate Development of SMR Systems in the 800 MHz Frequency Band.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 272 respondents; 272 responses.

Estimated Time per Response: .5 hours to 3.5 hours.

Frequency of Response: On occasion reporting requirements and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 154(i), 309(j) and 332 of the Communications Act of 1934, as amended.

Total Annual Burden: 173 hours.

Total Annual Cost: $78,000.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: The Commission is submitting this expiring information collection to the Office of Management and Budget (OMB) for approval of an extension request (no change in the public reporting and/or third party disclosure requirements). There is no change in the Commission's previous burden and cost estimates.

This collection will promote Congress' goal of regulatory parity for all Commercial Mobile Radio Services (CMRS) and encourage the participation of a wide variety of applicants, including small businesses, in the SMR industry. In addition, this collection will establish rules for the SMR services in order to streamline the licensing process and provide a flexible operating environment for licensees, foster competition, and promote the delivery of service to all areas of the country, including rural areas.

Federal Communications Commission.

Marlene H. Dortch,

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

[FR Doc. 2012–27794 Filed 11–15–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and further ways to reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it

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

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before January 15, 2013. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Leslie F. Smith, Federal Communications Commission (FCC), via the Internet at *Leslie.Smith@fcc.gov.* To submit your PRA comments by email, send them to *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Leslie F. Smith, Office of Managing Director, (202) 418–0217. For additional information, contact Leslie F. Smith at (202) 418–0217, or via the Internet at *PRA@fcc.gov.*, contact.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0392.

Title: 47 CFR Part 1 Subpart J—Pole Attachment Complaint Procedures.

Form Number: N/A.

Type of Review: Revision of currently approved collection.

Respondents: Businesses or other for-profit, and State, local or tribal governments.

Number of Respondents and Responses: 1,772 respondents; 1,772 responses.

Estimated Time per Response: 0.5 to 100 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure;

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 224.

Total Annual Burden: 2,629 hours.

Total Annual Cost: $450,000.

Privacy Act Impact Assessment: No privacy impacts.

Nature and Extent of Confidentiality: There is no need for confidentiality. However, respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of FCC rules.

Needs and Uses: The rules and regulations contained in 47 CFR Part 1 Subpart J provide complaint and enforcement procedures to ensure that telecommunications carriers and cable system operators have nondiscriminatory access to utility poles, ducts, conduits, and rights-of-way on rates, terms and conditions that are just and reasonable. The FCC will use the information collected under these rules to hear and resolve petitions for stay and complaints as mandated by Section 224 of the Communications Act of 1934, as amended. The information that is also filed is used to determine the merits of the petitions and complaints. Additionally, state certifications are used to make public notice of the states' authority to regulate rates, terms and conditions for pole attachments, and to determine the scope of the FCC's jurisdiction.

On April 7, 2011, the FCC released a *Report and Order and Order on Reconsideration,* Implementation of Section 224 of the Act; A National Broadband Plan for our Future, WC Docket No. 07–245 and GN Docket No. 09–51, FCC 11–50. This rulemaking added 47 CFR 1.1424.

Section 1.1424 states that the procedures for handling pole attachment complaints filed by incumbent local exchange carriers are the same as the procedures for handling other pole attachment complaints. Section 1.1424 further requires incumbent local exchange carriers that claim they are similarly-situated to other attachers to bear the burden of demonstrating their similarity.

The Commission has also revised Section 1.1403(b) which requires that requests for access to a utility's poles, ducts, conduits or rights-of-way by a telecommunications carrier or cable operator be in writing. If access is not granted within 45 days of the request for access, the utility must explain the denial or grant of access conditioned on the performance of make-ready by the 45th day.

The other applicable rule sections remain unchanged:

Section 1.1403(c) requires a utility to provide a cable television system operator or telecommunications carrier no less than 60 days written notice prior to removal of facilities, termination of any services to those facilities, increase in pole attachment rates, or modification of facilities.

Section 1.1403(d) allows a cable television system operator or telecommunications carrier to file a ''Petition for Temporary Stay'' of the action contained in a notice received pursuant to Section 1.1403(c) within 15 days of receipt of such notice. The ''Petition for Temporary Stay'' must contain, in concise terms, the relief sought, the reasons for such relief, including a showing of irreparable harm and likely cessation of cable television service or telecommunications service, a copy of the notice, and a certificate of service. The named respondent may file an answer within 7 days of the date the Petition was filed.

Section 1.1403(e) requires cable operators to notify pole owners upon offering telecommunications services.

Section 1.1404 specifies the information that must be included in a pole attachment complaint.

Section 1.1406(b) requires a complainant to file additional information supporting its complaint, if requested by the Commission.

Section 1.1407 requires the respondent to file a response within 30 days from the date the complaint was filed. The complainant then has 20 days from the date the response was filed to file a reply. The response and reply shall be served on all parties listed in the certificate of service.

Section 1.1414 requires states that regulate the rates, terms and conditions for pole attachments to file a certification with the FCC.

Section 1.1417 requires a utility to apportion the cost of providing unusable space on a pole so that such apportionment equals two-thirds of the costs of providing unusable space that would be allocated to such entity under an equal apportionment of such costs among all attaching entities. Section 1.1417 sets forth the procedures to be followed in establishing a maximum just and reasonable pole attachment rate.

Federal Communications Commission.

Marlene H. Dortch,

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

[FR Doc. 2012–27793 Filed 11–15–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 3667NF.

Name: Atlant (USA), Inc.

Address: 250 West Artesia Blvd., Compton, CA 90220.

Date Revoked: October 6, 2012.

Reason: Failed to maintain valid bonds.

License No.: 004242F.

Name: Salinas International Freight Co. dba Globe Express Services.

Address: 535 Regal Row, Dallas, TX 75247.

Date Revoked: October 10, 2012.
Reason: Voluntary surrender of license.

License No.: 020442N.
Name: JWJ Express Inc.
Address: 149–23 182nd Street, Suite 100, Jamaica, NY 11413.
Date Revoked: October 23, 2012.
Reason: Voluntary surrender of license.

License No.: 015574N.
Name: WW Messenger & Shipping Co.
Address: 150 Main Street, Unit 9, Orange, NJ 07050.
Date Revoked: October 15, 2012.
Reason: Failed to maintain a valid bond.

License No.: 019370F.
Name: Cheryl G. Wilson dba JC Logistics.
Address: 28612 Redondo Beach Drive South, Des Moines, WA 98198.
Date Revoked: October 23, 2012.
Reason: Voluntary surrender of license.

License No.: 019480NF.
Name: Intrans Logistics, Inc.
Address: 77 Paloma Avenue, Suite 33, Pacifica, CA 94044.
Date Revoked: October 5, 2012.
Reason: Failed to maintain valid bonds.

License No.: 019599F.
Name: Trans Global Services, L.L.C.
Address: 1600 Wilson Blvd., Suite 1210, Arlington, VA 22209.
Date Revoked: October 15, 2012.
Reason: Voluntary surrender of license.

License No.: 022069N.
Name: Unique Logistics International (ATL) LLC.
Address: 510 Plaza Drive, Suite 2290, Atlanta, GA 30349.
Date Revoked: October 15, 2012.
Reason: Failed to maintain a valid bond.

License No.: 022136N.
Name: Sterling Logistics Group, LLC.
Address: 18 Augusta Pines Drive, Suite 283–W, Spring, TX 77389.
Date Revoked: October 14, 2012.
Reason: Failed to maintain a valid bond.

License No.: 022330NF.
Name: Fluent Logistics LLC.
Address: 4770 Highway 165, Meggett, SC 29449.
Date Revoked: October 19, 2012.
Reason: Failed to maintain valid bonds.

License No.: 022432N.
Name: Acher and Chex International, LLC.
Address: 123 Polaris Drive, Walkersville, MD 27193.
Date Revoked: September 19, 2012.
Reason: Failed to maintain a valid bond.

License No.: 022554F.
Name: Saheed Olalekan Bello dba Sahbell International Services.
Address: 8180 Southwest Freeway, Houston, TX 77074.
Date Revoked: October 7, 2012.
Reason: Failed to maintain a valid bond.

License No.: 023553NF.
Name: Airbridge Corp.
Address: 22 Stonehurst Lane, Dix Hills, NY 11746.
Date Revoked: October 17, 2012.
Reason: Failed to maintain valid bonds.

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2012–27967 Filed 11–15–12; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting Notice for the President's Advisory Council on Faith-Based and Neighborhood Partnerships

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the President's Advisory Council on Faith-based and Neighborhood Partnerships announces the following meeting:

Name: President's Advisory Council on Faith-based and Neighborhood Partnerships Council Meeting.

Dates: Time and Date: Thursday, November 29th 10 a.m.–1:00 p.m. (EST).

Place: Meeting will be held at a location to be determined in the White House complex, 1600 Pennsylvania Ave. NW., Washington, DC. Space is extremely limited. Photo ID and RSVP are required to attend the event. Please RSVP to Ben O'Dell at *partnerships@hhs.gov.*

Status: Open to the public, limited only by space available.

Purpose: The Council brings together leaders and experts in fields related to the work of faith-based and neighborhood organizations in order to: Identify best practices and successful modes of delivering social services; evaluate the need for improvements in the implementation and coordination of public policies relating to faith-based and other neighborhood organizations; and make recommendations for changes in policies, programs, and practices.

Contact Person for Additional Information: Please contact Ben O'Dell for any additional information about the President's Advisory Council meeting at *partnerships@hhs.gov.*

Agenda: Please visit *http://www.whitehouse.gov/partnerships* for further updates on the Agenda for the meeting.

Public Comment: There will be an opportunity for public comment at the end of the meeting. Comments and questions can be sent in advance to *partnerships@hhs.gov.*

Dated: November 9, 2012.

Ben O'Dell,

Designated Federal Officer and Associate Director, HHS Center for Faith-based and Neighborhood Partnerships.

[FR Doc. 2012–27855 Filed 11–15–12; 8:45 am]

BILLING CODE 4154–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–13–13BF]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 and send comments to Ron Otten, at CDC 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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. Written comments should be received within 60 days of this notice.

Proposed Project

Spectrum of Flavoring Chemical-Related Lung Disease—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research

and prevention. The Occupational Safety and Health Act, Public Law 91–596 (section 20[a][1]), authorizes NIOSH to conduct research to advance the health and safety of workers. NIOSH is proposing to conduct a study characterizing the nature of restrictive lung disease occurring in flavoring and microwave popcorn workers.

Preliminary evidence suggests that flavorings exposures may be associated with restrictive lung disease in exposed workers. In two previous NIOSH health hazard evaluations, we found excesses of restrictive spirometry among workers in a flavoring manufacturing plant and a flavoring-exposed food production plant. There was virtually no obstructive lung disease in either of these health hazard evaluations. Over the course of eight cross-sectional studies at a microwave popcorn plant, we also found strong relationships between decreases in FEV1 and cumulative exposure estimates, without differentiating between obstructive and restrictive abnormalities.

NIOSH requests OMB approval to collect additional information on a subset of participants from previous NIOSH studies to determine if restrictive lung disease is occurring among flavoring and popcorn workers. Diagnostic methods for restrictive lung disease will be applied in field settings. This will include spirometry, lung volume testing such as total lung capacity (TLC) and diffusing capacity of the lung to carbon monoxide (DLCO), as well as high resolution computed tomography (HRCT), which can detect lung abnormalities consistent with interstitial lung disease. These medical tests are critical to establishing lung disease of a fibrotic or inflammatory nature in persons with spirometric restriction.

Recent literature has demonstrated that bronchiolitis obliterans and obstructive lung disease are related to flavoring exposures in an exposure-dependent way. However, secondary prevention of further impairment among flavoring workers with spirometric restriction and excessive declines in lung function of a restrictive nature is not occurring. Flavoring workers with restrictive abnormalities are not identified as having possible occupational lung disease, are not removed from further flavorings exposure, are not counseled about respiratory protection and work practices, and are unlikely to be successful in claims for work-related lung disease and medical expenses. These cases of restrictive spirometric abnormality do not motivate employers to implement controls to prevent lung injury to co-workers or to enhance medical surveillance programs.

Results from this study will benefit many stakeholders, including physicians who can appropriately manage workers with restrictive lung disease with consideration of enhanced respiratory protection or reassignment; workers who can make decisions regarding continued exposures and apply for compensation if warranted; companies who can set data driven priorities for preventive interventions; and policy makers who can recommend measures to prevent flavoring-related lung diseases.

For this study, we will recruit participants from two study populations: approximately 100 workers from a flavorings plant for whom we have spirometry data and 130 workers that had abnormal spirometry on any test from a previous NIOSH health hazard evaluation at a microwave popcorn plant. Thirty additional workers from the microwave popcorn plant who had normal spirometry on their last test also will be chosen at random.

NIOSH anticipates that information collection will begin during the summer of 2013 for the microwave popcorn workers and for the flavorings workers in the summer of 2014. Both study populations will be offered a questionnaire, spirometry, TLC test, DLCO, and HRCT of the chest. Those with abnormal spirometry will also be offered a bronchodilator test. Testing is expected to take between 3 to 3.25 hours per respondent. All testing will be conducted by trained NIOSH personnel, except for the HRCT chest scan, which will be done at a local hospital or radiology clinic. Participants will receive a letter which will explain their testing results. All study results will be stored at NIOSH.

The total estimated burden for the one-time collection of data is 822 hours. This is an overestimate of the actual burden to account for any possible waiting at the radiology clinic. Participation in this study is voluntary, and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Testing	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Popcorn workers with normal spirometry.	Questionnaire Spirometry DLCO TLC HRCT.	30	1	3	90
Popcorn workers with abnormal spirometry.	Questionnaire Spirometry DLCO TLC HRCT Bronchodilator test.	130	1	3.25	423
Flavoring workers with normal spirometry.	Questionnaire Spirometry DLCO TLC HRCT.	64	1	3	192
Flavoring workers with abnormal spirometry.	Questionnaire Spirometry DLCO TLC HRCT Bronchodilator test.	36	1	3.25	117
Total					822

Dated:November 2, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity OSI), Office of the Associate Director for Science OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–27835 Filed 11–15–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–0819]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance (OMB No. 0920–0819, Expiration 08/31/2012)—Reinstatement with Change—National Center for HIV, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Because the STD epidemiology in the United States is changing rapidly, CDC must continue to monitor disease indicators that are included in the STD surveillance currently being implemented. CDC is proposing to continue electronic information collection which includes information elements that are integrated into the existing nationally notifiable STDs. These information elements are beyond the scope of the OMB-approved collection called Weekly and Annual Morbidity and Mortality Reports (MMWR, OMB #0920–0007). This ongoing collection will have a title change from ''Sexually Transmitted Disease (STD) Morbidity Surveillance'' to ''Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance and provides evidence to better define STD distribution and epidemiology in the United States. The surveillance system modifies several data elements currently included in the MMWR collection and add others to produce a set of sensitive indicators. This surveillance will continue to provide the evidence to enhance our understanding of STDs, develop intervention strategies, and evaluate the impact of ongoing control efforts. CDC works closely with state and local STD control programs to monitor and respond to STD outbreaks and trends in STD-associated risk behavior. Users of data include, but are not limited to, congressional offices, state and local health agencies, health care providers, and other health-related groups.

CDC disseminates all STD surveillance information through the MMWR series of publications, including the MMWR, the CDC Surveillance Summaries, the Recommendations and Reports, and the annual Summary of Notifiable Diseases, United States. Additionally, DSTDP publishes an annual STD-specific surveillance summary and supplements in hard copy and on the Internet *http://www.cdc.gov/std/Stats/.* CDC will use the findings from this and other STD surveillance to develop guidelines, control strategies, and impact measures that monitor trends in STDs in the United States. We expect a total of 57 sites in state, city, and territory health departments will be submitting STD morbidity information to CDC each week.

There is no cost to respondents other than their time. The total estimated annualized burden hours are 989.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Types of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Health Departments	Electronic STD Case report	50	52	20/60
Territorial Health Agencies	Electronic STD Case report	5	52	20/60
City and county health departments	Electronic STD Case report	2	52	20/60

Dated: November 2, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–27832 Filed 11–15–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Breast Cancer in Young Women (ACBCYW)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 9:30 a.m.–3:30 p.m. EST, December 13, 2012.

Place: The meeting will be held via teleconference.

Teleconference login information is as follows:

For Public:

TOLL-FREE PHONE #: 800–857–4875.

Participant passcode: 9377.

Net Conference URL: *https://www.mymeetings.com/nc/join/.*

Conference number: PW6978681.

Audience passcode: 9377, or

Public can join the event directly:

https://www.mymeetings.com/nc/join.php?i=PW6978681&p=9377&t=c.

There is also a toll number for anyone outside of the USA:

TOLL # 1–212–287–1661.

Participant passcode: 9377.

Please go to the ACBCYW meeting Web page to register for this meeting:

http://www.cdc.gov/cancer/breast/what_cdc_is_doing/conference.htm.

Status: Open to the public, limited only by the number of phone lines available.

Purpose: The committee provides advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; and the Director, CDC, regarding the formative research, development, implementation and evaluation of evidence-based activities designed to prevent breast cancer (particularly among those at heightened risk) and promote the early detection and support of young women who develop the disease. The advice provided by the Committee will assist in ensuring scientific quality, timeliness, utility, and dissemination of credible appropriate messages and resource materials.

Matters To Be Discussed: The agenda will include discussions on approaches to increase awareness of clinicians/practitioners regarding topics such as breast health, symptoms, diagnosis, and treatment of breast cancer in young women; and information needs and delivery mechanisms for women at higher risks for developing breast cancer.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Temeika L. Fairley, Ph.D., Designated Federal Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 5770 Buford Hwy, NE., Mailstop K52, Atlanta, Georgia 30341, Telephone (770) 488–4518, Fax (770) 488–4760, Email: *acbcyw@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and Agency for Toxic Substances and Disease Registry.

Dated: November 8, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–27901 Filed 11–15–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Co-Exclusive License: Veterinary Vaccines for Rift Valley Fever Virus

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), is thinking about giving a co-exclusive license in Africa, in the field of use of veterinary vaccines, to practice the inventions listed in the patent applications referred to below to Deltamune Ltd., having a place of business in Centurion, South Africa. The patent rights in these inventions have been assigned to the government of the United States of America. The patent applications(s) to be licensed are:

US Provisional Application 61/016,065, filed 12/21/2007, entitled ''Development of Rift Valley Fever Virus Utilizing Reverse Genetics,'' US Provisional Application 61/042,987, filed 4/7/2008, entitled ''Recombinant Rift Valley Fever (RVF) Viruses and Method of Use,'' PCT Application PCT/US2008/087023, filed 12/16/2008, entitled ''Recombinant Rift Valley Fever (RVF) Viruses and Method of Use,'' US National Stage Application 12/809,561, filed 6/18/2010, entitled ''Recombinant Rift Valley Fever (RVF) Viruses and Methods of Use,'' and all related continuing and foreign patents/patent applications for the technology family. CDC Technology ID No. I–008–08.

Status: Pending.

Priority Date(s):

61/042,987: 4/7/2008

61/016,065: 12/21/2007

The planned co-exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

Technology: The technology allows for the generation of precisely defined attenuated vaccine constructs that contain complete deletions of critical virulence factors of Rift Valley Fever (RVF) virus. These attenuated vaccines constructs still have the ability to induce robust protective immunity following the administration of a single vaccine dose in a rat model of lethal disease. The vaccines can protect immunized animals against virulent virus challenge. The vaccine candidates also allow for the differentiation of naturally infected and vaccinated animals—a feature that is critical in agricultural settings. This approach will allow for the rapid generation of effective, safe RVF vaccine candidates to control and prevent the spread of wild-type RVF virus in a variety of settings, including preventing the infection of humans or animals during endemic, epidemic or epizootic situations in affected countries, or for prophylactic use among humans in high risk occupational settings, or following intentional release of RVF virus during bioterrorism.

DATES: Only written comments and/or applications for a license which are received by CDC on or before December 17, 2012 will be considered.

ADDRESSES: Requests for a copy of these patent applications, inquiries, comments, and other materials relating to the planned license should be directed to Donald Prather, J.D., Ph.D., Technology Licensing and Marketing Specialist, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K–79, Atlanta, GA 30341, Telephone: (770) 488–8612; Facsimile: (770) 488–8615; Email: *dmprather@cdc.gov*.

SUPPLEMENTARY INFORMATION: Applications for a license filed in response to this notice will be treated as objections to giving the planned license.

Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 8, 2012.

J. Ronald Campbell,

Director, Division of Executive Secretariat, Centers for Disease Control and Prevention.

[FR Doc. 2012–27896 Filed 11–15–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Exclusive License: Veterinary Vaccines for Rift Valley Fever Virus

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), is thinking of giving a co-exclusive license in Africa, and an exclusive license in all territories other than Africa, in the field of use of veterinary vaccines, to practice the inventions listed in the patent applications referred to below to Merial Limited, having a place of business in Duluth, Georgia. The patent rights in these inventions have been assigned to the government of the United States of America. The patent application(s) to be licensed are:

US Provisional Application 61/016,065, filed 12/21/2007, entitled ''Development of Rift Valley Fever Virus Utilizing Reverse Genetics,'' US Provisional Application 61/

042,987, filed 4/7/2008, entitled ''Recombinant Rift Valley Fever (RVF) Viruses and Method of Use,'' PCT Application PCT/US2008/087023, filed 12/16/2008, entitled ''Recombinant Rift Valley Fever (RVF) Viruses and Method of Use,'' US National Stage Application 12/809,561, filed 6/18/2010, entitled ''Recombinant Rift Valley Fever (RVF) Viruses and Methods of Use,'' and all related continuing and foreign patents/patent applications for the technology family. CDC Technology ID No. I–008–08.

Status: Pending.

Priority Date(s):

61/042,987 4/7/2008.

61/016,065 12/21/2007.

The planned co-exclusive license and exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

Technology: The technology allows for the generation of precisely defined attenuated vaccine constructs that contain complete deletions of critical virulence factors of Rift Valley Fever (RVF) virus. These attenuated vaccines constructs still have the ability to induce robust protective immunity following the administration of a single vaccine dose in a rat model of lethal disease. The vaccines can protect immunized animals against virulent virus challenge. The vaccine candidates also allow for the differentiation of naturally infected and vaccinated animals—a feature that is critical in agricultural settings. This approach will allow for the rapid generation of effective, safe RVF vaccine candidates to control and prevent the spread of wild-type RVF virus in a variety of settings, including preventing the infection of humans or animals during endemic, epidemic or epizootic situations in affected countries, or for prophylactic use among humans in high risk occupational settings, or following intentional release of RVF virus during bioterrorism.

DATES: Only written comments and/or applications for a license which are received by CDC on or before December 17, 2012 will be considered.

ADDRESSES: Requests for a copy of these patent applications, inquiries, comments, and other materials relating to the planned license should be directed to Donald Prather, J.D., Ph.D., Technology Licensing and Marketing Specialist, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K–79, Atlanta, GA 30341, Telephone: (770) 488–8612; Facsimile: (770) 488–8615; Email: *dmprather@cdc.gov*.

SUPPLEMENTARY INFORMATION: Applications for a license filed in response to this notice will be treated as objections to giving the planned license.

Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 8, 2012.

J. Ronald Campbell,

Director, Division of Executive Secretariat, Centers for Disease Control and Prevention.

[FR Doc. 2012–27897 Filed 11–15–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Exclusive License: Multiple-Valent Opsonophagocytic Assay Selection Panel Arrays

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), is thinking about giving a worldwide, exclusive license to practice the inventions listed in the patent referred to below to Flow Applications, Inc., having a place of business in Okawville, Illinois. The patent rights in these inventions have been assigned to the government of the United States of America. The patent to be licensed is:

US Patent 7,642,068, entitled, ''Multiple-Valent Opsonophagocytic Assay Selection Panel Arrays and Uses Therefor'', issued 1/5/2010. CDC Technology ID No. I–035–04.

Status: Patent Issued.

Priority Date: 4/22/2005.

Issue Date: 1/5/2010.

The planned exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

Technology: This technology utilizes a specific medium for the selection of up to 90 different *Streptococcus pneumoniae* serotypes following a viability opsonophagocytosis assay. This medium includes different antibiotics, growth factors for pneumococcus, and a colorimetric detection agent. These specific antibiotic panels can be preserved for later use in conjunction with a panel of selected pneumococcal strains that will allow for the measurement of functional antibodies elicited by pneumococcal vaccines.

DATES: Only written comments and/or applications for a license which are received by CDC on or before December 3, 2012 will be considered.

ADDRESSES: Requests for a copy of this patent, inquiries, comments, and other materials relating to the contemplated license should be directed to Donald Prather, J.D., Ph.D., Technology Licensing and Marketing Specialist, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K–79, Atlanta, GA 30341, Telephone: (770) 488–8612; Facsimile: (770) 488–8615: Email: *dwj5@cdc.gov.*

SUPPLEMENTARY INFORMATION: Applications for a license filed in response to this notice will be treated as objections to giving the planned license.

Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 8, 2012.

J. Ronald Campbell,

Director, Division of Executive Secretariat Centers for Disease Control and Prevention.

[FR Doc. 2012–27895 Filed 11–15–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Standard Test Procedures Approval Process for Respirators To Be Used in Wildland Fire-Fighting Operations; Standard Test Procedures for Composite Multi-Gas and Particulate Protection and Approval Process for Respirators To Be Used in Wildland Fire-Fighting Operations

AGENCY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Respirators with Composite Protection for Wildland Fire-Fighting Operations; Notice of Testing and Evaluation.

SUMMARY: The Centers for Disease Control and Prevention's (CDC) National

Institute for Occupational Safety and Health (NIOSH) intends to employ existing provisions in 42 CFR Part 84 to test and approve air-purifying respirators (APRs) and powered air-purifying respirators (PAPRs) that provide composite multi-gas and particulate protection for inhalation hazards associated with wildland fire-fighting. NIOSH will evaluate candidate respirators for inhalation protections tailored against exposures identified in the National Fire Protection Association (NFPA) 1984 standard on respirators for wildland fire-fighting (WFF) operations. Under 42 CFR Part 84 requirements, NIOSH approval is necessary for the complete evaluation of WFF respirators pursuant to NFPA 1984 (2011).

SUPPLEMENTARY INFORMATION:

Background

Wildland firefighting presents many hazards to firefighters, including inhalation exposure to smoke and other combustion (fire) byproducts. Studies indicate that most wildland firefighters work in smoke levels that are not expected to cause health problems or exceed legal and recommended limits.[1] However, wildland firefighters occasionally experience smoke levels that exceed guidelines recommended by occupational health experts, and are higher than Federal occupational safety and health regulations allow. Because manufacturers have not yet developed respiratory protection for this occupational setting, firefighters battling wild fires often resort to using devices not approved by NIOSH, or NIOSH-approved filtering facepiece respirators which are not designed for this use, or no respiratory protection at all. Without a NIOSH-approved respirator designed to protect against the combination of particulates, gases and vapors generally produced by wildfires, firefighters cannot be sure that they are receiving adequate or any protection at all. Filtering facepiece respirators approved under the current NIOSH standards provide no protection against fire gases or vapors and may structurally fail at the elevated temperatures encountered in wildland firefighting environments.

NIOSH is now accepting applications for respiratory protective devices designed for the inhalation hazards of this occupational setting.

On July 10, 2012 NIOSH issued a letter to manufacturers[2] announcing that NIOSH was prepared to evaluate respirators used for protection against the inhalation hazards identified in the National Fire Protection Association (NFPA) standard 1984 (2011 Edition).[3] This new evaluation will be conducted in accordance with a Memorandum of Understanding between the NIOSH National Personal Protective Technology Laboratory (NPPTL) and the Safety Equipment Institute (SEI), a non-governmental non-profit organization that administers third-party certification programs to certify a broad range of safety and protective products. Under this MOU, NIOSH/NPPTL and SEI will coordinate their certification programs. SEI will evaluate candidate respirators for compliance with NFPA 1984–2011, *Standard on Respirators for Wildland Fire-Fighting Operations,* which includes Tentative Interim Amendment (TIA) No. 11–1.

Under NFPA 1984, the wildland firefighter respirator must be approved by NIOSH as an APR or a PAPR. NIOSH has developed test procedures for a composite particulate and multi-gas protection for APR and PAPR approvals in accordance with 42 CFR 84.60(b); 84.63(a), (b), (c), and (d); 84.110(c); and 84.190(b). The standard test procedures are available upon request and will be available on the NIOSH NPPTL Web site at: *http://www.cdc.gov/niosh/npptl/stps/APresp.html.*

FOR FURTHER INFORMATION CONTACT: Tim Rehak, NIOSH National Personal Protective Technology Laboratory (NPPTL), P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236; (412) 386–5200 (this is not a toll-free number).

Dated: November 8, 2012.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2012–27898 Filed 11–15–12; 8:45 am]

BILLING CODE 4163–19–P

[1] See: Reinhardt,TE, Ottmar, RD. 2000. Smoke exposure at western wildfires. Res. Pap. PNW–RP–525. Portland, OR: U.S. Department of Agriculture, Forest Service, Pacific Northwest Research Station.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10028, CMS–10180, CMS–R–199 and CMS–10443]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Children's Health Insurance Program (CHIP) Report on Payables and Receivables; *Use:* Collection of CHIP data and the calculation of the CHIP Incurred But Not Reported (IBNR) estimate are pertinent to CMS' financial audit. The CFO auditors have reported the lack of an estimate for CHIP IBNR payables and receivables as a reportable condition in the FY 2005 audit of CMS's financial statements. It is essential that CMS collect the necessary data from State agencies in FY 2006, so that CMS continues to receive an unqualified audit opinion on its financial statements. Program expenditures for the CHIP have increased since its inception; as such, CHIP receivables and payables may materially impact the financial statements. The CHIP Report on Payables and Receivables will provide the information needed to calculate the CHIP IBNR.; *Form Number:* CMS–10180 (OMB#: 0938–0988); Frequency: Reporting—Annually; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 392. (For policy questions regarding this collection contact Michele Myers at 410–786–7911. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Report on Payables and Receivables; *Use:* The Chief Financial Officers (CFO) Act of 1990, as amended by the Government Management Reform Act (GMRA) of 1994, requires government agencies to produce auditable financial statements. Because the Centers for Medicare & Medicaid Services (CMS) fulfills its

mission through its contractors and the States; these entities are the primary source of information for the financial statements. There are three basic categories of data: expenses, payables, and receivables. The CMS–64 is used to collect data on Medicaid expenses. The CMS–R–199 collects Medicaid payable and receivable accounting data from the States. *Form Number:* CMS–R–199 (OMB#: 0938–0697); Frequency: Reporting—Annually; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 336. (For policy questions regarding this collection contact Michele Myers at 410–786–7911. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Health Insurance Assistance Program (SHIP) Client Contact Form, Public and Media Activity Report Form, and Resource Report Form. *Use:* Section 4360(f) of the Omnibus Budget Reconciliation Act (OBRA) 1990 requires the Secretary to provide a series of reports to the U.S. Congress on the performance of the program and its impact on beneficiaries and to obtain important informational feedback from beneficiaries. Further, in response to requirements of the Balanced Budget Act of 1997, CMS launched a comprehensive five-year campaign, the National Medicare Education Program (NMEP), to raise awareness among beneficiaries about their Medicare health plan options and help them assess the advantages and disadvantages each choice holds for them. The Medicare Modernization Act (MMA) of 2003 required State Health Insurance Assistance Programs (SHIPs) to be actively engaged in the implementation of the Medicare Prescription Drug Program (Part D). MIPPA legislation and Affordable Care Act legislation required SHIPs to provide enrollment assistance for the Limited Income Subsidy (LIS) and Medicare Savings Program (MSP). The goal is to ensure that beneficiaries are making an informed choice, regardless of whether they stay in Original Medicare or choose new options. CMS is responsible to Congress for demonstrating improvement over time in the level of awareness and understanding beneficiaries have about health plan options. The SHIPs are an integral component of this initiative. The information collected is used to fulfill the reporting requirements described in Section 4360(f) of OBRA 1990. CMS will utilize this data. The data will be accumulated and analyzed to measure SHIP performance in order to determine whether and to what extent the SHIPs have met the goals of improved CMS customer service to beneficiaries and better understanding by beneficiaries of their health insurance options. Further, the information will be used in the administration of the grants, to measure performance and appropriate use of the funds by the state grantees, to identify gaps in services and technical support needed by SHIPs, and to identify and share best practices.

The overall burden of hours and expected number of respondents increase is based on projected future service growth and projected future increases in staffing to accommodate the increased demand to utilize the SHIP network to raise awareness about new CMS policies, outreach initiatives, or both. However, the instruments themselves have not changed. *Form Number:* CMS–10028 (OCN: 0938–0850); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 17,838; *Total Annual Responses:* 2,346,465. *Total Annual Hours:* 195,642. (For policy questions regarding this collection contact Gregory Price at 410–786–4041. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* New collection. *Title of Information Collection:* Transcatheter Valve Therapy Registry and KCCQ–10. *Use:* The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, ''Transcatheter Aortic Valve Replacement (TAVR)''. The TAVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all cause mortality and quality of life. CMS finds that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TAVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TAVR technologies for the treatment of aortic stenosis.

The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ–10) to assess heath status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0–100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ–10 is in accordance with Section 1142 of the Social Security Act (the Act) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, The TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. *Form Number:* CMS–10443 (OCN: 0938-New); *Frequency:* Annual; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 12,000; *Total Annual Responses:* 24,000; *Total Annual Hours:* 7,000. (For policy questions regarding this collection contact JoAnna Baldwin at 410–786–7205. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site

address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on December 17, 2012. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: November 9, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–27841 Filed 11–15–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0164]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by December 17, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Draft Guidance for Industry on Safety Labeling Changes; Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Draft Guidance for Industry on Safety Labeling Changes; Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910-New)

This draft guidance provides information on the implementation of section 901 of the Food and Drug Administration Amendments Act of 2007, which authorizes FDA to require certain drug and biological product application holders to make safety related labeling changes based upon new safety information that becomes available after the drug or biological product is approved under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or the Public Health Service Act. FDA plans to request safety labeling changes by sending a notification letter to the application holder. Under section 505(o)(4)(B) of the FD&C Act (21 U.S.C. 355(o)(4)(B)), the application holder must respond to FDA's notification by submitting a labeling supplement or notifying FDA that the applicant does not believe the labeling change is warranted and submitting a statement detailing the reasons why the application holder does not believe a change is warranted (a rebuttal statement).

The submission of rebuttal statements may result in the collection of information that is not already approved by OMB. Based on FDA's experience thus far with safety labeling changes requirements under section 505(o)(4) of the FD&C Act, FDA estimates that approximately six application holders will elect to submit approximately one rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, in the draft guidance, the Agency states that new labeling prepared in response to a safety labeling change notification should be available on the application holder's Web site within 10 calendar days of approval, which may result in the collection of information that is not already approved by OMB. FDA estimates that approximately 197 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

In the **Federal Register** of April 13, 2011 (76 FR 20686), FDA published a 60-day notice requesting public comment on the draft version of this guidance. None of the comments we received pertained to the information collection provisions.

FDA estimates the burden of the collections of information that have not already been approved by OMB is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rebuttal statement	6	1	6	6	36

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of submission	Number of respondents	Annual frequency per disclosure	Total annual disclosures	Hours per disclosure	Total hours
Post approved labeling on application holder's Web site	197	1	197	4	788

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This draft guidance also refers to previously approved collections of information. Specifically, the draft guidance describes: Labeling supplements for new drug applications, abbreviated new drug applications, and biologics license applications submitted under 21 CFR 314.70, 314.71, 314.97, and 601.12, and the content and format of prescription drug labeling submitted under 21 CFR 201.56 and 201.57. These collections of information are subject to review by OMB under the PRA and are approved under OMB control numbers 0910–0001, 0910–0338, and 0910–0572. Section V of the draft guidance refers to the guidance entitled ''Formal Dispute Resolution: Appeals Above the Division Level,'' which describes collections of information approved under OMB control number 0910–0430.

Dated: November 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27881 Filed 11–15–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public. This meeting is being rescheduled due to the postponement of the November 1, 2012, meeting due to unanticipated weather conditions caused by hurricane Sandy.

Name of Committee: Neurological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 10, 2012, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Grand Ballroom, Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993–0002, 301–796–5290, *Natasha.Facey@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On December 10, 2012, the committee will discuss current knowledge about the safety and effectiveness of the CoAxia NeuroFlo Catheter device for the intended use of diverting cardiac output to the cerebral vasculature via partial occlusion of the descending aorta, including in patients with acute ischemic stroke within 14 hours of symptom onset.

The CoAxia NeuroFlo Catheter is a 7F multilumen device with two balloons mounted near the distal tip. The proximal end has a multiport manifold that provides access for the guidewire, monitoring of blood pressure, and independent inflation of the individual balloons. The device is placed in the descending aorta. On March 30, 2005, a humanitarian device exemption application for the CoAxia NeuroFlo Catheter was approved for the following indication for use: The CoAxia NeuroFlo Catheter is intended for the treatment of cerebral ischemia resulting from symptomatic vasospasm following aneurismal subarachnoid hemorrhage, secured by either surgical or endovascular intervention for patients who have failed maximal medical management.

Of note, the CoAxia NeuroFlo Catheter is identical in design to the CoAxia FloControl, which is currently cleared for the following general indications for use:

1. The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature (K023914).

2. The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature, which includes the descending aorta (K090970).

CoAxia has submitted a de novo application for the NeuroFlo for the following indication: The CoAxia NeuroFlo Catheter is intended for use in diversion of cardiac output via partial occlusion of the descending aorta, including patients with acute ischemic stroke within 14 hours of symptom onset. The CoAxia NeuroFlo Catheter is also intended for use in selectively stopping or controlling blood flow in the peripheral vasculature, which includes the descending aorta.

FDA is convening this committee to seek expert scientific and clinical opinion on the risks and benefits of this device based on the available premarket and postmarket data. In particular, the committee will be asked to discuss the safety and effectiveness data from the ''Safety and Efficacy of NeuroFlo Technology in Ischemic Stroke'' (SENTIS) clinical trial as they relate to the proposed indications for use.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 4, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 26, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 28, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Committee Management Staff, 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27934 Filed 11–15–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1037]

Establishing a List of Qualifying Pathogens That Have the Potential To Pose a Serious Threat to Public Health; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain input on establishing a list of qualifying pathogens (i.e., those that have the potential to pose a serious threat to public health), as required under the Food and Drug Administration Safety and Innovation Act (FDASIA). This public hearing is being held to obtain comments from the public to determine the methodology that should be used in developing the list of qualifying pathogens, and to elicit suggestions for adding specific pathogens to the list.

DATES: *Date and Time:* The public hearing will be held on December 18, 2012, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the hearing may be extended or may end early.

Location: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Contact Person: Lee Lemley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–7563, FAX: 301–847–8753, email: *CDER–GAINPublicMtg@fda.hhs.gov*.

Registration: The public hearing is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

If you need special accommodations due to a disability, please contact Lee Lemley (see *Contact Person*) at least 7 days in advance.

Requests for Oral Presentations: If you wish to make an oral presentation during the public hearing, you must register by submitting either an electronic or written request by close of business on December 3, 2012. You must provide your name, title, business affiliation (if applicable), address, email address, and phone and type of organization you represent (e.g., industry, consumer organization), and a brief summary of the presentation (including the discussion topic(s) that will be addressed) to Lee Lemley (see *Contact Person*). You should identify which question(s) set forth in section II of this document you wish to address so that FDA can consider that in organizing the presentations.

FDA will notify registered presenters of their scheduled times, and will make available an agenda at *http://www.fda.gov/Drugs/NewsEvents/ucm319619.htm*. Once FDA notifies registered presenters of their scheduled times, presenters should submit an electronic copy of their presentation to Lee Lemley (see *Contact Person*) no later than December 12, 2012. Persons registered to make an oral presentation should check in before the hearing, and are encouraged to arrive early to ensure the designated order of presentation.

A live Webcast of this public hearing will be viewable at the following Web site: *https://collaboration.fda.gov/gain121812/*. A video record of the public hearing will be available at the same Web site for 1 year.

Comments: Regardless of attendance at the public hearing, interested persons may submit either written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic comments to *http://www.regulations.gov*. Submit electronic or written comments by December 3, 2012. You should annotate and organize your comments so that they identify the specific questions to which they refer. 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*.

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open until January 25, 2013.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management

(see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

Title VIII of FDASIA (Pub. L. 112–144), entitled ''Generating Antibiotic Incentives Now (GAIN),'' amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add new section 505E (21 U.S.C. 355E), among other things. This new section of the FD&C Act is designed to encourage development of treatments for serious or life-threatening infections caused by bacteria or fungi. For an application for a drug that is designated a ''qualified infectious disease product'' under section 505E(d) of the FD&C Act, section 505E(a) provides an extension of 5 years of market exclusivity to the exclusivity periods provided by sections 505(c)(3)(E)(ii) through (c)(3)(E)(iv) (21 U.S.C. 355(c)(3)(E)(ii) through (c)(3)(E)(iv)), 505(j)(5)(F)(ii) through (j)(5)(F)(iv) (21 U.S.C. 355(j)(5)(F)(ii) through (j)(5)(F)(iv)), 505A (21 U.S.C. 355a), and 527 (21 U.S.C. 360cc) of the FD&C Act. However, as section 505E(c) of the FD&C Act states, not all applications for a ''qualified infectious disease product'' are eligible for the additional market exclusivity. In addition, an application for a drug designated as a ''qualified infectious disease product'' is eligible for priority review and fast track status (sections 524A and 506(a)(1) of the FD&C Act (21 U.S.C. 356(a)(1))), respectively.

The term ''qualifying infectious disease product'' refers to an antibacterial or antifungal human drug that is intended to treat serious or life-threatening infections (section 505E(g) of the FD&C Act). It includes treatments for diseases caused by antibiotic- or antifungal-resistant pathogens (including new or emerging pathogens), or ''qualifying pathogens'' listed by the Secretary of the Department of Health and Human Services (and, by delegation, FDA) under section 505E(f) (section 505E(g) of the FD&C Act).

According to the statute, ''the term 'qualifying pathogen' means a pathogen identified and listed by the Secretary * * * that has the potential to pose a serious threat to public health, such as[:] (A) resistant [G]ram positive pathogens, including methicillin-resistant *Staphylococcus aureus,* vancomycin-resistant *Staphylococcus aureus,* and vancomycin-resistant *[E]nterococcus;* (B) multi-drug resistant [G]ram[-]negative bacteria, including *Acinetobacter, Klebsiella, Pseudomonas,* and *E. coli* species; (C) multi-drug resistant tuberculosis; and (D) *Clostridium difficile''* (section 505E(f)(1) of the FD&C Act). FDA is required under the law to consider four factors in establishing and maintaining the list of qualifying pathogens:

- The impact on the public health due to drug-resistant organisms in humans;
- The rate of growth of drug-resistant organisms in humans;
- The increase in resistance rates in humans; and
- The morbidity and mortality in humans.

(section 505E(f)(2)(B)(i) of the FD&C Act). Furthermore, in determining which pathogens should be listed, consultation with infectious disease and antibiotic resistance experts, including those in the medical and clinical research communities, along with the Centers for Disease Control and Prevention (CDC), is required (section 505E(f)(2)(B)(ii) of the FD&C Act).

II. Purpose and Scope of the Hearing

We are holding this hearing to fulfill the statutory consultation requirement and to obtain public comment on the following issues related to establishing the list of qualifying pathogens described in section 505E(f) of the FD&C Act:

1. FDASIA requires FDA to ''consider'' the following factors in establishing and maintaining the list of qualifying pathogens:

- The impact on the public health due to drug-resistant organisms in humans;
- The rate of growth of drug-resistant organisms in humans;
- The increase in resistance rates in humans; and
- The morbidity and mortality in humans.

How should these factors be applied to a pathogen to determine whether it should be included in the list?

2. Aside from the considerations noted in question 1 (i.e., those required by section 505(E)(f)(2)(B)(i) of the FD&C Act), are there any other factors FDA should consider when establishing and maintaining the list of qualifying pathogens? If so, how should these factors be applied to a pathogen to determine whether it should be included in the list?

3. Which specific pathogens do you believe should be listed as qualifying pathogens? Provide justification for your recommendations, including how you applied the considerations described in section 505E(f)(2)(B)(i) of the FD&C Act, and any other factors that you considered, in recommending the pathogen for inclusion on the list of qualifying pathogens.

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (see 21 CFR part 10, subpart C). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: November 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27931 Filed 11–15–12; 8:45 am]

BILLING CODE 4160–01–P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Program Comment Issued for Streamlining Section 106 Review for Actions Affecting Post-1945 Concrete and Steel Bridges

AGENCY: Advisory Council on Historic Preservation.

ACTION: Program Comment issued for streamlining Section 106 review for undertakings affecting post-1945 concrete and steel bridges.

SUMMARY: The Advisory Council on Historic Preservation (ACHP) issued a

Program Comment at the request of the U.S. Department of Transportation Federal Highway Administration to relieve it and other federal agencies from the requirement under Section 106 of the National Historic Preservation Act to consider the effects of undertakings on common bridges and culverts constructed of concrete or steel after 1945. The federal agencies using the Program Comment must still complete Section 106 review for the undertaking, including the identification of historic properties and consideration of effects of the undertaking on historic properties other than the common bridge itself.

DATES: The Program Comment was issued by the ACHP on November 2, 2012.

ADDRESSES: Address all questions concerning the Program Comment to Carol Legard, Office of Federal Agency Programs, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue NW., Suite 803, Washington, DC 20004. Fax (202) 606–8522. You may submit electronic questions to: *clegard@achp.gov*.

FOR FURTHER INFORMATION CONTACT: Carol Legard, (202) 606–8522, *clegard@achp.gov*.

SUPPLEMENTARY INFORMATION: Section 106 of the National Historic Preservation Act (Section 106) requires federal agencies to consider the effects of their undertakings on historic properties and to provide the Advisory Council on Historic Preservation (ACHP) a reasonable opportunity to comment with regard to such undertakings. The ACHP has issued the regulations that set forth the process through which Federal agencies comply with these duties. Those regulations are codified under 36 CFR part 800 (Section 106 regulations).

Under Section 800.14(e) of those regulations, agencies can request the ACHP to issue a ''Program Comment'' on a particular category of undertakings in lieu of conducting reviews of each individual undertaking under such category, as set forth in 36 CFR 800.3 through 800.7. An agency can meet its Section 106 responsibilities with regard to the effects of particular aspects of those undertakings by taking into account an applicable Program Comment that has been issued by the ACHP and following the steps set forth in that comment.

I. Background

The ACHP has issued a Program Comment to relieve all federal agencies from the Section 106 requirement to consider the effects of undertakings on common bridges and culverts constructed of concrete or steel after 1945. The ACHP membership voted in favor of issuing the Program Comment via an unassembled vote that concluded on November 2, 2012.

According to the requirements for obtaining a Program Comment, the Federal Highway Administration (FHWA) formally requested the ACHP to comment on the effects of a category of undertakings in lieu of conducting individual reviews for effects to certain types of bridges commonly constructed in the United States since 1945. Bridges of the types covered in the Program Comment were constructed in vast numbers from plans that quickly became standardized around the middle of the 20th century. These bridges are generally undistinguished from an engineering or architectural perspective, are considered to have little value for preservation in place, and are rarely viable candidates for relocation. However, because they may meet or approach the age criteria for evaluation as historic properties, considerable time and resources are currently expended to address effects to them on a case-by-case basis under the Section 106 process. The Program Comment applies to effects of undertakings on certain common concrete and steel bridges lacking distinction, not previously listed in or determined eligible for listing in the National Register of Historic Places, and not located within or adjacent to historic districts. The Program Comment proposed by FHWA was received by the ACHP on August 6, 2012.

To develop the Program Comment, FHWA met with individuals from the ACHP staff, the National Conference of State Historic Preservation Officers, the American Association of State Highway and Transportation Officials, and the National Trust for Historic Preservation. With the assistance of these individuals, FHWA prepared an initial draft of the proposed Program Comment which was then shared with key stakeholders and additional organizations and individuals with expertise in historic bridges and in the Section 106 review process. This outreach effort resulted in a number of revisions intended to address concerns raised about the applicability of the Program Comment, the ability of states to identify examples of common bridges that should be excluded from the Program Comment, and the types and range of bridges that would be exempted from Section 106 review. FHWA worked with the ACHP in developing the new draft, which was discussed at the ACHP Federal Agency Program Committee meeting on August 8, 2012.

Upon submitting its formal request to the ACHP, FHWA took additional steps to inform the public and stakeholders about the proposed Program Comment, including an email distribution, posting on the agency web site, and a notice published in the **Federal Register** on September 5, 2012 (**Federal Register** Volume 77, Number 172, pages 54652–54655). In response, the Federal Highway Administration received comments from 14 individuals and organizations.

In accordance with our regulations at 36 CFR 800.14(e), the ACHP is responsible for obtaining the views of State Historic Preservation Officers (SHPOs) and Tribal Historic Preservation Officers before reaching a decision on issuing a Program Comment. Although the Program Comment was drafted so that it does not apply to tribal lands, the ACHP transmitted the proposed Program Comment to Indian tribes and Tribal Historic Preservation Officers to ensure that their views were considered in its decision on whether to issue the program comment. The ACHP requested comments on the Program Comment, as submitted by FHWA, on September 7, 2012.

As a result of both FHWA's **Federal Register** notice and the ACHP's solicitation of views from SHPOs and Tribal Historic Preservation Officers, comments were received from six SHPOs, one Indian tribe, one Native Hawaiian Organization, and 12 other individuals and organizations.

The proposed Program Comment received strong support from the American Public Works Association (APWA), National Association of County Engineers (NACE), American Road and Transportation Builders Association (ARTBA), the Commissioner of Highways for the Commonwealth of Virginia, the New York State County Highway Superintendents Association (NYSCHSA), and the County of Los Angeles Department of Public Works. Comments from these organizations stressed that the Program Comment is a logical, common sense approach that will save taxpayers money and allow needed infrastructure improvements to be completed more efficiently. The President of the NYSCHSA stated that by excluding these common bridges from Section 106 review, taxpayers could save up to $78 million over a 10-year period.

Four respondents to the **Federal Register** notice objected to the premise that post-1945 concrete and steel highway bridges are generally undistinguished, having little value for

preservation in place. One also took exception to statements in the introduction and background sections of the Program Comment that, in her view, indicated a lack of understanding of the significance and rehabilitation potential for post-1945 common bridges. These four reviewers, and four SHPOs, further disagreed with FHWA that examples of common bridge types of exceptional significance can be readily identified without a statewide inventory by knowledgeable professional cultural resource specialists. The reviewers, two of which are historic bridge experts working as consultants, argued that streamlining Section 106 review for bridges, even those built after 1945, is best accomplished by completing a statewide historic bridge inventory and individual determinations of historic significance based on a statewide historic context and generally accepted scholarship.

Two commenters expressed confusion about how the identification of exceptional bridges can be completed by December 31, 2012, particularly where the main source of data is the National Bridge Inventory (NBI). Distrust for the accuracy of information in the NBI and the fact that a number of states lack recent historic bridge inventories were the reasons these parties were concerned about the ability of the FHWA Division in each state to identify especially important examples of the common bridge types within the tight timeframe provided in the review draft.

In response to these concerns, the Program Comment was revised to extend the timeframe for completing the list of exceptional bridges to March 31, 2013. It also encourages, but does not require, FHWA Divisions to complete the list by that date. If additional time is needed to complete the list, it will be granted. Also, FHWA Divisions may add to the list of exceptional bridges, as more information becomes available regarding the historic bridges in a state. The Program Comment also now clarifies that to complete the list of exceptional bridges, a statewide survey or context does not need to be developed where none exists. The list need not be exhaustive; the intent behind the list is to be able to exclude readily recognizable exceptional bridges from the Program Comment. Although the commenters are correct that this may not be sufficient in some states to identify all exceptionally significant bridges, we believe that the Program Comment establishes a good balance between protecting the most significant historic bridges of these common types and eliminating repetitive and redundant documentation and reviews that can be costly to the government and have limited value to the broader public.

One Federally Recognized Indian tribe and one Native Hawaiian Organization commented on the Program Comment. Both expressed concern that the Program Comment may be seen as a broad waiver of Section 106 review for projects affecting historic bridges, leading to the destruction of other types of sites as a result of construction. To address this concern, the Introduction (Section I) and Section III (Applicability) were revised to explicitly and clearly state that while the Program Comment relieves Federal agencies from the Section 106 requirement to consider the effects of undertakings on the bridge types identified in Section V, it is not a waiver from Section 106 requirements for the consideration of other historic properties that may be affected by a bridge rehabilitation or replacement project. It further clarifies that the Program Comment is not a waiver from applicable Federal requirements to consult with Indian tribes or Native Hawaiian organizations (NHOs) regarding undertakings that may affect historic properties to which a tribe or NHO ascribe traditional cultural and religious significance.

Three commenters proposed changes to the common bridge types covered by the Program Comment (Section V). One proposed that pre-stressed concrete should be included as a discrete bridge type and that all pre-stressed concrete bridges built prior to 1966 be excluded from the Program Comment. The ACHP declined to make this change as it would be inconsistent with the other bridge types in Section V, which are based on structure type (design) and material, and not just the material with which it is constructed. Other recommendations were incorporated into the final Program Comment including: Removing reinforced concrete rigid frames, metal rigid frames, and curved metal girders from the list of common types (they are, in fact, not as common as the other types); and adding culverts and reinforced concrete boxes among the common bridge types covered by the Program Comment.

Two commenters offered recommendations for improving the programmatic mitigation in Section VI. One recommended including specifics regarding the manner in which the FHWA will encourage the update of inventories. The other offered additional suggestions for mitigation. One additional mitigation measure was incorporated into the Program Comment based on these recommendations. Section VI now requires FHWA to complete and make available to the public a brief illustrated history of post-1945 highway bridge engineering and design to document for the general public the innovations and contributions of the bridges to transportation in the post-World War II era. FHWA is required to complete this illustrated history and documentation using Historic American Engineering Record (HAER) standards of at least one example of each common bridge type before December 31, 2013. A third programmatic mitigation measure was left unchanged: A commitment for FHWA to encourage State transportation agencies that have not recently done so to update inventories of historic bridges in their states. The ACHP agrees with commenters that updating and maintaining statewide historic bridge inventories and management plans for historic bridges is the best way to plan for the protection and preservation of the State's most significant bridges. However, requiring State transportation agencies to complete these inventories would place an unfair burden on states without the resources to do these studies, and we do not agree that such inventories are necessary to identify exceptional examples in a state, provided the state DOT and Federal Highway Administration consults with the SHPO and others in developing the list of exceptional bridges, as required.

The ACHP received comments on the FHWA proposed Program Comment from six SHPOs: Delaware, Hawaii, Nevada, New Hampshire, Puerto Rico, and Wisconsin. Wisconsin and Nevada SHPOs support the Program Comment and offered minor suggestions for improving Section IV (Considerations) which were incorporated into the final document.

Four SHPO representatives expressed objections or strong reservations to the approach because of concerns that important post-1945 concrete and steel bridges would remain unidentified and unprotected in the absence of a comprehensive statewide historic bridge survey. As with some of the commenters on the **Federal Register** notice (summarized above), these SHPO reviewers equated the elimination of individual review requirements for common bridge types with a lack of historic significance. The ACHP has revised the Program Comment to clarify that the intent is to streamline Section 106 review by replacing individual documentation and treatment of the common bridge types in Section V with the programmatic mitigation in Section VI. The purpose of the considerations in

Section IV of the Program Comment is not to identify and protect all significant bridges, but to provide the Federal Highway Administration in each State an opportunity to identify and exclude from the Program Comment: (1) Bridges that have already been listed or determined eligible for listing in the National Register, and (2) common post-1945 concrete and steel bridges that are known to have exceptional significance. Although a statewide inventory to identify exceptional bridges is not a requirement for agencies wishing to apply the Program Comment to undertakings affecting post-1945 bridges in a state, FHWA will encourage states to update inventories of historic bridges to better ensure that bridges meeting the considerations in Section IV are identified and considered early in the Section 106 review process.

The National Conference of State Historic Preservation Officers (NCSHPO) worked closely with FHWA to develop the Program Comment, and has expressed strong support for it.

Finally, Federal agencies may only use the Program Comment in states where the relevant FHWA Division has completed and filed a list of exceptional common bridges with the FHWA Federal Preservation Officer (FPO) in accordance with Section IV. While the ACHP does not intend to limit the usefulness of the Program Comment to federal agencies wishing to use it, we note that the effectiveness of the Program Comment hinges on the FHWA Divisions in each state taking the step to identify bridges that should be exempted from the Program Comment. We encourage Federal agencies other than FHWA wishing to use the Program Comment to contact the relevant FHWA Division office or the State Historic Preservation Office to find out the status of its efforts to complete the list required in Section IV. The FHWA FPO has agreed to post on FHWA's Web site (*http://www.environment.fhwa.dot.gov/histpres/index.asp*) information about the lists once they are submitted. Other agencies may check with the FHWA FPO or check the Web site to determine if a list of exceptional bridges has been completed by a state Division of FHWA. FHWA is committed to working with states and FHWA Divisions to ensure that the requirements of the Program Comment are communicated through the publication of guidance, FHWA's Web site, and coordination by Headquarters and the FPO.

II. Final Text of the Program Comment

The following is the text of the proposed Program Comment:

Program Comment for Common Post-1945 Concrete and Steel Bridges

I. Introduction

Every year, the Federal Highway Administration (FHWA) funds the rehabilitation and replacement of hundreds of bridges under the Federal-aid program administered across the U.S. by State departments of transportation (DOT) and the Federal Lands Highway program. Other Federal agencies are also involved with projects affecting bridges through Federal assistance, approvals, or permits. Many of the bridges affected by these programs are of common types constructed by State transportation agencies after 1945, using reinforced concrete or steel beams and designs that quickly became standardized. These common bridge types are generally undistinguished, and although some of them may be eligible for inclusion in the National Register of Historic Places, when repair or replacement is needed, they are rarely viable candidates for either preservation in place or relocation. Yet, every federally funded or permitted undertaking affecting such a bridge requires review and consultation pursuant to Section 106 of the National Historic Preservation Act (Section 106), 16 U.S.C. 470f to assess whether the bridge is eligible for inclusion in the National Register and, if so, to resolve adverse effects to it. The regulations implementing Section 106, codified at 36 CFR part 800, describe the procedures Federal agencies must follow to meet this obligation.

Alternate compliance methods, provided by the Section 106 regulations, allow agencies to meet these Section 106 obligations but tailor the process to their mission and needs. Section 800.14(e) of the regulations provides that any agency may request a ''Program Comment'' from the ACHP in lieu of case-by-case review. The benefit of a Program Comment is that it allows a federal agency to comply with Section 106 in a single action for a class of undertakings rather than addressing each undertaking as a separate action. At FHWA's request, the ACHP has issued the following Program Comment in accordance with 36 CFR § 800.14(e) in order to waive, with limited exceptions, case-by-case Section 106 consideration of effects on common post-1945 bridges. This Program Comment is available for use by all federal agencies and State officials delegated the responsibility to comply with Section 106 for the particular undertakings by statute or a program alternative under 36 CFR § 800.14 (federal agencies). It relieves federal agencies from the need, under Section 106, to individually consider the effects of undertakings on the bridges described in Section V of this Program Comment, with the exceptions noted in Section IV.

It is important to note that this Program Comment is not a waiver from Section 106 review for undertakings that may affect common bridges or other historic properties as described in Section V. Neither is it a waiver from applicable federal requirements to consult with Indian tribes or Native Hawaiian organizations (NHO) regarding undertakings that may affect historic properties to which a tribe or NHO ascribes traditional cultural and religious significance. Federal agency officials must still complete Section 106 review and consider effects of the undertaking on historic properties other than the common bridge itself. Such effects to other historic properties may be direct or indirect, and must be considered by the federal agency official whether or not the Program Comment is applicable to the subject bridge.

II. Background

In October 2005, the National Cooperative Highway Research Program published ''A Context for Common Historic Bridge Types.'' That context revealed that a great many of the bridge structures built after 1935, and especially since 1946, are strictly utilitarian and lacking in distinctive engineering or architectural qualities. Increasing standardization associated with highway design as a result of growing federal funding and the evolving standards of the American Association of State Highway and Transportation Officials (AASHTO) both contributed to the uniformity of design in bridges of certain types.

Information about America's bridges, including their age and condition, is readily available in FHWA's National Bridge Inventory (NBI). The NBI is a collection of information (database) covering just under 600,000 of the nation's bridges located on public roads, including Interstate Highways, U.S. highways, State and county roads, as well as publicly accessible bridges on federal lands. It presents a State by State summary analysis of the number, location, and general condition of highway bridges within each State. This database contains technical and engineering information about hundreds of thousands of bridges in the United States, including year built, bridge type, condition and many other fields. Some 45,000 bridges in the NBI are rated as structurally deficient, meaning that portions of the bridge may be in poor condition. Approximately 61,680 are identified as functionally obsolete, meaning that the design of the bridge does not meet current guidelines for its use, such as lack of safety shoulders or the inability to handle certain traffic volume, speed, size, or weight. Bridges in these categories are frequent candidates for replacement. This Program Comment is intended to eliminate the administrative burden of considering the effects of replacement on these bridges on a case-by-case basis and make delivery of these critical projects more efficient in recognition of the very limited preservation value of the vast majority of common post-1945 bridges.

III. Applicability

This Program Comment relieves federal agencies from the Section 106 requirement to consider the effects of undertakings on the bridge types identified in Section V of this Program Comment, except for those subject to the considerations noted in Section IV of this Program Comment.

Undertakings include those that involve applications from State transportation agencies or local governments for federal permits, approvals, or assistance that will result in alteration, replacement, or

demolition of one or more of the common bridges or culverts listed in Section V below (common bridges). All federal agencies may take advantage of the streamlining provided by this Program Comment. Federal agencies may use data from the NBI or existing State surveys to support the determination that a particular bridge is a common bridge under this Program Comment. However, if data from the NBI is used, that information must be verified in the field by a qualified engineer or cultural resource professional to ensure that the date and type have been correctly recorded and that the bridge does not meet any of the other considerations under Section IV.

The Program Comment applies to common bridges regardless of ownership, except for those located on tribal lands.[1] As noted above, even if the undertaking involves a common bridge not subject to considerations under Section IV, federal agency officials must still complete Section 106 review for the undertaking, including the identification of historic properties and consideration of effects of the undertaking on historic properties other than the common bridge itself. Such effects to other historic properties may be direct or indirect, and must be considered by the federal agency official whether or not the Program Comment is applicable to the subject bridge. For example, bridge replacement projects may have the following types of effects to non-common bridge historic properties that would need to be considered:

—disturbance to archeological sites as a result of construction-related ground disturbing activities;
—change in physical features that contribute to historic significance of a historic property, including alterations that a new bridge may have on the historic setting and feeling of an adjacent historic district;
—change in traffic patterns that may affect the setting, feeling, and association of a historic district; or
—effects to other historic properties based on the need for temporary construction, detours, or rights-of-way.

A federal agency is not required to use this Program Comment. Federal agencies that choose not to use this Program Comment must comply with Section 106 through the process in the Section 106 regulations at 36 CFR §§ 800.3 through 800.7, or 36 CFR § 800.8(c), or another existing program alternative under 36 CFR § 800.14. Any federal agency that chooses to use this Program Comment for an undertaking should notify consulting parties that it will use it with regard to the effects of the undertaking on the bridge types identified in Section V of this Program Comment.

IV. Considerations

Prior to utilizing this Program Comment for an undertaking that may affect a common bridge, a federal agency, based on the work of a qualified cultural resource specialist, must complete a review to determine if any of the considerations listed below apply to the bridge at issue. If the federal agency determines that the common bridge in question meets any of these considerations, the agency may not utilize this Program Comment with regard to that common bridge.

(A) The bridge is listed in or has previously been determined eligible for the National Register of Historic Places or is located adjacent to or within a National Register listed or eligible historic district, including linear historic districts such as a parkway, historic road, or canal;

(B) The bridge in question is or includes spans of the following types: Arch bridges, truss bridges, bridges with movable spans, suspension bridges, cable-stayed bridges, or covered bridges; or

(C) The bridge was identified in a list created through the process detailed below as having exceptional significance for association with an event or individual, or being a very early or particularly important example of its type in a State or the nation, having distinctive engineering or architectural features that depart from standard designs, such as an aesthetic railing or balustrade, includes spans of exceptional length or complexity, or displaying other elements that were engineered to respond to a unique environmental context.

Before the Program Comment may be used for undertakings in a State, the relevant FHWA Division must first develop a list of bridges in that State that are of the types considered common bridges, but that also meet the considerations in IV.C above, and therefore fall outside the scope of this Program Comment. Each FHWA Division wishing to apply the provisions of this Program Comment must organize a meeting of the relevant SHPO, DOT, and other interested parties in order to develop the list of bridges that meet the criteria considerations in IV.C. The list should be finalized and submitted to the Federal Preservation Officer of FHWA by March 31, 2013. FHWA Divisions are not required to develop a statewide survey or context studies to support the development of such lists where none exist. The list is not intended to be exhaustive, but will be informed by input received at the meeting. The intent behind the list is to be able to exclude readily recognizable exceptional bridges from the Program Comment. Where States already have a current (within the last 5 years) Programmatic Agreement, inventory, or management plan for historic bridges that identifies common bridges meeting any of the listed considerations, the data included in those Programmatic Agreements, inventories, or management plans may suffice to create the list. States lacking up to date historic bridge inventories may subsequently identify additional bridges to include on the list of exceptional bridges excluded from the Program Comment based on information obtained in a field verification required in Section III of this Program Comment.

V. Description of Common Bridges Within the Scope of This Program Comment

Based on the historic bridge context, the NBI, information developed in statewide bridge inventories across the United States, and consultation with the National Conference of SHPOs and other stakeholders, the following common bridge types are considered well-documented standardized designs that lack individual distinction.[2] It is understood that some of the bridges that fall into the specified types may be eligible for the National Register under local or State significance. Nevertheless, provided none of the considerations specified in Section IV above apply, the following are the common bridge types that fall within the scope of this Program Comment:

(A) Reinforced concrete slab bridges
  (i) Reinforced concrete cast-in-place slabs
  (ii) Reinforced concrete pre-cast slabs
  (iii) Pre-stressed concrete slabs
(B) Reinforced concrete beam and girder bridges
  (i) Reinforced concrete Tee Beams
  (ii) Reinforced concrete channel beams
  (iii) Pre-stressed concrete I-Beams and Bulb Tees
  (iv) Pre-stressed concrete box beams
(C) Steel Multi-Beam or Multi-Girder bridges
  (i) Steel-rolled multi-beams
  (ii) Steel fabricated (built up) girders
(D) Culverts and reinforced concrete boxes
  (i) Reinforced concrete boxes
  (ii) Concrete box culverts
  (iii) Concrete pipe culverts
  (iv) Steel pipe culverts

VI. Programmatic Mitigation

The programmatic mitigation measures in this section resolve adverse effects that could result from the potential replacement of common bridges and provide appropriate documentation of those common bridges covered by this program comment. By completing the requirements of Section IV, federal agencies will ensure that this Program Comment is appropriately applied to individual undertakings affecting common bridges. The measures included in this Section, when completed by FHWA, will provide a long-term record of these common bridge types and information about the historic and technological significance of this period of innovation in transportation.

(A) If a suitable example from at least one State is not already included in the Historic American Engineering Record (HAER) collection, one set of HAER documentation, including at least narrative history and photographs, for each bridge type in Section V shall be prepared and submitted by FHWA for acceptance by HAER before December 31, 2013. The FHWA will coordinate with HAER to determine which, if any, of these types are not yet represented in the HAER collection and will work with the FHWA Division offices and State DOTs to identify a candidate for each type not already represented.

(B) FHWA will complete a brief illustrated history of post-1945 highway bridge engineering and design to document for the general public the innovations and

[1] Indian tribes wishing to use the streamlining measures in this Program Comment for common bridges on lands under their jurisdiction are encouraged to enter into program alternatives pursuant to 36 CFR 800.14.

[2] Descriptions and examples of these common bridge types can be found in *A Context for Common Historic Bridge Types*. NCHRP Project 25–25, task 15, October 2005 (*http://onlinepubs.trb.org/onlinepubs/archive/NotesDocs/25-25%2815%29_FR.pdf*).

contributions to transportation in the Post World War II era. The illustrated history will be published as a brochure and/or posted on the Internet, and shall be completed and available to the public prior to December 31, 2013.

(C) The FHWA will encourage State transportation agencies that have not done so within the last 5 years to update inventories of historic bridges in their States to better ensure that bridges meeting the considerations in Section IV above are identified and considered early in the Section 106 review process.

VII. Definitions

If not specifically addressed below, terms used within this Program Comment shall be defined consistent with the definitions provided in 36 CFR Part 800.

''*Common Bridge*'' is, for purposes of this Program Comment, a common post-1945 bridge or culvert of a type identified in Section V.

''*Program Comment*'' is an alternative to Section 106 review that allows a Federal agency to request the ACHP to comment on a category of undertakings in lieu of conducting individual reviews under Sections 800.4 through 800.6 of the regulations (36 CFR Part 800).

''*Qualified cultural resource specialist*'' means an individual meeting the Secretary of the Interior's professional qualifications for historian or architectural historian by virtue of education and experience to carry out historic preservation work.

Authority: 36 CFR 800.14(e).

Dated: November 8, 2012.

John M. Fowler,

Executive Director.

[FR Doc. 2012–27866 Filed 11–15–12; 8:45 am]

BILLING CODE 4310–K6–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2012–0046]

Protected Critical Infrastructure Information (PCII) Office Self-Assessment Questionnaire

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 60-day notice and request for comments; New Information Collection Request: 1670—NEW.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of Infrastructure Protection (IP), Infrastructure Information Collection Division (IICD), Protected Critical Infrastructure Information (PCII) Program will submit the following Information Collection Request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until January 15, 2013. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to DHS/NPPD/IP/IICD, 245 Murray Lane, SW., Mail Stop 0602, Arlington,VA 20598–0602. Emailed requests should go to Joseph Maltby, *joseph.maltby@dhs.gov*. Written comments should reach the contact person listed no later than January 15, 2013. Comments must be identified by ''DHS–2012–0046''and may be submitted by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*.
- Email: Include the docket number in the subject line of the message.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

SUPPLEMENTARY INFORMATION: Congress created the PCII Program under the Critical Infrastructure Information Act of 2002 for DHS to encourage voluntary information sharing by owners and operators of critical infrastructure and protected systems. IICD administers the PCII Program. The PCII Program is implemented by 6 CFR part 29, Procedures for Handling Critical Infrastructure Information; Final Rule (the Regulation), issued in 2006. PCII refers to critical infrastructure information not customarily in the public domain and related to the security of critical infrastructure or protected systems, which is voluntarily submitted to DHS for homeland security purposes and validated under the authority of the PCII Program Manager. The PCII Program provides a statutory exemption from release of information under the Freedom of Information Act and state and local sunshine laws, and prohibits the use of the information in civil litigation.

The PCII Program is responsible for ensuring compliance with the regulation's uniform procedures for the handling, use, dissemination, and safeguarding of PCII. In this capacity, the PCII Program oversees a community of stakeholders, including submitters of critical infrastructure information, authorized users of PCII and accredited Federal, state and local entities with homeland security duties. The PCII Program is required by its authorizing regulation to assist the PCII Officers in overseeing their own accredited PCII programs at the state and local level. *See* 6 CFR 29.4(d). This questionnaire is designed to gather information from PCII Officers that will be used by the NPPD/IP PCII Program to assess state and local programs, their compliance with PCII rules and requirements, and the specific needs of their accredited programs. These assessments are designed to help the DHS PCII Program and Officers to ensure that PCII is being properly protected and to limit the potential for mishandling and improper disclosures. OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection, Infrastructure Information Collection Division, Protected Critical Infrastructure Information Program.

Title: Protected Critical Infrastructure Information (PCII) Office Self-Assessment Questionnaire.

OMB Number: 1670–NEW.

Frequency: Annually.

Affected Public: PCII Officers.

Number of Respondents: 80 (estimate).

Estimated Time per Respondent: 1 hour.

Total Burden Hours: 80 annual burden hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0 (This assessment will reside on existing PCII information storage systems).

Total Burden Cost (operating/maintaining): $8,316.

Dated: November 8, 2012.

Scott Libby,

Acting Chief Information Officer, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. 2012–27966 Filed 11–15–12; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3350–EM; Docket ID FEMA–2011–0001]

Massachusetts; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the Commonwealth of Massachusetts (FEMA–3350–EM), dated October 28, 2012, and related determinations.

DATES: *Effective Date:* October 28, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 28, 2012, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in the Commonwealth of Massachusetts resulting from Hurricane Sandy beginning on October 27, 2012, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the Commonwealth of Massachusetts.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Justo Hernández, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the Commonwealth of Massachusetts have been designated as adversely affected by this declared emergency:

All counties in the Commonwealth of Massachusetts for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27883 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3360–EM; Docket ID FEMA–2011–0001]

New Hampshire; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of New Hampshire (FEMA–3360–EM), dated October 30, 2012, and related determinations.

DATES: *Effective Date:* October 30, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 30, 2012, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of New Hampshire resulting from Hurricane Sandy beginning on October 26, 2012, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of New Hampshire.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Kevin L. Hannes, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of New Hampshire have been designated as adversely affected by this declared emergency:

All counties in the State of New Hampshire for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27888 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3355–EM; Docket ID FEMA–2011–0001]

Rhode Island; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Rhode Island (FEMA–3355–EM), dated October 29, 2012, and related determinations.

DATES: *Effective Date:* October 29, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 29, 2012, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Rhode Island resulting from Hurricane Sandy beginning on October 26, 2012, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of Rhode Island.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, James N. Russo, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of Rhode Island have been designated as adversely affected by this declared emergency:

All counties in the State of Rhode Island for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27887 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3351–EM; Docket ID FEMA–2012–0002]

New York; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of New York (FEMA–3351–EM), dated October 28, 2012, and related determinations.

DATES: *Effective Date:* October 28, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 28, 2012, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of New York resulting from Hurricane Sandy beginning on October 27, 2012, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of New York.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that

pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Philip E. Parr, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of New York have been designated as adversely affected by this declared emergency:

All counties in the State of New York for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27885 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3353–EM; Docket ID FEMA–2011–0001]

Connecticut; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Connecticut (FEMA–3353–EM), dated October 28, 2012, and related determinations.

DATES: *Effective Date:* October 28, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 28, 2012, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Connecticut resulting from Hurricane Sandy beginning on October 27, 2012, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of Connecticut.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Albert Lewis, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of Connecticut have been designated as adversely affected by this declared emergency:

All counties in the State of Connecticut for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27884 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3354–EM;Docket ID FEMA–2012–0002]

New Jersey; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of New Jersey (FEMA–3354–EM), dated October 28, 2012, and related determinations.

DATES: *Effective Date:* October 28, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 28, 2012, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of New Jersey resulting from Hurricane Sandy beginning on October 26, 2012, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of New Jersey.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any

Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Elizabeth Turner, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of New Jersey have been designated as adversely affected by this declared emergency:

All counties in the State of New Jersey for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27877 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3354–EM; Docket ID FEMA–2012–0002]

New Jersey; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for State of New Jersey (FEMA–3354–EM), dated October 28, 2012, and related determinations.

DATES: *Effective Date:* November 3, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael J. Hall of FEMA is appointed to act as the Federal Coordinating Officer for this emergency.

This action terminates the appointment of Elizabeth Turner as Federal Coordinating Officer for this emergency.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27880 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3352–EM; Docket ID FEMA–2012–0002]

District of Columbia; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the District of Columbia (FEMA–3352–EM), dated October 28, 2012, and related determinations.

DATES: *Effective Date:* November 5, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Jack Schuback, of FEMA is appointed to act as the Federal Coordinating Officer for this emergency.

This action terminates the appointment of Steven S. Ward as Federal Coordinating Officer for this emergency.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27886 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3351–EM: Docket ID FEMA–2012–0002]

New York; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency disaster declaration for State of New York (FEMA–3351–EM), dated October 28, 2012, and related determinations.

DATES: *Effective Date:* November 3, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and

Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael F. Byrne, of FEMA is appointed to act as the Federal Coordinating Officer for this emergency.

This action terminates the appointment of Philip E. Parr as Federal Coordinating Officer for this emergency.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27882 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3357–EM; Docket ID FEMA–2012–0002]

Delaware; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Delaware (FEMA–3357–EM), dated October 29, 2012, and related determinations.

DATES: *Effective Date:* November 5, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Jack Schuback, of FEMA is appointed to act as the Federal Coordinating Officer for this emergency.

This action terminates the appointment of Regis Leo Phelan as Federal Coordinating Officer for this emergency.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant).

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27879 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4087–DR; Docket ID FEMA–2012–0002]

Connecticut; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Connecticut (FEMA–4087–DR), dated October 30, 2012, and related determinations.

DATES: *Effective Date:* October 30, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 30, 2012, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Connecticut resulting from Hurricane Sandy beginning on October 27, 2012, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Connecticut.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance, assistance for debris removal and emergency protective measures (Categories A and B), including direct federal assistance, under the Public Assistance program in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate subject to completion of Preliminary Damage Assessments (PDAs).

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance, Hazard Mitigation, and Other Needs Assistance will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Albert Lewis, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Connecticut have been designated as adversely affected by this major disaster:

Fairfield, Middlesex, New Haven, and New London Counties and the Mashantucket Pequot Tribal Nation and Mohegan Tribal Nation located within New London County for Individual Assistance.

Fairfield, Middlesex, New Haven, and New London Counties and the Mashantucket Pequot Tribal Nation and Mohegan Tribal Nation located within New London County for debris removal and emergency protective measures (Categories A and B), including direct federal assistance, under the Public Assistance program.

All counties and Indian Tribes in the State of Connecticut are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used

for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27889 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4088–DR; Docket ID FEMA–2012–0002]

Utah; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Utah (FEMA–4088–DR), dated November 3, 2012, and related determinations.

DATES: *Effective Date:* November 3, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated November 3, 2012, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Utah resulting from a severe storm and flooding on September 11, 2012, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Utah.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Gary R. Stanley, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Utah have been designated as adversely affected by this major disaster:

Washington County for Public Assistance.

All counties within the State of Utah are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27876 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4086–DR; Docket ID FEMA–2012–0002]

New Jersey; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of New Jersey (FEMA–4086–DR), dated October 30, 2012, and related determinations.

DATES: *Effective Date:* November 5, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of New Jersey is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 30, 2012.

Burlington, Camden, Cumberland, Gloucester, Hunterdon, Mercer, Morris, Passaic, Salem, Sussex, and Warren Counties for Individual Assistance (already designated for Public Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–27878 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation of Dixie Services, Inc., as a Commercial Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation of Dixie Services, Inc., as a commercial laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12, Dixie Services, Inc., 1706 First Street, Galena Park, TX 77547, has been accredited to

test petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12. Anyone wishing to employ this entity to conduct laboratory analyses should request and receive written assurances from the entity that it is accredited by the U.S. Customs and Border Protection to conduct the specific test requested. Alternatively, inquires regarding the specific test this entity is accredited to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/linkhandler/cgov/trade/automated/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf.*

DATES: The accreditation of Dixie Services, Inc., as commercial laboratory became effective on July 12, 2012. The next triennial inspection date will be scheduled for July 2015.

FOR FURTHER INFORMATION CONTACT: Christopher Mocella, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: November 8, 2012.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2012–27851 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2012–0041]

Advisory Committee on Commercial Operations of Customs and Border Protection (COAC)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Advisory Committee on Commercial Operations of Customs and Border Protection (COAC) will meet on December 4, 2012, in Washington, DC. The meeting will be open to the public.

DATES: COAC will meet on Tuesday, December 4, 2012, from 1:00 p.m. to 6:00 p.m. EST. Please note that the meeting may close early if the committee has completed its business.

Registration: If you plan on attending, please register either online at *https://apps.cbp.gov/te_registration/index.asp?w=111* or by email to *tradeevents@dhs.gov,* or by fax to 202–325–4290 by close-of-business on November 30,2012.

If you have completed an online on-site registration and wish to cancel your registration, you may do so at *https://apps.cbp.gov/te_registration/cancel.asp?w=111.* Please feel free to share this information with interested members of your organizations or associations.

ADDRESSES: The meeting will be held at Ronald Reagan Building in the Horizon Ballroom, 1300 Pennsylvania Avenue NW., Washington, DC 20229. All visitors to the Ronald Reagan Building must show a state-issued ID or Passport to proceed through the security checkpoint to be admitted to the building.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection at 202–344–1661 as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the committee as listed in the ''Agenda'' section below.

Comments must be submitted in writing no later than November 26, 2012, and must be identified by USCBP–2012–0041 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: Tradeevents@dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* 202–325–4290.
- *Mail:* Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Room 3.5A, Washington, DC 20229.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. Do not submit personal information to this docket.

Docket: For access to the docket to read background documents or comments received by the COAC, go to *http://www.regulations.gov.*

There will be three public comment periods held during the meeting on December 4, 2012. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Contact the individual listed below to register as a speaker. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page at the time of the meeting.

FOR FURTHER INFORMATION CONTACT: Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Room 3.5A, Washington, DC 20229; telephone 202–344–1440; facsimile 202–325–4290.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. App. (Pub. L. 92–463). The COAC provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within DHS or the Department of the Treasury.

Agenda

The COAC will hear from the following subcommittees on the topics listed below and then will review, deliberate, provide observations and formulate recommendations on how to proceed on those topics:

- The work of the Trade Facilitation Subcommittee: Recommendations and resolutions on CBP's Trade Transformation initiatives, recommendations on the role of the customs brokers in regard to the Centers of Excellence and Expertise (CEEs), and recommendations based on the results from the COAC Industry Survey regarding the expected benefits of the CEEs.
- The work of the Role of the Broker Subcommittee: Recommendations and resolutions on various aspects of CBP's effort to revise the role of the customs broker in the CBP regulations (19 CFR Part 111) which includes whether the initiative in the area of continuing education should be pursued, requirements for brokers to obtain *bona fides* for their importer clients before transacting customs business on the client's behalf, and comments on possible revision to CBP Form 5106 (Importer Identification Input Record). In addition, recommendations will be made regarding the role of customs brokers in the CEEs.
- The work of Automated Commercial Environment (ACE) Strategic Communications Working Group: Presentation of a white paper and recommendation how CBP should

proceed in communicating with the trade community as the agency shifts from the Automated Commercial System (ACS) to ACE as functionality becomes available.

• The work of the One U.S. Government at the Border Subcommittee: Recommendation for addressing a One U.S. Government Approach to Trusted Trader Programs and provide the subcommittee term end report.

• The Intellectual Property Rights Enforcement Subcommittee's work on providing CBP with guidance on new tools to be used in the port of entry to help identify counterfeit products, the distribution chain management and serialization pilot project, and modification to the CBP recordation database of federally registered trademarks, trade names and copyrights.

• The Anti-Dumping/Countervailing Duties Subcommittee's term end report and a discussion on the impact of trade enforcement and trade intelligence initiatives.

• The Bond Subcommittee's work on proposed modifications to the CBP Form 5106 (Importer Identification Input Record), liquidated damages/mitigation guidelines, and the use of single transaction bonds (STBs) when additional security is merited. The Subcommittee will respond to the CBP Deputy Commissioner's request to look into the possibility of issuing bonds prior to the foreign departure of goods that are intended for importation into the United States.

• An update from CBP's Agriculture Programs and Trade Liaison on the July 2012 USDA/Animal Plant Health Inspection Service (APHIS) and CBP Joint Stakeholder Conference.

Prior to the COAC taking action on any of these topics of the eight above-mentioned subcommittees, working groups, and Agriculture Programs and Trade Liaison, members of the public will have an opportunity to provide comments orally or, for comments submitted electronically during the meeting, by reading the comments into the record.

The COAC will also receive term-end reports, updates and discuss the following Initiatives and Subcommittee topics that were discussed throughout the 12th Term meetings as set forth below:

• The National Strategy for Global Supply Chain Security as it relates to an effort to solicit, consolidate, and provide to DHS sector and stakeholder input on implementation of the National Strategy.

• The work of the Land Border Security Subcommittee: updates and observations on the Customs—the 21st Century Border Management Initiative and Beyond the Border initiatives.

• The Air Cargo Security Subcommittee's work on the Air Cargo Advance Screening (ACAS) pilot, and a discussion of the operational involvement of freight forwarders as well as the next steps in drafting a notice of proposed rulemaking.

• The Export Subcommittee's work on where it stands in identifying incentives for U.S. exporters to participate in Customs-Trade Partnership Against Terrorism (C–TPAT)/Authorized Economic Operator (AEO) programs and a review of the subcommittee's scope and goals for the 13th Term COAC.

Dated: November 9, 2012.

Maria Luisa O'Connell,

Senior Advisor for Trade, Office of Trade Relations.

[FR Doc. 2012–27850 Filed 11–15–12; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5670–N–01]

Notice of Intent To Prepare an Environmental Impact Statement for the HOPE SF Development at Sunnydale and Velasco Public Housing Developments, San Francisco, CA

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of Intent to Prepare an EIS and to Conduct Public Scoping Meeting.

SUMMARY: The Department of Housing and Urban Development (HUD) gives notice to the public, agencies, and Indian tribes that the City and County of San Francisco's Mayor's Office of Housing (MOH) as the Responsible Entity in accordance with 24 CFR 58.2, intends to prepare a Draft Environmental Impact Report/Environmental Impact Statement (EIR/EIS) for the HOPE SF Development at the Sunnydale and Velasco Public Housing Developments (Sunnydale HOPE SF Master Plan Project). The EIR/EIS will be a joint National Environmental Policy Act (NEPA) and California Environmental Quality Act (CEQA) document.

The EIR will satisfy requirements of CEQA (Public Resources Code 21000 et seq.) and the State CEQA Guidelines (14 California Code of Regulations 15000 et seq.), which require that state and local government agencies consider the environmental consequences of projects over which they have discretionary authority before acting on those projects. The Proposed Action is subject to NEPA, because funding for the project may include HUD funds from programs subject to regulation by 24 CFR part 58; these include, but are not limited to, Community Development Block Grant (CDBG) funds under Title I of the Housing and Community Development Act of 1974; Home Investment Partnership Program (HOME) grants under Title II of the Cranston-Gonzales National Affordable Housing Act of 1990, as amended; Project Based Section 8 Vouchers under Section 8(o)(13) of the United States Housing Act of 1937; and/or Public Housing operating subsidies for mixed income developments authorized under the U.S. Housing Act of 1937, Section 35. In accordance with specific statutory authority and HUD's regulations at 24 CFR part 58 (Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities), HUD has provided for assumption of its NEPA authority and NEPA lead agency responsibility by the City and County of San Francisco. This notice is issued in accordance with the Council on Environmental Quality (CEQ) regulations at 40 CFR parts 1500–1508.

A Draft EIR/EIS will be prepared for the Proposed Action described herein. Comments relating to the Draft EIR/EIS are requested and will be accepted by the contact person listed below. When the Draft EIR/EIS is completed, a notice will be sent to individuals and groups known to have an interest in the Draft EIR/EIS and particularly in the environmental impact issues identified therein. Any person or agency interested in receiving a notice and making comment on the Draft EIR/EIS should contact the person listed below within 30 days of publication of this notice.

This EIS will be a NEPA document intended to satisfy requirements of Federal environmental statutes. In accordance with specific statutory authority and HUD's regulations at 24 CFR part 58 (Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities), HUD has provided for assumption of its NEPA authority and NEPA lead agency responsibility by the City and County of San Francisco. The EIR will be a CEQA document intended to satisfy State environmental statutes (Public Resources Code 21000 et seq. and 14 California Code of Regulations 15000 et seq.).

ADDRESSES: All interested agencies, tribes, groups, and persons are invited to submit written comments on the scope of the Draft EIS to the contact person shown below. Comments received will be considered in the preparation and distribution of the Draft EIS. Particularly solicited is information on reports or other environmental studies planned or completed in the project area, major issues that the EIS should consider, recommended mitigation measures, and alternatives to the Proposed Action. Federal agencies having jurisdiction by law, special expertise or other special interest should report their interest and indicate their readiness to aid in the EIS effort as a ''Cooperating Agency.''

FOR FURTHER INFORMATION CONTACT: Eugene Flannery, Environmental Compliance Manager, City and County of San Francisco Mayor's Office of Housing, 1 South Van Ness Avenue, 5th Floor, San Francisco, CA 94103; Phone: (415) 701–5598; Fax (415) 701–5501; email: *eugene.flannery@sfgov.org.* The Environmental Review Record and information regarding the scoping meeting will be posted online at *http://sf-moh.org/index.aspx?page=155.*

SUPPLEMENTARY INFORMATION:

A. Background

The MOH, acting under authority of section 104(g) of the Housing and Community Development Act of 1974 (42 U.S.C. 5304(g)), section 288 of the HOME Investment Partnerships Act (42 U.S.C. 12838), section 26 of the United States Housing Act of 1937 (42 U.S.C. 1437x) and HUD's regulations at 24 CFR part 58, in cooperation with other interested agencies, will prepare an EIS to analyze potential impacts of the Sunnydale HOPE SF Master Plan Project.

Constructed in 1941 and 1963 respectively, the Sunnydale and Velasco Public Housing Developments together form the City's largest public housing community. Located in the Visitacion Valley area of San Francisco, the project site is bounded by Hahn Street to the east, Velasco Avenue to the south, Brookdale Avenue to the west, and McLaren Park to the north and northwest. It includes Assessor's Blocks 6310-Lot 1, Block 6311-Lot 1, Block 6312-Lot 1, Block 6313-Lot 1, Block 6314-Lot 1, and Block 6315-Lot 1. The 2,127,187-square-foot (approximately 50-acre) project site slopes down from west (Brookdale Avenue) to east (Hahn Street), at slopes ranging from 15.5 percent at its highest and steepest point to a 2-percent slope at the lower elevations. The average grade change is 9 percent. Elevations range from 250 feet above sea level (asl) at the western edge of the site to 75 feet asl at the southeastern corner.

The project site is a quarter of a mile north of Geneva Avenue, which is roughly the border between the City of San Francisco and Daly City and also leads to the I–280 freeway to the west. The project site is approximately three-quarters of a mile west of Bayshore Boulevard, which is a main street that connects the neighborhood to U.S. Highway 101 to the east. Single-family residential and small-multifamily residential uses are immediately adjacent to the site to the south and east, and these uses characterize most of the Visitacion Valley neighborhood. The north and west is McLaren Park, which is the City's second largest park at 312 acres. The park's Gleneagles Golf Course and Herz Playground are directly north of the project site. A sloped natural area of McLaren Park with a walking path to the Crocker Amazon Playground abuts the project site to the west. Also to the west is the partially occupied McLaren campus of the San Francisco Unified School District, which currently houses a pre-kindergarten school.

The Sunnydale and Velasco Public Housing Developments consist of 785 residential units and the Willie Brown Community Center (including the Housing Authority's Leasing Center) located in 94 buildings that are one and two stories (20–35 feet) in height. The buildings are laid out according to the site topography, as are the streets; neither follow the grid pattern of the surrounding neighborhood. In between the buildings is open space of grass and unmaintained landscaping with three play areas. A bungalow on Velasco Street is occupied by Wu Yee Children's Services, which operates a child care program for the neighborhood. Several asphalt surface parking lots are located throughout the site and provide 430 off street parking spaces. The streets internal to the project site provide parking for another 452 automobiles. Three bus stops are located within the project site.

The Sunnydale HOPE SF Master Plan (Proposed Action) would replace all 785 units, the current utility and open space infrastructure, re-align the streets and add new community facilities and park spaces. The Proposed Action would consist of the development of up to 1,700 new residential units that are a mix of public housing replacement units, new affordable units and new market rate units in buildings that range from 40–65 feet in height. The Proposed Action would also include up to 6 acres of new park spaces within the project site, up to 72,500 square feet of community facilities including a new community center, neighborhood-serving retail space, and a child care program.

Alternatives to the Proposed Action

There are three alternatives to the Proposed Action to be analyzed in the EIS. Alternative 1 is a variation of the project density. Alternative sites for the project were explored early in the process, and it was determined that no other more viable site was available.

Alternative 1—Reduced Development Alternative

Number of Units: 1,372.
Maximum Height: 65 feet.
Acreage: 48.8 acres (no change).
Percent Reduction in Units Compared to Proposed Action: 19 percent.

Alternative 2—Replacement of Existing Public Housing Units

Number of Units: 785 units.
Acreage: 48.8 acres.
No new Community Center, no retail, no additional open space.
Percent Reduction in Units Compared to Proposed Action: 53 percent.

Alternative 3—No Project Alternative

The No Project Alternative would analyze the ''no action'' alternative, which would be the continuation of uses on the site; therefore, existing buildings and tenants would remain at the project site and no new buildings or uses would be constructed.

B. Need for the EIS

The proposed project may constitute an action significantly affecting the quality of the human environment and an EIS will be prepared on this project by the City and County of San Francisco's MOH in accordance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Responses to this notice will be used to: (1) Determine significant environmental issues, (2) identify data that the EIS should address, and (3) identify agencies and other parties that will participate in the EIS process and the basis for their involvement.

C. Scoping

A public joint EIR/EIS scoping meeting will be held on a date within the comment period and after at least 15 days of publishing this Notice of Intent. Notices of the scoping meeting will be mailed when the date has been determined. The joint EIR/EIS scoping meeting will provide an opportunity for the public to learn more about the project and provide input to the

environmental process. At the meeting, the public will be able to view graphics illustrating preliminary planning work and talk with MOH staff, and members of the consultant team providing technical analysis to the project. Translators will be available. Written comments and testimony concerning the scope of the joint EIR/EIS will be accepted at this meeting. In accordance with 40 CFR 1501.7 affected Federal, State, and local agencies, any affected Indian tribe, and other interested parties will be sent a scoping notice. Owners and occupants within a 300-foot radius will also be notified of the scoping process. In accordance with 24 CFR 58.59, the scoping hearing will be preceded by a notice of public hearing published in the local news media 15 days before the hearing date.

D. Probable Environmental Effects

The following subject areas will be analyzed in the combined EIR/EIS for probable environmental effects: Land Use and Planning (land use patterns, relationship to plans/policies and regulations; Visual Quality/Aesthetics (views/light and glare); Socioeconomics and Community (demographic character changes, displacement); Environmental Justice (disproportionately high and adverse effects on minority and low income populations); Cultural/Historic Resources; Transportation and Circulation; Noise (construction and operational); Air Quality (construction and operational); Greenhouse Gas Emissions; Wind and Shadow; Recreation; Utilities and Service Systems (water supply, stormwater, sewer, solid waste); Public Services (fire, police, schools, parks); Biological Resources; Geology/Soils; Hydrology/Water Quality (erosion control and drainage); Toxic and Hazardous Materials; Mineral and Energy Resources; and Agriculture and Forest Resources.

Questions may be directed to the individual named in this notice under the heading **FOR FURTHER INFORMATION CONTACT**.

Dated: November 8, 2012.

Mark Johnston,

Assistant Secretary for Community Planning and Development (Acting).

[FR Doc. 2012–27985 Filed 11–15–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5601–N–45]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AIR FORCE: Mr. Robert Moore, Air Force Real Property Agency, 143 Billy Mitchell Blvd., San Antonio, TX 78226, (210) 925–3047; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property

Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084; INTERIOR: Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 1801 Pennsylvania Ave. NW., 4th Floor, Washington, DC 20006: 202–254–5522 (These are not toll-free numbers).

Dated: November 8, 2012.

Ann Marie Oliva,

Deputy Assistant Secretary for Special Needs (Acting).

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 11/16/2012

Suitable/Available Properties

Building

Mississippi

Tract 102–12A
516 ½ South Canal St.
Natchez MS 39120
Landholding Agency: Interior
Property Number: 61201240022
Status: Unutilized
Comments: off-site removal only; 2 floors; garage apt.; 240 mons. vacant; staircase not safe to use; entire bldg. needs to be gutted; asbestos identified; contact Interior for info. on accessibility/removal

Tract 102–11B
516 South Canal St.
Natchez MS 39120
Landholding Agency: Interior
Property Number: 61201240023
Status: Unutilized
Directions: Natchez Nat'l Historical Park
Comments: Off-site removal only; 2,522 sf.; workshop; 24 mons. vacant; missing siding, part of roof & all windows; contact Interior for info. on accessibility/removal

Tract 102–11A
516 South Canal St.
Natchez MS 39120
Landholding Agency: Interior
Property Number: 61201240027
Status: Unutilized
Directions: Natchez Nat'l Historic Park
Comments: Off-site removal only; 1,617 sf.; vacant 24 mons.; very poor conditions; no roof, exterior siding or windows; contact Interior for info. on accessibility/removal

Nebraska

Hummel Park Radio Station
11808 John Pershing Dr.
Omaha NE 68112
Landholding Agency: GSA
Property Number: 54201240005
Status: Surplus
GSA Number: 7–D–NE–0536
Comments: Bldg. 1,040 sf.; sits on 4.87 acres +\ −; support for antenna operations; good conditions

North Carolina

Tract 01–106
129 Green Acres Lane
Greensboro NC 27410
Landholding Agency: Interior
Property Number: 61201240015
Status: Unutilized
Directions: Guilford Courthouse Nat'l Military Park
Comments: Off-site removal only; 1,647 sf.; 24 mons. vacant; erosion on structure; rapidly worsening

Tract 01–134
121 Green Acres Lane
Greensboro NC 27410
Landholding Agency: Interior
Property Number: 61201240016
Status: Unutilized
Directions: Guilford Courthouse Nat'l Military Park
Comments: Off-site removal only; 1,385 sf.; 72 mons. vacant; erosion on structure; rapidly worsening; lead/asbestos identified

Tract 01–141
119 British Lakes Dr.
Greensboro NC 27410
Landholding Agency: Interior
Property Number: 61201240017
Status: Unutilized
Directions: Guilford Courthouse Nat'l Military Park
Comments: Off-site removal only; 988 sf.; 53 mons. vacant; extensive deterioration

Tract 01–144 A
3500 Battleground Ave.
Greensboro NC 27410
Landholding Agency: Interior
Property Number: 61201240018
Status: Unutilized
Directions: Guilford Courthouse Nat'l Military Park
Comments: Off-site removal only; 104 sf.; 53 mons. vacant; interior stripped out; conditions rapidly worsening; lead identified

Tract 01–144B
103 British Lakes Dr.
Greensboro NC 27410
Landholding Agency: Interior
Property Number: 61201240025
Status: Unutilized
Directions: Guilford Courthouse Nat'l Military Park
Comments: Off-site removal only; 630 sf.; extensive deterioration

Tract 01–162
107 British Lakes Dr.
Greensboro NC 27410
Landholding Agency: Interior
Property Number: 61201240026
Status: Unutilized
Directions: Guilford Courthouse Nat'l Military Park
Comments: Off-site removal only; 315 sf.; extensive deterioration; asbestos/lead identified; fuel leakage

Land

OREGON

BOR Land
Hyatt Lake Safe Property
Hyatt Reservoir Area
Ashland OR
Landholding Agency: Interior
Property Number: 61201240011
Status: Unutilized
Comments: 3.5 acres +/ −; timberland; practical access along eastern side; remote mountain property; winter seasons access can be very difficult

Unsuitable Properties

Building

Alabama

Building 853
25 South LeMay
Maxwell AFB AL 36112
Landholding Agency: Air Force
Property Number: 18201240002
Status: Underutilized
Comments: Located on active military installation; public access denied & no alternative method to gain access w/out compromising nat'l security
Reasons: Secured Area

Georgia

Tract 102–10; Water Pump House
2316 Akers Dr.
Atlanta GA 30339
Landholding Agency: Interior
Property Number: 61201240012
Status: Unutilized
Directions: Chattahoochee River Nat'l Recreation Area
Comments: Documented deficiencies; bldg. collapsing; 50% of roof missing; removal will most likely result in complete collapse
Reasons: Extensive deterioration

Tract 102–10; Ranger House Barn
2361 Akers Dr.
Atlanta GA 30339
Landholding Agency: Interior
Property Number: 61201240013
Status: Unutilized
Directions: Chattahoochee River Nat'l Recreation Area
Comments: Documented deficiencies; 50% of roof missing; trees fallen into bldg.—destroying the structural foundation; removal will most likely result in complete collapse
Reasons: Extensive deterioration

Tract 102–10; Ranger Oper. Bldg
2361 Akers Dr.
Atlanta GA 30339
Landholding Agency: Interior
Property Number: 61201240014
Status: Unutilized
Directions: Chattahoochee River Nat'l Recreation Area
Comments: Documented deficiencies; bldg. collapsing; 50% of roof missing; removal will most likely result in complete collapse
Reasons: Extensive deterioration

Idaho

Rural Parcels
Bureau of Reclamation
Burley ID 83318
Landholding Agency: GSA
Property Number: 54201240007
Status: Excess
GSA Number: 9–I–ID–0581
Comments: Parcels are landlocked btw. privately-owned properties where access would be denied to access the parcels; property prone to flooding; has not been corrected/contained
Reasons: Floodway, Not accessible by road

Mississippi

Tract 102–20B
24 Green St.
Natchez MS 39120
Landholding Agency: Interior
Property Number: 61201240019

Status: Unutilized
Directions: Natchez Nat'l Historical Park
Comments: Documented deficiencies; roof sagging; large tree has grown within structure; severe decay
Reasons: Extensive deterioration

Tract 102–12C
2 Rumble St.
Natchez MS 39120
Landholding Agency: Interior
Property Number: 61201240020
Status: Unutilized
Directions: Natchez Nat'l Historical Park
Comments: Documented deficiencies; roof has large holes/partially collapse; structure has severe dry rot; removal will most likely result in complete collapse
Reasons: Extensive deterioration

Tract 102–12B
1 Rumble St.
Natchez MS 39120
Landholding Agency: Interior
Property Number: 61201240021
Status: Unutilized
Directions: Natchez Nat'l Historical Park
Comments: Documented deficiencies; roof has large holes/partially collapse; structure has severe dry rot; removal will most likely result in completely collapse
Reasons: Extensive deterioration

Tract 102–09
512 South Canal St.
Natchez MS 39120
Landholding Agency: Interior
Property Number: 61201240024
Status: Unutilized
Directions: Natchez Nat'l Historical Park
Comments: Documented deficiencies; verge of collapsing; roof has partially collapsed; floors/walls are caved in; removal of property will most likely result in complete collapse
Reasons: Extensive deterioration

[FR Doc. 2012–27675 Filed 11–15–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5669–N–01]

Notice of Intent To Prepare an Environmental Impact Statement (EIS) for the Halletts Point Rezoning Project, Queens, NY

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of Intent to Prepare an EIS.

SUMMARY: This provides notice to the public, agencies, and Indian tribes that the City of New York—Department of Housing Preservation & Development (HPD), as the Responsible Entity in accordance with 24 CFR 58.2(a)(7), and the New York City Department of City Planning (DCP) serving as lead agency on behalf of the City Planning Commission (CPC) in accordance with City Environmental Quality Review (CEQR), Executive Order No. 91, and the New York State Environmental Quality Review Act (SEQRA), 6 NYCRR 617, intend to prepare a Draft Environmental Impact Statement (EIS) for the Halletts Point Rezoning Project. The EIS will be a joint National Environmental Policy Act (NEPA) and CEQR document. The EIS will satisfy requirements of SEQR (6 NYCRR 617.8) and CEQR (Sections 6–08 and 6–12 of Executive Order No. 91 of 1977 as amended), which require that state and local government agencies consider the environmental consequences of projects over which they have discretionary authority before acting on those projects. The proposed action is subject to NEPA because the proposed disposition of NYCHA property at Astoria Houses will require a federal approval from HUD under Section 18 of the U.S. Housing Act of 1937. This notice is in accordance with the Council on Environmental Quality (CEQ) regulations at 40 CFR parts 1500–1508.

A Draft EIS will be prepared for the proposed action described herein. Comments relating to the Draft EIS are requested and will be accepted by the contact person listed below. When the Draft EIS is completed, a notice will be sent to individuals and groups known to have an interest in the Draft EIS and particularly in the environmental impact issues identified therein. Any person or agency interested in receiving a notice and making comment on the Draft EIS should contact the person listed below up to 30 days following publication of this notice.

The EIS will be a NEPA document intended to satisfy requirements of federal environmental statutes. In accordance with specific statutory authority at Section 26 of the U.S. Housing Act (42 U.S.C. 1437x) and HUD's regulations at 24 CFR part 58 (Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities), HUD has provided for assumption of its NEPA authority and NEPA lead agency responsibility by HPD. The EIS will be a CEQR document intended to satisfy State and City environmental statutes as described above.

ADDRESSES: All interested agencies, tribes, groups, and persons are invited to submit written comments on the project named in this notice and on the Draft EIS to the contact person shown in this notice. The office of the contact person should receive comments and all comments so received will be considered prior to the preparation and distribution of the Draft EIS. Particularly solicited is information on reports or other environmental studies planned or completed in the project area, major issues that the EIS should consider, recommended mitigation measures, and alternatives associated with the proposed action. Federal agencies having jurisdiction by law, special expertise, or other special interest should report their interest and indicate their readiness to aid in the EIS effort as a ''Cooperating Agency.''

FOR FURTHER INFORMATION CONTACT: Patrick Blanchfield, Director of Environmental Planning, City of New York—Department of Housing Preservation & Development, 100 Gold Street, Room 9I–7, New York, NY 10038; Fax: (212) 863–5052; email: *blanchfp@hpd.nyc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

HPD, acting under authority of Section 26 of the United States Housing Act of 1937 and HUD's regulations at 24 CFR part 58, in cooperation with other interested agencies, will prepare an EIS to analyze potential impacts of the Halletts Point Rezoning Project.

The proposed new development would occur on approximately 9.65 acres in the Astoria neighborhood of Queens, New York, adjacent to the East River on the Halletts Point peninsula. The project site affected by the proposed actions comprises all or portions of eight tax lots: Block 913, Lot 1; Block 915, Lot 6; Block 916, Lots 1 and 10; Block 490, Lots 1, 11, 100, and 101. In total, there would be development of twelve buildings. Building 1 (Block 915, Lot 6) would be located on the block bounded by 27th Avenue to the south, 1st Street to the west, 26th Avenue to the north, and 2nd Street to the east. Buildings 2 through 5 (Block 490, Lots 1 and 11 and Block 916, Lots 1 and 10), including the mapped streetbeds of 26th and 27th Avenues between 1st Street and the East River, would be bounded by Hallet's Cove Playground (Block 490, Lot 100) to the south, the East River to the west, Whitey Ford Field (Block 913, Lot 1) to the north, and 1st Street to the east. The land on which Buildings 1 through 5would be constructed is privately owned. The privately owned portions of the project site consist of light industrial uses, vacant buildings, and open land used for temporary storage of vehicles and equipment.

Buildings 6 through 8 would be located within the existing New York City Housing Authority (NYCHA) Astoria Houses campus (Block 490, Lot 101) bounded by 27th Avenue, 1st Street, and 8th Street. The Astoria

Houses contains 22 six- and seven-story residential buildings on an approximately 27-acre campus with a total of 1,103 residential units, as well as surface parking lots, a day care center and senior center, basketball courts and playgrounds, walkways, and other landscaped areas. The campus was completed in 1951. The project requires the disposition of three parcels of public housing property within Astoria Houses to private developers for the construction of residential buildings with ground floor retail space. The existing uses on these sites, including parking and trash facilities, would be relocated elsewhere within the Astoria Houses campus. Additionally, the project would include a public easement on Astoria Houses property to allow for Astoria Boulevard, which currently terminates in two cul-de-sacs, to become a through street bisecting the Astoria Houses development.

In order to facilitate the proposed mixed-use development project, discretionary approvals from the City Planning Commission (CPC) would be required, including a number of zoning map changes; zoning text amendments; Large-Scale General Development (LSGD) special permits related to bulk; waterfront special permits, authorizations, and certifications; and mapping actions. These discretionary approvals are subject to review under the City's Uniform Land Use Review Procedure (ULURP), which requires a determination pursuant to CEQR. In addition to the proposed actions subject to CPC approval, the proposed project will require approval from other City, State, and Federal agencies, including disposition of public housing property (i.e., NYCHA property), use of development rights associated with lands underwater, jurisdictional transfer of parkland, and potential financing approval for affordable housing.

The proposed actions would facilitate the development of a total of approximately 2.67 million gross square feet (gsf) consisting of a total of approximately 2.15 million gsf of residential space (2,573 housing units including 2,161 market-rate and 412 affordable housing units); approximately 68,000 gsf of retail space; and approximately 1,253 garage parking spaces and 85 on-site surface parking spaces. The proposed project would also include approximately 96,000 sf (2.2 acres) of publicly accessible open space, including a waterfront esplanade along the East River and upland connections to 1st Street. In addition, it is expected that a number of street improvements and improvements to stormwater and sanitary sewer infrastructure would be provided to support the new development.

The new development on Buildings 1 through 5 would consist of seven new buildings with high-rise towers rising from low- to mid-rise bases. On Buildings 1 through 5, the proposed project would include residential, retail, and parking uses in low- to mid-rise bases and residential uses in high-rise towers. The low- to mid-rise bases would include one level of below-grade parking and up to four floors of additional parking above-grade. The above-grade parking would be located in the building cores, wrapped by residential and retail uses. The residential uses wrapping the parking garages would consist of townhouses below apartment units. Ground floor retail would line portions of 1st Street and the demapped portion of 27th Avenue, leading to the waterfront. An approximately 30,000 gsf retail space (designed for a supermarket use) would be located on the ground floor of Building 1. The parking garages in the building cores may be topped by a rooftop terrace for use by the buildings' tenants. The structures on Buildings 1 through 5 would range from 16 to 30 stories in height (160 to 300 feet). The low- to mid-rise bases would be a minimum of four stories and would range from approximately 40 to 80 feet in height. Buildings 6 and 7 would contain four new mid-rise buildings rising to a maximum height of 100 feet and 110 feet, respectively (10 and 11 stories). These structures would contain residential and retail uses and surface parking. Local retail uses would be located along 27th Avenue and surface parking lots would be provided at the rear of the buildings. In addition to the Applicant's proposed development program for Buildings 1 through 7, the proposed actions would facilitate a proposal by NYCHA to dispose of the site for Building 8 along Astoria Boulevard for development pursuant to a future RFP. Building 8 would contain one new high-rise building rising to a maximum height of 240 feet (24 stories). This structure would contain market-rate residential units and retail uses and garage parking. Local retail uses would be located on Astoria Boulevard at the intersection of 1st Street.

Alternatives to the Proposed Action

Alternatives to the proposed action will be analyzed in the EIS. Typically the alternatives section in an EIS is examines development options that would tend to reduce project-related impacts. The full range of alternatives will be defined when the full extent of the proposed project's impacts is identified, but at this time, it is anticipated that they will include the following:

Alternative 1—No Action Alternative

The No Action Alternative would analyze the continuation of uses on the site; therefore, existing buildings and tenants would remain at the project site and no new buildings or uses would be constructed.

Alternative 2—No Unmitigated Adverse Impacts Alternative

If significant adverse impacts are identified in the EIS, the No Adverse Impacts Alternative will describe the modifications to the project that would be needed to avoid any such impacts.

Other possible alternatives may be developed in consultation with DCP, NYCHA, and HPD during the EIS preparation process and may be suggested by the public during the scoping of the EIS.

B. Need for the EIS

The proposed project may constitute an action significantly affecting the quality of the human environment and an EIS will be prepared on this project in accordance with CEQR and NEPA. Responses to this notice will be used to: (1) Determine significant environmental issues, (2) identify data that the EIS should address, and (3) identify agencies and other parties that will participate in the EIS process and the basis for their involvement.

C. Scoping

A public EIS scoping meeting will be held on a date within the comment period and after at least 15 days of publishing this Notice of Intent. Notices of the scoping meeting will be published in the New York City Record and a newspaper of general circulation when the date has been determined. The EIS scoping meeting, which will also satisfy the scoping meeting requirement for CEQR, will provide an opportunity for the public to learn more about the project and provide input to the environmental process. At the meeting, an overview of the project will be presented and members of the public will be invited to comment on the proposed project and the scope of work for the environmental analyses in the EIS. Written comments and testimony concerning the scope of the EIS will be accepted at this meeting. In accordance with 40 CFR 1501.7, affected Federal, State, and local agencies, any affected Indian tribe, and other interested parties will be sent a scoping notice. In accordance with 24 CFR 58.59, the scoping hearing will be preceded by a

notice of public hearing published in the local news media at least 15 days before the hearing date.

D. Probable Environmental Effects

The following subject areas will be analyzed in the combined EIS for probable environmental effects: Land Use, Zoning, and Public Policy; Socioeconomic Conditions; Community Facilities and Services; Open Space; Shadows; Historic Resources; Urban Design/Visual Resources; Natural Resources (including a floodplain analysis); Hazardous Materials; Water and Sewer Infrastructure; Solid Waste and Sanitation Services; Energy; Transportation (including traffic, parking, pedestrian conditions, and transit); Air Quality; Greenhouse Gases; Noise; Neighborhood Character; Construction Impacts; Public Health; and Environmental Justice.

Questions may be directed to the individual named in this notice under the heading **FOR FURTHER INFORMATION CONTACT**.

Dated: November 8, 2012.

Mark Johnston,

Assistant Secretary for Community Planning and Development (Acting).

[FR Doc. 2012–27987 Filed 11–15–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2012–N273; FXIA16710900000P5–123–FF09A30000]

Endangered Species; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

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

ADDRESSES: Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358–2280; or email *DMAFR@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2280 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES.** If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. 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.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken.

III. Permit Applications

A. Endangered Species

Applicant: NOAA Fisheries/Pacific Islands Regional Office, Honolulu, HI; PRT–022729

The applicant requests reissuance of their permit to introduce from the high seas samples and/or whole carcasses of green sea turtle (*Chelonia mydas*), leatherback sea turtle (*Dermochelys coriacea*), hawksbill sea turtle (*Eretmochelys imbricata*), olive ridley sea turtle (*Lepidochelys olivacea*), Kemp's ridley sea turtle (*Lepidochelys kempii*), and short-tailed albatross (*Diomedea albatrus*) for the purpose of enhancement of the species through scientific research. This notice covers activities conducted by the applicant over a 5-year period.

Applicant: Dallas Zoo, Dallas, TX; PRT–89103A

The applicant requests a permit to re-import two captive bred Western gorillas (*Gorilla gorilla*) from Canada for the purpose of enhancement of propagation or survival of the species.

Applicant: Eugene & Janelle Herrmann, Shoreline, WA; PRT–226351

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for radiated tortoise (*Astrochelys radiata*) and spotted pond turtle (*Geoclemys hamiltonii*) to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Life Fellowship Bird Sanctuary, Seffner, FL; PRT–680582

The applicant requests renewal of their captive-bred wildlife registration

under 50 CFR 17.21(g) for the following families and species, to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Families:
- Psittacidae (*does not* include thick-billed parrots)

Species:
- Galapagos tortoise (*Chelonoidis nigra*)
- Radiated tortoise (*Astrochelys radiata*)

Applicant: Reid Park Zoo, Tucson, AZ; PRT–677573

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the following families, to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Families:
- Bovidae
- Cebidae
- Cercopithecidae
- Equidae
- Felidae (does not include jaguar, margay, or ocelot)
- Hominidae
- Hylobatidae
- Macropodidae
- Tapiridae
- Columbidae
- Rheidae
- Sturnidae (does not include *Aplonis pelzelni*)

Applicant: Springhill Wildlife Park, Calvert, TX; PRT–002692

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the leopard (*Panthera pardus*) to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Utah's Hogle Zoo, Salt Lake City, UT; PRT–680356

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the following families, to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Families:
- Cebidae
- Cercopithecidae
- Felidae
- Lemuridae
- Hominidae

Applicant: Festival Fun Parks LLC, dba Silver Springs Attraction, Silver Springs, FL; PRT–734011

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the following families and species, to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Families:
- Bovidae
- Cebidae
- Hylobatidae
- Lemuridae
- Tapiridae
- Ursidae
- Alligatoridae
- Crocodylidae (includes Gavials)
- Testudinidae

Applicant: Lionshare Farm Zoological LLC, Greenwich, CT; PRT–88756A

The applicant requests a permit to import one captive-bred male and one captive-bred female cheetah (*Acinonyx jubatus*) from the Hoedspruit Endangered Species Center, South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Global Health and Education Foundation, Danville, CA; PRT 71447A

The applicant requests a permit to export the following whole mount trophies; three dama gazelle (*Nanger dama*), one barasingha (*Rucervus duvaucelii*), one Eld's deer (*Rucervus eldii*), one Arabian oryx (*Oryx leucoryx*), two Scimitar horned oryx (*Oryx dammah*), and one addax (*Addax nasomaculatus*) culled from captive herds maintained in the state of Texas to Shanghai Science and Technology Museum, Shanghai, China, for the purpose of enhancement of the survival of the species.

Applicant: Richard Gracy, Dripping Springs, TX; PRT–76015A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*) and addax (*Addax nasomaculatus*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Richard Gracy, Dripping Springs, TX; PRT–76016A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*) and addax (*Addax nasomaculatus*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Sheila Emerson, Chatham, VA; PRT–83683A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the golden parakeet (*Guarouba guarouba*) to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Daniel Ray, Palmer, TX; PRT–84309A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Coleman Ranches Ltd., Ackerly, TX; PRT–83485A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*) and addax (*Addax nasomaculatus*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Coleman Ranches Ltd., Ackerly, TX; PRT–89067A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*) and addax (*Addax nasomaculatus*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: David Brigham, Austin, TX; PRT–85304A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Rafter O Ranch, Junction, TX; PRT–86456A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the barasingha (*Rucervus duvaucelii*), Eld's deer (*Rucervus eldii*), scimitar-horned oryx (*Oryx dammah*), Arabian oryx (*Oryx leucoryx*), addax (*Addax nasomaculatus*), dama gazelle (*Nanger dama*), and red lechwe (*Kobus*

leche) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Rafter O Ranch, Junction, TX; PRT–86676A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Campo De Rio Medio Ranch, Corpus Christi, TX; PRT–86465A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Hondeaux Oaks, LLC, Hondo, TX; PRT–86469A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the barasingha (*Rucervus duvaucelii*), Eld's deer (*Rucervus eldii*), scimitar-horned oryx (*Oryx dammah*), Arabian oryx (*Oryx leucoryx*), addax (*Addax nasomaculatus*), dama gazelle (*Nanger dama*), and red lechwe (*Kobus leche*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Hondeaux Oaks, LLC, Hondo, TX; PRT–86609A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*) and addax (*Addax nasomaculatus*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Double Arrow Bow Hunting, Harwood, TX; PRT–88038A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the barasingha (*Rucervus duvaucelii*) and scimitar-horned oryx (*Oryx dammah*), to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Double Arrow Bow Hunting, Harwood, TX; PRT–88044A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess barasingha (*Rucervus duvaucelii*) and scimitar-horned oryx (*Oryx dammah*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Still Fox Ranch, San Antonio, TX; PRT–88288A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the barasingha (*Rucervus duvaucelii*), Eld's deer (*Rucervus eldii*), scimitar-horned oryx (*Oryx dammah*), Arabian oryx (*Oryx leucoryx*), addax (*Addax nasomaculatus*), bontebok (*Damaliscus pygargus pygargus*), dama gazelle (*Nanger dama*), and red lechwe (*Kobus leche*), to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Still Fox Ranch, San Antonio, TX; PRT–88290A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*) and addax (*Addax nasomaculatus*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Circle E Ranch, Bedias, TX; PRT–88649A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the barasingha (*Rucervus duvaucelii*), scimitar-horned oryx (*Oryx dammah*), addax (*Addax nasomaculatus*), dama gazelle (*Nanger dama*), and red lechwe (*Kobus leche*), to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Circle E Ranch, Bedias, TX; PRT–88651A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess barasingha (*Rucervus duvaucelii*), scimitar-horned oryx (*Oryx dammah*), addax (*Addax nasomaculatus*), and red lechwe (*Kobus leche*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Jonathan Stewart, Albuquerque, NM; PRT–88840A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the golden parakeet (*Guarouba guarouba*) to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Wild Wonders Zoofari, Bonsall, CA; PRT–88777A

The applicant requests a permit to import one captive-bred female cheetah (*Acinonyx jubatus*) from the De Wildt Cheetah Breeding Center, South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Living Treasures Wild Animal Park, New Castle, PA; PRT–88909A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species, to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Species:

- Ring-tailed lemur (*Lemur catta*)
- Black and white ruffed lemur (*Varecia variegata*)
- Red ruffed lemur (*Varecia rubra*)
- Cotton-top tamarin (*Saguinus oedipus*)
- Lar gibbon (*Hylobates lar*)
- Leopard (*Panthera pardus*)
- Grevy's Zebra (*Equus grevyi*)
- Asian Wild Ass (*Equus hemionus*)
- South American tapir (*Tapirus terrestris*)
- Red lechwe (*Kobus leche*)
- Salmon-crested cockatoo (*Cacatua moluccensis*)
- Radiated tortoise (*Astrochelys radiata*)
- Galapagos tortoise (*Chelonoidis nigra*)

Applicant: Clifton Lincoln, Dartmouth, MA; PRT–88901A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the radiated tortoise (*Astrochelys radiata*) to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Azlin Taxidermy, Clute, TX; PRT–79576A

The applicant request a permit to export the sport-hunted trophy of one addax *(Addax nasomaculatus)* and one scimitar horned oryx *(oryx dammah)* culled from a captive herd in the state of Texas, for the purpose of enhancement of the survival of the species.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Dale Watkins, Phoenix, AZ; PRT–89174A

Applicant: Thomas Hoffmann, Little Rock, AR; PRT–89172A

Applicant: Armand Brachman, Corcoran, MN; PRT–89040A

Applicant: Brittany Phillips, Houston, TX; PRT–78891A

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2012–27937 Filed 11–15–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Renewal of Agency Information Collection for Class III Gaming; Tribal Revenue Allocation Plans; Gaming on Trust Lands

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of submission to OMB.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Assistant Secretary—Indian Affairs is submitting to the Office of Management and Budget (OMB) a request for renewal for the collection of information for Class III Gaming Procedures authorized by OMB Control Number 1076–0149, Tribal Revenue Allocation Plans authorized by OMB Control Number 1076–0152, and Gaming on Trust Lands Acquired After October 17, 1988 authorized by OMB Control Number 1076–0158. These information collections expire November 30, 2012.

DATE: Interested persons are invited to submit comments on or before December 17, 2012.

ADDRESSES: You may submit comments on the information collections to the Desk Officer for the Department of the Interior at the Office of Management and Budget, by facsimile to (202) 395–5806 or you may send an email to: *OIRA_Submission@omb.eop.gov.* Please send a copy of your comments to Nancy Pierskalla, U.S. Department of the Interior, Office of Indian Gaming, 1849 C Street NW., Mail Stop 3657, Washington, DC 20240; email: *Nancy.Pierskalla@bia.gov.*

FOR FURTHER INFORMATION CONTACT: Nancy Pierskalla, (202) 219–4066. You may review the information collection requests online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Assistant Secretary—Indian Affairs is seeking comments on the Class III Gaming Procedures, Tribal Revenue Allocation Plans, and Gaming on Trust Lands Acquired after October 17, 1988, as we prepare to renew these collections as required by the Paperwork Reduction Act of 1995. This information is necessary for the BIA, Office of Indian Gaming, to ensure that the applicable requirements for IGRA, 25 U.S.C. 2701 et seq., are met with regard to Class III gaming procedures, tribal revenue allocation plans, and applications for gaming on trust lands acquired after October 17, 1988.

II. Request for Comments

The BIA requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) Ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. 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.

III. Data

OMB Control Number: 1076–0149.

Title: Class III Gaming Procedures, 25 CFR 291.

Brief Description of Collection: The collection of information will ensure that the provisions of IGRA and other applicable requirements are met when federally recognized tribes submit Class III procedures for review and approval by the Secretary of the Interior. Sections 291.4, 291.10, 291.12 and 291.15 of 25 CFR 291, Class III Gaming Procedures, specify the information collection requirement. An Indian tribe must ask the Secretary to issue Class III gaming procedures. The information to be collected includes: The name of the tribe, the name of the State, tribal documents, State documents, regulatory schemes, the proposed procedures, and other documents deemed necessary.

Type of Review: Extension without change of currently approved collection.

Respondents: Federally recognized Indian tribes.

Number of Respondents: 12.

Estimated Time per Response: 320 hours.

Estimated Total Annual Hour Burden: 3,840 hours.

* * * * *

OMB Control Number: 1076–0152.

Title: Tribal Revenue Allocation Plans, 25 CFR Part 290.

Brief Description of Collection: An Indian tribe must ask the Secretary to approve a tribal revenue allocation plan. In order for Indian tribes to distribute net gaming revenues in the form of per capita payments, information is needed by the BIA to ensure that tribal revenue allocation plans include (1) assurances that certain statutory requirements are met, (2) a breakdown of the specific used to which net gaming revenues will be allocated, (3) eligibility requirements for participation, (4) tax liability notification, and (5) the assurance of the protection and preservation of the per capita share of minors and legal incompetents. Sections 290.12, 290.17, 290.24 and 290.26 of 25 CFR Part 290, Tribal Revenue Allocation Plans, specify the information collection

requirement. The information to be collected includes: The name of the tribe, tribal documents, the allocation plan, and other documents deemed necessary.

Type of Review: Extension without change of currently approved collection.

Respondents: Federally recognized Indian tribes.

Number of Respondents: 20.

Estimated Time per Response: 100 hours.

Estimated Total Annual Hour Burden: 2,000 hours.

* * * * *

OMB Control Number: 1076–0158.

Title: Gaming on Trust Lands Acquired After October 17, 1988, 25 CFR part 292.

Brief Description of Collection: The collection of information will ensure that the provisions of IGRA, Federal law, and the trust obligations of the United States are met when federally recognized tribes submit an application under 25 CFR part 292. The applications covered by this OMB Control No. are those seeking a secretarial determination that a gaming establishment on land acquired in trust after October 17, 1988 would be in the best interest of the Indian tribe and its members, and would not be detrimental to the surround community.

Type of Review: Extension without change of currently approved collection.

Respondents: Federally recognized Indian tribes.

Number of Respondents: 2.

Estimated Time per Response: 1,000 hours.

Frequency of Response: Once.

Estimated Total Annual Hour Burden: 2,000 hours.

Dated: November 8, 2012.

John Ashley,

Acting Assistant Director for Information Resources.

[FR Doc. 2012–27902 Filed 11–15–12; 8:45 am]

BILLING CODE 4310–4M–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAD07000 L12200000 PA0000]

Notice of Closure of Airport Mesa/Carizzo Creek Shooting Area in Eastern San Diego County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) has closed approximately 210 acres of public land described as the Airport Mesa/Carrizo Creek shooting area located in eastern San Diego County, California. The closure order prohibits recreational shooting and target practice. The use of firearms will continue to be allowed for hunting consistent with California Department of Fish and Game regulations and seasons. This closure order is necessary in order to protect U.S. Border Patrol agents as they perform their duties along the top of Airport Mesa.

DATES: The closure order is effective as of June 19, 2012, until June 19, 2014.

FOR FURTHER INFORMATION CONTACT: Daniel Steward, BLM El Centro Field Office, 1661 S. 4th St., El Centro, CA 92243, telephone 760–337–4400.

SUPPLEMENTARY INFORMATION: The BLM recognizes that recreational target shooting is a valid use of public lands, and seeks to balance this with the need to provide for public safety. The BLM El Centro Field Office prepared an environmental assessment (EA) for this temporary closure (DOI–BLM–CA–D070–2012–0058–EA). This 2-year temporary closure will allow the BLM to proceed through a land use plan amendment process and utilize public input to consider a permanent closure of the area and options for alternative shooting areas.

The purpose of this closure order is to protect persons, property, and public land and resources, and the protection of U.S. Border Patrol agents as they perform their duties along the top of Airport Mesa.

The closure order is in accordance with provisions of the Federal Land Policy and Management Act of 1976 (Pub. L. 94–579, 90 stat. 2743, 43 U.S.C. 1701 *et. seq.*) and 43 CFR 8360.0–7.

The order closes the following public lands in eastern San Diego County to recreational shooting and target practice:

San Bernardino Base and Meridian,

T. 18 S., R. 8 E.,
Sec. 3, S½SW¼SE¼ and S½SE¼SE¼;
Sec. 10, lot 9, N½NE¼, and SE¼NE¼;
Sec. 11, lot 12 and SW¼NW¼.

The areas described aggregate 230.20 acres, according to the official plats of the surveys of the said lands, on file in the Bureau of Land Management.

The following persons are exempt from the identified restrictions:

(1) Federal, State, or local law enforcement officers, while engaged in the execution of their official duties;

(2) BLM personnel or their representatives while engaged in the execution of their official duties;

(3) Any member of an organized rescue, firefighting force, or emergency medical services organization while in the performance of their official duties;

(4) Any person in receipt of a written authorization of exemption obtained from the authorized officer; and

(5) Any person with a legal California hunting license in their possession and in the legal act of hunting.

This Notice and maps of the restricted area will be clearly posted at main entry points to the Airport Mesa shooting area and will also be available at the BLM El Centro Field Office.

Authority: 43 CFR 8364.1; 43 CFR 8360.0–7.

Margaret L. Goodro,

Field Manager.

[FR Doc. 2012–27932 Filed 11–15–12; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAC07000 L13100000 EI0000 LXSIGEOT0000]

Notice of Availability of the Draft Environmental Impact Statement and Environmental Impact Report for the Casa Diablo IV Geothermal Development Project, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA); the Federal Land Policy and Management Act of 1976, as amended; and the California Environmental Quality Act of 1970 (CEQA); the Bureau of Land Management (BLM) Bishop Field Office, Bishop, California; the United States Forest Service (USFS) Inyo National Forest; and the Great Basin Unified Air Pollution Control District (GBUAPCD) (a California state agency) have prepared a Draft Environmental Impact Statement (EIS)/Environmental Impact Report (EIR) for the proposed Casa Diablo IV Geothermal Development Project near the Town of Mammoth Lakes in Mono County, California. This notice announces the opening of the public comment period.

DATES: To ensure comments will be considered, comments on the Draft EIS/EIR must be received within 60 days following the date the Environmental Protection Agency publishes this Notice of Availability in the **Federal Register**. The BLM and cooperating agencies will announce future meetings or hearings and any other public involvement activities at least 15 days in advance

through public notices, media releases, and/or mailings.

ADDRESSES: Written comments on the Draft EIS/EIR for the Casa Diablo IV Geothermal Development Project may be submitted by any of the following methods:

- *Web site: http://www.blm.gov/ca/st/en/fo/bishop.html.*
- *Email: cabipubcom@ca.blm.gov;* Subject: Casa Diablo IV Geothermal Development Project Draft EIS/EIR.
- *Fax:* 760–872–5050.
- *Mail:* BLM, Bishop Field Office, 351 Pacu Lane, Suite 100, Bishop, CA 93514; Attn: Casa Diablo IV Geothermal Development Project Draft EIS/EIR, c/o Collin Reinhardt, Project Manager.

Oral comments may be submitted to Margie DeRose via telephone at 760–873–2424 or in person at the Inyo National Forest, Supervisor's Office, 351 Pacu Lane, Suite 200, Bishop, CA 93514. Oral comments may also be submitted at any public meeting that is designed to elicit public comments.

Copies of the Draft EIS/EIR for the Casa Diablo IV Geothermal Development Project are available at the Bishop Field Office at the above address and at the Mono County Library at 400 Sierra Park Road, Mammoth Lakes, California.

FOR FURTHER INFORMATION CONTACT: Collin Reinhardt, Project Manager, telephone 760–872–5024; address 351 Pacu Lane, Suite 100, Bishop, CA 93514; email *creinhardt@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Draft EIS/EIR analyzes the potential impacts of authorizing the proposed Casa Diablo IV Geothermal Development Project near the Town of Mammoth Lakes in Mono County, California. In accordance with the Geothermal Steam Act of 1970, as amended (30 U.S.C. 1001 *et seq.*), the BLM Bishop Field Office is the lead Federal agency responsible for permitting the proposed project and for completing the required environmental analysis under NEPA. The USFS Inyo National Forest is a cooperating Federal agency. The GBUAPCD is the lead State agency responsible for permitting the proposed project and for completing the required environmental analysis under the CEQA.

The purpose and need for action is to respond to an application to construct and operate the proposed Casa Diablo IV Geothermal Development Project on Federal geothermal leases administered by the BLM Bishop Field Office. The proposed project would be located on Inyo National Forest lands and adjacent private lands within portions of Federal geothermal leases CACA–11667, CACA–14407, CACA–14408, and CACA–11672. The leases proposed for development are part of an existing geothermal unit, which is currently providing energy sufficient to power three operating geothermal plants.

The applicant's proposed action includes the construction of a new 33-MW binary geothermal power plant, which would be the fourth geothermal plant in the vicinity; up to 16 wells for production and reinjection, drilled to an approximate 1,600- to 2,500-ft depth; and associated pipelines. A 650-ft long transmission line is proposed to interconnect the new power plant to the existing Southern California Edison (SCE) substation at Substation Road. The proposed Casa Diablo IV plant, access roads, well pads, pipelines and transmission line would occupy approximately 80 acres. Of the 16 proposed production/injection well locations, 14 were previously analyzed and approved by the BLM as exploration wells in EA–170–02–15 (2001) and EA–170–05–04 (2005). Three of these exploration wells have already been drilled as of the time of the publication of this notice. The proposed well field contains two existing production wells and associated pipelines that currently serve the three existing power plants in the area. The BLM published a Notice of Intent (NOI) to prepare a joint EIS/EIR on March 25, 2011, in the **Federal Register** (76 FR 16806). Publication of the NOI initiated a public scoping period, which included two public scoping meetings. Comments received through the scoping process and consultations carried out pursuant to Section 106 of the National Historic Preservation Act and other Federal mandates identified the following issues and concerns that have been incorporated into the Draft EIS/EIR: Potential effects on air quality, biological resources including vegetation and wildlife, cultural resources and Native American concerns, public health and safety, recreation resources, and surface and groundwater resources.

Alternatives identified and evaluated in the Draft EIS/EIR include: Alternative 1, the applicant's proposed action which is outlined above; Alternative 2, which considers an alternative location for the proposed power plant; Alternative 3, which considers alternative pipeline alignments in Basalt Canyon and slightly alters the location of one proposed well; and Alternative 4, the no action alternative which would limit geothermal development activities on the affected leases to those previously authorized by the BLM. In accordance with NEPA (40 CFR 1502.14(e)), the BLM and USFS have identified Alternative 3 as the preferred alternative. The GBUAPCD has also identified Alternative 3 as the ''environmentally superior alternative'' pursuant to the CEQA (14 C.C.R. 15126.6(e)(2)).

Public comments and information submitted, including names, street addresses, and email addresses of persons who submit comments, will be available for public review at the above address during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

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.

Authority: 40 CFR 1506.6, 40 CFR 1506.10.

Bernadette Lovato,

Bishop Field Manager.

[FR Doc. 2012–27768 Filed 11–15–12; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWYR05000.L51100000.GN0000. LVEMK10CW370–WYW–140590]

Notice of Availability of the Draft Environmental Impact Statement for the Gas Hills In Situ Recovery Uranium Project, Fremont and Natrona Counties, WY

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), the Bureau of Land Management (BLM) has prepared a Draft Environmental Impact Statement (EIS) for the Gas Hills In Situ Recovery (ISR) Uranium Project and by this notice

is announcing the opening of the comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Gas Hills ISR Uranium Project draft EIS within 45 days following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**. The BLM will announce future meetings and any other public involvement activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: Comments on the Gas Hills ISR Uranium Project may be submitted by any of the following methods:

- *Web site: www.blm.gov/wy/st/en/info/NEPA/documents/lfo/gashills.html.*
- *Email: Gas_Hills_Uranium_EIS_WY@blm.gov.*
- *Fax: 307–332–8444.*
- *Mail or hand delivery:* Bureau of Land Management, Attn: Kristin Yannone, Lander Field Office, 1335 Main Street, Lander, WY 82520.

Documents pertinent to this proposal may be examined at the following BLM offices:

- Lander Field Office, 1335 Main Street, Lander, Wyoming 82520;
- High Plains District Office, 2987 Prospector Drive, Casper, Wyoming 82604;
- Wind River/Bighorn Basin District Office, 101 South 23rd, Worland, Wyoming 82401; and
- Wyoming State Office, 5353 Yellowstone Road, Cheyenne, Wyoming 82009; Interested persons may also view the documents online at: *http://www.blm.gov/wy/st/en/info/NEPA/documents/lfo/gashills.html.*

FOR FURTHER INFORMATION CONTACT: Kristin Yannone, Project Manager, telephone: 307–332–8400; address: mail: 1335 Main Street, Lander, WY 82520; email: *Gas_Hills_Uranium_EIS_WY@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The applicant, Power Resources, Inc. (PRI), a wholly owned subsidiary of Cameco US Holdings, Inc., doing business as Cameco Resources, has filed a plan of operations pursuant to 43 CFR subpart 3809 regulations to construct uranium recovery facilities including: Waste water disposal facilities; access roads; pipelines and utility lines; delineation, injection and production wells; and improvement of one existing and construction of one new equipment-housing satellite facility used in the ISR process. The project would be located in eastern Fremont and western Natrona counties, approximately 45 road miles east of Riverton, Wyoming, and approximately 65 road miles west of Casper, Wyoming.

The boundary of the Gas Hills Project Area (GHPA) encompasses approximately 8,500 acres, of which approximately 1,300 acres would incur surface disturbance from the proposed project. Approximately 15 percent of the surface within the GHPA has been disturbed by past mining and exploration activities. This disturbance includes an existing warehouse structure (the Carol Shop) and access road (the AML Road).

If the proposed mining operation is not approved, existing reclamation responsibilities under the No-Action Alternative would require Cameco to remove and reclaim the existing disturbance once ongoing exploratory activities are concluded. This reclamation would include a minimum of 26.7 acres for the removal of the Carol Shop. If no other use for the existing 1.8 miles of road were identified, it would need to be removed and reclaimed, an additional 10.9 acres. Additional notice-level activities resulting from exploration would need to be reclaimed as well for a total of 40.2 acres. The use of the road and Carol Shop have been allowed during active exploration in the area and currently maintained mill-site claims.

The Plan of Operations identifies five production areas, or mine units, with subsurface ore bodies within the Wind River Formation for ISR extraction. Construction, operation, groundwater restoration, and surface reclamation of five mine units would occur during an estimated period of approximately 25 years. At the end of the project, all surface structures would be removed, and all disturbances would be re-contoured and reclaimed. In accordance with Nuclear Regulatory Commission (NRC) regulations, any radiological contaminated wastes, including any processing pipe and equipment as well as solid residue or liners from evaporation ponds, would be removed from the Project Area and disposed of in accordance with regulations.

The Draft EIS addresses the direct, indirect, and cumulative impacts of the Proposed Action and two alternatives including the No Action Alternative and the Resource Protection Alternative.

The Proposed Action Alternative is the project proposed by Cameco as identified by the Plan of Operations, the NRC license application, and the Wyoming Department of Environmental Quality Land Quality Division's Mine Permit Application #687.

Under the Resource Protection Alternative, the project would utilize the same ISR process occurring over the same time period as the Proposed Action, but modifications to the project would reduce surface disturbance and heavy truck transportation. Modifications would include on-site resin processing to produce slurry, submittal of an annual development plan, construction timing constraints, a disturbance offset for an additional satellite facility, reduced number of evaporation ponds, enhanced reclamation, and power line burial.

The Notice of Intent to prepare an EIS was published in the **Federal Register** on September 7, 2010 (75 FR 54384). Key issues identified during scoping included: Alternative reclamation and restoration criteria and timing; alternative transportation routes; alternative wastewater treatment, storage, and disposal; potential groundwater restoration issues; enforcement of reclamation or restoration; impacts to area recreation, grazing, and hunting; impacts to surface waters from runoff; the potential to impact sage-grouse, migratory birds, mule deer, and antelope; adequate opportunity for comment by the public; and adequate analysis of cumulative impacts.

The public is encouraged to comment on any of the draft alternatives. The BLM asks that those submitting comments make them as specific as possible with reference to chapters, page numbers, and paragraphs in the draft EIS document. Comments that contain only opinions or preferences will not receive a formal response; however, they will be considered and included as part of the BLM decision-making process. The most useful comments will include new technical or scientific information, identification of data gaps in the impact analysis, or technical or scientific rationale for opinions or preference.

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 may ask us in your comment to withhold your personal identifying information from public review, we

cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10)

Donald A. Simpson,

State Director, Wyoming.

[FR Doc. 2012–27771 Filed 11–15–12; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[L51010000.FX0000.LVRWA11A2990. LLAZP02000.XXX; AZA35079]

Notice of Availability of the Draft Environmental Impact Statement for the Proposed Sun Valley to Morgan 500/230kV Transmission Line Project (Formerly Called TS–5 to TS–9), Arizona, and the Draft Bradshaw-Harquahala Resource Management Plan Amendment and Notice of Public Hearings

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) has prepared a Draft Environmental Impact Statement (EIS) for the Proposed Sun Valley to Morgan 500/230-kilovolt (kV) Transmission Line Project (Project) and Draft Bradshaw-Harquahala Resource Management Plan (RMP) amendment for the BLM Hassayampa Field Office, and by this notice is announcing the opening of the comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Draft EIS and Draft RMP amendment within 90 days following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**. The BLM will hold public hearings on the Draft EIS and Draft RMP amendment on December 11, 2012, in Peoria, Arizona; December 12 in Wittmann, Arizona; and December 13 in Phoenix, Arizona. All of the public hearings will begin with an open house at 5:30 p.m., followed by a presentation at 6 p.m. Further details about these hearings and any other public involvement activities will be published at least 15 days in advance through public notices, media releases, and/or mailings.

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

- *Web site: http://www.blm.gov/az/st/en.html.*
- *Email: SunValley-Morgan@blm.gov.*
- *Fax:* 623–580–5580.
- *Mail:* BLM Phoenix District Office, Hassayampa Field Office, Attention: Joe Incardine/Sun Valley-Morgan Project, 21605 North 7th Avenue, Phoenix, Arizona 85207–2929.

Copies of the Draft EIS and Draft RMP amendment are available in the BLM Hassayampa Field Office at the above address.

FOR FURTHER INFORMATION CONTACT: Joe Incardine, BLM National Project Manager, telephone 801–539–4118; address BLM Phoenix District Office, Hassayampa Field Office, 21605 North 7th Avenue, Phoenix, Arizona 85027–2929; email *jincardi@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Arizona Public Service Company (APS) submitted a right-of-way (ROW) application to construct, operate, and maintain a 500/230kV overhead transmission line from the Sun Valley Substation to the Morgan Substation in Maricopa County. The Project would be located on a combination of BLM-managed lands, Arizona State Trust lands, and private lands in northern Maricopa County, northwest of Phoenix, Arizona. The Project is an overhead transmission line, approximately 38 miles long, on monopole structures. The BLM-managed lands within the Project area are managed under the existing Bradshaw-Harquahala Resource Management Plan (RMP).

Environmental and social concerns and issues were identified through internal and public scoping. The issues addressed in the EIS that shaped the Project's scope and alternatives include:

- Need and reliability;
- RMP amendment;
- Project design features, mitigation measures, and alternatives;
- Air and climate;
- Biological resources;
- Cultural resources;
- Health and safety;
- Recreation;
- Socioeconomic;
- Scenic/Visual; and
- Transportation and traffic.

In addition to the Proposed Action and No Action Alternative, three Action Alternative routes and one sub-alternative route (as proposed by the Arizona State Land Department) were analyzed in detail in the Draft EIS. As proposed, the Project would require an RMP amendment because the current RMP requires high-voltage transmission lines crossing BLM-managed lands to be within designated utility corridors, and a utility corridor for the proposed ROW on public lands was not established in the current RMP, the proposed action is within a designated transportation corridor. In addition, the Visual Resource Management (VRM) class designation would need to be amended from Class III to Class IV for those BLM-managed lands where views would be dominated by the transmission line, and thus would not meet the objectives of the current VRM designation. The VRM class would also be changed for those BLM-managed public lands north and south of State Route (SR) 74 surrounding the proposed transmission line ROW (i.e., the existing transportation corridor north of SR 74 and the key-shaped piece south of SR 74) in order to avoid creating narrow linear strips with different VRM classes.

An interdisciplinary approach was used to develop the Draft EIS in order to consider the variety of resource issues and concerns identified. An amendment to the Bradshaw Harquahala RMP would be based upon the following planning criteria:

- The amendment will be completed in compliance with FLPMA, NEPA, and all other relevant Federal laws, Executive Orders, and management policies of the BLM;
- Where existing planning decisions are still valid, those decisions will remain unchanged and be incorporated into the new amendment; and
- The amendment will recognize valid existing rights.

The BLM has identified a modified Proposed Action route crossing BLM-managed lands as the Agency Preferred Alternative route for the proposed transmission line, including best management practices and mitigative measures. Mitigative measures could consist of minor route deviations for micro-siting of structures or segments of the line at the time of route engineering to reduce impacts to visual and other sensitive resources. However, mitigative measures would still allow for the transmission line route to remain within the Arizona Corporation Commission-certificated route.

Under the Agency Preferred Alternative, the BLM would amend the RMP to:

- Designate a 200-foot-wide single-use utility corridor on public lands managed by the BLM north of SR 74;

• Designate a multi-use utility corridor on 1,021 acres of public lands managed by the BLM south of SR 74 to address potential future BLM management considerations; and

• Change the existing VRM class designations of 2,362 acres north of SR 74 and 1,013 acres south of SR 74 from Class III to Class IV to allow for the newly established utility corridors.

Once the RMP were amended, the BLM would approve a 200-foot-wide ROW within the newly designated utility corridor on public lands managed by the BLM north of SR 74 and within the existing designated utility corridor northeast of the Sun Valley Substation.

The BLM will utilize and coordinate the NEPA comment period to satisfy the public involvement process for Section 106 of the National Historic Preservation Act (16 U.S.C. 470) as provided for in 36 CFR 800.2(d)(3). Native American tribal consultations will be conducted in accordance with policy, and tribal concerns, including impacts on Indian trust assets, will be given due consideration. Federal, State, and local agencies, along with other stakeholders that may be interested or affected by the BLM's decisions on this project, are invited to participate in the public comment process. The BLM has determined that public hearings to solicit comments on the Draft EIS are necessary. Accordingly, the BLM invites all interested persons to participate in one of the following public hearings:

Public Hearing Locations

Centennial High School, 14388 North 79th Avenue, Peoria, Arizona 85381—December 11, 2012

Nadaburg Elementary School, 21419 West Dove Valley Road, Wittmann, Arizona 85361—December 12, 2012

BLM National Training Center, 9828 North 31st Avenue, Phoenix, Arizona 85051—December 13, 2012

All public hearings begin with an open house at 5:30 p.m., followed by a presentation at 6 p.m.

Interested parties are invited to present oral statements at the hearings. For information on facilities or services for persons with disabilities or to request special assistance at the hearing, contact Ellen Carr at 480–629–4705 or email *ellen.carr@galileoaz.com* or in writing at 4700 South McClintock Drive, Tempe, Arizona 85282, at least 5 business days before the date of the hearing.

The hearings will be conducted in accordance with 455 DM 1 and the BLM NEPA Handbook by a representative designated by the BLM.

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.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2.

Raymond Suazo,

State Director.

[FR Doc. 2012–27929 Filed 11–15–12; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000–L63100000–HD0000–13XL1165AF: HAG13–0048]

Filing of Plats of Survey: Oregon/Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management, Oregon State Office, Portland, Oregon, 30 days from the date of this publication.

Willamette Meridian

Oregon

T. 28 S., R. 3 W., accepted October 25, 2012
T. 21 S., R. 7 W., accepted October 25, 2012
T. 17 S., R. 7 W., accepted October 25, 2012
T. 3 N., R. 3 W., accepted October 25, 2012
T. 25 S., R. 1 W., accepted October 25, 2012
T. 27 S., R. 2 W., accepted October 25, 2012
T. 8 S., R. 20 E., accepted November 2, 2012

Washington

T. 36 N., R. 7 E., accepted October 25, 2012
T. 30 N., R. 7 W., accepted November 6, 2012

ADDRESSES: A copy of the plats may be obtained from the Public Room at the Bureau of Land Management, Oregon State Office, 333 SW. 1st Avenue, Portland, Oregon 97204, upon required payment.

FOR FURTHER INFORMATION CONTACT: Kyle Hensley, (503) 808–6132, Branch of Geographic Sciences, Bureau of Land Management, 333 SW. 1st Avenue, Portland, Oregon 97204. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: A person or party who wishes to protest against this survey must file a written notice with the Oregon State Director, Bureau of Land Management, stating that they wish to protest. A statement of reasons for a protest may be filed with the notice of protest and must be filed with the Oregon State Director within thirty days after the protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved. 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.

Timothy J. Moore,

Acting, Chief Cadastral Surveyor of Oregon/Washington.

[FR Doc. 2012–27822 Filed 11–15–12; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–MWR–CR–11394; PPMWUGRR00.PPMRSCR1Y.CU0000]

60-Day Notice of Intention To Request Clearance of Collection of Information; Opportunity for Public Comment

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This IC is scheduled to expire on May 31, 2013. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

DATES: To ensure we are able to consider your comments, we must receive them on or before January 15, 2013.

ADDRESSES: Please send your comments on the IC to Madonna L. Baucum, Information Collection Clearance Officer, National Park Service, 1201 I Street NW., MS 1242, Washington, DC 20005 (mail); or *madonna_baucum@nps.gov* (email). Please reference OMB Control Number ''1024–0232, National Park Service National Underground Railroad Network to Freedom'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Diane Miller, National Manager, National Underground Railroad Network to Freedom Program, National Park Service, Midwest Regional Office, 601 Riverfront Dr., Omaha, Nebraska 68102; via fax at (402) 661–1982; or via email at *diane_miller@nps.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Public Law 105–23, National Underground Railroad Network to Freedom Act of 1998, requires the establishment of a network justifiably associated with the Underground Railroad. The Network is designed to be a collection of sites, facilities, and programs, both governmental and non-governmental, around the United States with a verifiable association with the historic Underground Railroad movement. The National Park Service National Underground Railroad Network to Freedom application form is completed by Federal agencies, State Historic Preservation Offices, other State agencies, local governments, organizations, and individuals. We use the information collected to determine eligibility to become part of the Network. We are requesting a 3-year term of approval for this information collection activity.

Respondents must verify associations and characteristics through descriptive texts that are the result of historical research. Evaluations are based on subjective analysis of the information provided, which often includes copies of rare documents and photographs. Much of the information is submitted in electronic format, but, at the present time, there is no automated way to gather all of the required information.

II. Data

OMB Control Number: 1024–0232.

Title: National Park Service National Underground Railroad Network to Freedom.

Form(s): National Park Service National Underground Railroad Network to Freedom application form.

Type of Request: Extension of a currently approved collection of information.

Description of Respondents: State, tribal, and local governments; Federal agencies; businesses; non-profit organizations; and individuals.

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion.

Estimated Number of Annual Respondents: 45.

Completion Time per Response: 25 hours.

Estimated Total Annual Burden Hours: 1,125.

Estimated Annual Nonhour Burden Cost: None.

III. Comments

We invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden to respondents, including use of automated information techniques or other forms of information technology.

Please note that the comments submitted in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. 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 it will be done.

Dated: November 6, 2012.

Madonna L. Baucum,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2012–27829 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–EH–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–11613; 2200–1100–665]

Notice of Inventory Completion: U.S. Department of Energy Oak Ridge Office, Oak Ridge, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Energy Oak Ridge Office has completed an inventory of human remains and associated funerary object, in consultation with the appropriate Indian tribes, and has determined that there is a cultural affiliation between the human remains and the associated funerary object and a present-day Indian tribe. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary object may contact the U.S. Department of Energy Oak Ridge Office. Repatriation of the human remains and associated funerary object to the Indian tribe stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains and associated funerary object should contact the U.S. Department of Energy Oak Ridge Office at the address below by December 17, 2012.

ADDRESSES: Katatra Vasquez, U.S. Department of Energy Oak Ridge Office, P.O. Box 2001, SE–32, Oak Ridge, TN 37831, telephone (865) 576–0835.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary object in the possession of the U.S. Department of Energy Oak Ridge Office. The human remains and associated funerary object were removed from Roane County, TN.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary object. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the U.S.

Department of Energy Oak Ridge Office professional staff in consultation with representatives of the Cherokee Nation; Chickasaw Nation; Choctaw Nation of Oklahoma; Eastern Band of Cherokee; Eastern Shawnee Tribe of Oklahoma; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); Quapaw Tribe of Indians; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

History and Description of the Remains

In July 1981, human remains representing, at minimum, one individual were removed from site 40RE86 in Roane County, TN, as a result of an archeological investigation. The site dates to the Mississippian period (specifically, the eastern Tennessee Dallas Phase, A.D. 1300 to 1600). Based on the associated pottery found at the site, the human remains date to about A.D. 1400. No known individuals were identified. The one associated funerary object is a small shell tempered vessel.

The Dallas Phase people of the Upper Tennessee Valley are not clearly identifiable as being culturally affiliated with a modern-day tribe. However, based on consultation and the totality of circumstances surrounding acquisition of the human remains and associated funerary object, the U.S. Department of Energy Oak Ridge Office has determined by a reasonable belief that the human remains and associated funerary object are culturally affiliated with the Eastern Band of Cherokee Indians.

Determinations Made by the U.S. Department of Energy Oak Ridge Office

Officials of the U.S. Department of Energy Oak Ridge Office have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the one object described above is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Eastern Band of Cherokee Indians.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary object should contact Katatra Vasquez, U.S. Department of Energy Oak Ridge Office, P.O. Box 2001, SE–32, Oak Ridge, TN 37831, telephone (865) 576–0835 before December 17, 2012. Repatriation of the human remains and associated funerary object to the Eastern Band of Cherokee Indians may proceed after that date if no additional claimants come forward.

The U.S. Department of Energy Oak Ridge Office is responsible for notifying the Cherokee Nation; Chickasaw Nation; Choctaw Nation of Oklahoma; Eastern Band of Cherokee; Eastern Shawnee Tribe of Oklahoma; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); Quapaw Tribe of Indians; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma, that this notice has been published.

Dated: October 25, 2012.

David Tarler,

Acting Manager, National NAGPRA Program.

[FR Doc. 2012–27953 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–11493; 2200–1100–665]

Notice of Inventory Completion: U.S. Department of Agriculture, Forest Service, Ozark-St. Francis National Forests, Russellville, AR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture (USDA), Forest Service, Ozark-St. Francis National Forests has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects may contact the Ozark-St. Francis National Forests. Repatriation of the human remains and associated funerary objects to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains and associated funerary objects should contact the Ozark-St. Francis National Forests at the address below by December 17, 2012.

ADDRESSES: Judith L. Henry, Forest Supervisor, USDA Forest Service, Ozark-St. Francis National Forests, Russellville, AR 72801, telephone (479) 964–7202.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the possession of the Ozark-St. Francis National Forests. The human remains and associated funerary objects were removed from private land and donated to the Ozark-St. Francis National Forests by private collectors.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Ozark-St. Francis National Forests professional staff in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Quassarte Tribal Town; Caddo Nation of Oklahoma; Cherokee Nation; Chickasaw Nation; Choctaw Nation of Oklahoma; Delaware Nation, Oklahoma; Eastern Shawnee Tribe of Oklahoma; Jena Band of Choctaw Indians; Kialegee Tribal Town; Miami Tribe of Oklahoma; Mississippi Band of Choctaw Indians; Peoria Tribe of Indians of Oklahoma; Quapaw Tribe of Indians; Shawnee Tribe; The Muscogee (Creek) Nation; The Osage Nation (previously listed as the Osage Tribe); The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; Tunica-Biloxi Indian Tribe; United Keetoowah Band of Cherokee Indians in Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma.

History and Description of the Remains

In 1970 and 1971, human remains representing, at minimum, 16 individuals were removed from site 3NW101, on private property, in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. No known individuals were identified. The 74 associated funerary objects from identified burials include 25 ceramic vessels, 15 dart points, 19 knives, 2 blanks, 6 scrapers,

1 perforator, 1 chisel, 1 gorget, 1 charcoal sample, 1 flake, 1 axe, and 1 deer mandible. Two funerary objects were reported by the Gregoires but were missing when the collection was donated; they are 1 elbow pipe and 1 mano. The site dates from A.D. 653 to 881. It is affiliated to the Caddo Nation of Oklahoma through the Fourche Maline-related archeological complexes (e.g. Mulberry River Culture and Limestone Complex).

Determinations Made by the USDA Forest Service, Ozark-St. Francis National Forests

Officials of the USDA Forest Service, Ozark-St. Francis National Forests have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 16 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 74 objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Caddo Nation of Oklahoma.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should contact Judith L. Henry, Forest Supervisor, USDA Forest Service Ozark-St. Francis National Forests, Russellville, AR 72801, telephone (479) 964–7202, before December 17, 2012. Repatriation of the human remains and associated funerary objects to the Caddo Nation of Oklahoma may proceed after that date if no additional claimants come forward.

The USDA Forest Service, Ozark-St. Francis National Forests, is responsible for notifying the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Quassarte Tribal Town; Caddo Nation of Oklahoma; Cherokee Nation; Chickasaw Nation; Choctaw Nation of Oklahoma; Delaware Nation, Oklahoma; Eastern Shawnee Tribe of Oklahoma; Jena Band of Choctaw Indians; Kialegee Tribal Town; Miami Tribe of Oklahoma; Mississippi Band of Choctaw Indians; Peoria Tribe of Indians of Oklahoma; Quapaw Tribe of Indians; Shawnee Tribe; The Muscogee (Creek) Nation; The Osage Nation (previously listed as the Osage Tribe); The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; Tunica-Biloxi Indian Tribe; United Keetoowah Band of Cherokee Indians in Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma, that this notice has been published.

Dated: October 12, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–27952 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Designation of Four (4) Individuals and Five (5) Entities Pursuant to Executive Order 13628 of October 9, 2012

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (''OFAC'') is publishing the name of four (4) individuals and five (5) entities designated on November 8, 2012, as persons whose property and interests in property are blocked pursuant to Executive Order 13628 of October 9, 2012, ''Authorizing the Implementation of Certain Sanctions Set Forth in the Iran Threat Reduction and Syria Human Rights Act of 2012 and Additional Sanctions With Respect to Iran.''

DATES: The designation by the Director of OFAC of the four (4) individuals and five (5) entities identified in this notice, pursuant to Executive Order 13628 of October 9, 2012, is effective November 8, 2012.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance and Evaluation, 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.treasury.gov/ofac*) or via facsimile through a 24-hour fax-on demand service tel.: (202) 622–0077.

Background

On October 9, 2012, the President issued Executive Order 13628, ''Authorizing the Implementation of Certain Sanctions Set Forth in the Iran Threat Reduction and Syria Human Rights Act of 2012 and Additional Sanctions With Respect to Iran'' (the ''Order''), pursuant to the International Emergency Economic Powers Act (50 U.S. C. 1701 *et seq.*), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), the Iran Sanctions Act of 1996 (Pub. L. 104–172) (50 U.S.C. 1701 note), as amended, the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (Pub. L. 111–195) (22 U.S.C. 8501 *et seq.*), as amended, the Iran Threat Reduction and Syria Human Rights Act of 2012 (Pub. L. 112–158), Section 212(f) of the Immigration and Nationality Act of 1952, as amended (8 U.S.C. 1182(f)), and Section 301 of title 3, United States Code.

Section 3 of the Order blocks, with certain exceptions, all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person, of persons determined by the Secretary of the Treasury, in consultation with, or at the recommendation of, the Secretary of State, to satisfy certain criteria set forth in the Order.

On November 8, 2012, the Director of OFAC, in consultation with or at the recommendation of, the Secretary of State, designated, pursuant to Section 3 of the Order, four (4) individuals and five (5) entities whose names have been added to the list of Specially Designated Nationals and Blocked Persons and whose property and interests in property are blocked. The listing for these individuals and entities is below.

Individuals:

1. MOGHADAM, Ismail Ahmadi (a.k.a. AHMADI MOGHADAM, Ismail; a.k.a. AHMADI MOGHADDAM, Esma'il; a.k.a. AHMADI–MOGHADDAM, Esma'il; a.k.a. AHMADI–MOGHADDAM, Esmail; a.k.a. AHMADI–MOQADDAM, Esma'il; a.k.a. MOGHADDAM, Esameel Ahmadi; a.k.a. MOGHADDAM, Ismail Ahmadi); DOB 1961; POB Tehran, Iran; Head of Iranian Police; Alternate Title, Chief, Iran's Law Enforcement Forces; Alternate Title, Police Chief, Alternate Title, Commander of Iran's Law Enforcement Force; Alternate Title, Brigadier General (individual) [SYRIA] [IRAN–HR] [IRAN–TRA]
2. FAZLI, Ali; DOB 20 Apr 1961; alt. DOB 1951; POB Sarkan, Hamedan Province, Iran; Rank Brigadier General; Title Basij Deputy Commander (individual) [IRAN–TRA]
3. JALILI, Rasool (a.k.a. JALILI, RASOUL), 90 Park Ave, Farahzadi St, Tehran, Iran; DOB 19 Aug 1961; POB Eghlid, Fars Province, Iran; Web site *http://www.jalili.ir;* alt. Web site

http://sharif.edu/~jalili; email Address *jalili@sharif.edu; alt.* email Address *rjalili@yahoo.com;* alt. email Address *rasoul.jalili@peykasa.ir;* Passport N15792968; Associate Professor, Department of Computer Engineering, Sharif University of Technology; Alternate Title, Editor-In-Chief of ISeCure; Alternate Title, Dean of Scientific and International Cooperation, Sharif University of Technology; Alternate Title, Head, Information Technology Group, Sharif University of Technology (individual) [IRAN–TRA]

4. TAGHIPOUR, Reza (a.k.a. TAGHIPOUR ANVARI, Reza); DOB 1957; POB Maragheh, Iran; Minister of Communications and Information Technology; Minister for Information and Communications (individual) [IRAN–TRA]

Entities

1. AMNAFZAR GOSTAR–E SHARIF (a.k.a. AMNAFZAR; a.k.a. AMNAFZAR CORPORATION; a.k.a.SHARIF SECUREWARE), 5th Floor, No. 35, Qasemi St, North Side of Sharif University, Azadi Avenue, Tehran, Iran; No. 131, Pardis Technology Park, Pardis, Iran; Unit 3, 2nd Floor, No. 1176, Between 52, 54 VakilAbadi Blvd., Mashhad, Iran; Shahid Beheshti Ave, Sahand St., No. 20, 3rd, Tehran 1587677518, Iran; Web site *http://www.amnafzar.com;* email Address info@amnafzar.com [IRAN–TRA]
2. CENTER TO INVESTIGATE ORGANIZED CRIME (a.k.a. CENTER FOR INSPECTING ORGANISED CRIMES; a.k.a. CENTER FOR THE STUDY OF ORGANIZED CRIME; a.k.a. CYBER CRIME OFFICE), Tehran, Iran; Web site *http://www.gerdab*.ir [IRAN–TRA]
3. MINISTRY OF CULTURE AND ISLAMIC GUIDANCE, Bahrestan Square, Avenue Kamalolmolik, Tehran, Iran [IRAN–TRA]
4. PEYKASA (a.k.a. PEYKASA MESSAGE–WARE CO.), No. 10, #4 Alley, Sadeghi Street, West Corner of Sharif University, Zazadi Avenue, Tehran, Iran; Web site *http://peykasa.com;* Email Address *info@peykasa.ir;* alt. email Address *rasoul.jalili@peykasa.ir* [IRAN–TRA]
5. PRESS SUPERVISORY BOARD (a.k.a. IRANIAN PRESS SUPERVISORY BOARD), Tehran, Iran [IRAN–TRA]

Dated: November 8, 2012.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2012–27938 Filed 11–15–12; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–11492; 2200–1100–665]

Notice of Inventory Completion: U.S. Department of Agriculture, Forest Service, Ozark-St. Francis National Forests, Russellville, AR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture (USDA), Forest Service, Ozark-St. Francis National Forests has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects may contact the Ozark-St. Francis National Forests. Repatriation of the human remains and associated funerary objects to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains and associated funerary objects should contact the Ozark-St. Francis National Forests at the address below by December 17, 2012.

ADDRESSES: Judith L. Henry, Forest Supervisor, USDA Forest Service, Ozark-St. Francis National Forests, Russellville, AR 72801, telephone (479) 964–7202.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the possession of the Ozark-St. Francis National Forests. The human remains and associated funerary objects were removed from lands on the Ozark-St. Francis National Forests or were removed from private land and donated to the Ozark-St. Francis National Forests by private collectors.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Ozark-St. Francis National Forests professional staff in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Quassarte Tribal Town; Caddo Nation of Oklahoma; Cherokee Nation; Chickasaw Nation; Choctaw Nation of Oklahoma; Delaware Nation, Oklahoma; Eastern Shawnee Tribe of Oklahoma; Jena Band of Choctaw Indians; Kialegee Tribal Town; Miami Tribe of Oklahoma; Mississippi Band of Choctaw Indians; Peoria Tribe of Indians of Oklahoma; Quapaw Tribe of Indians; Shawnee Tribe; The Muscogee (Creek) Nation; The Osage Nation (previously listed as the Osage Tribe); The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; Tunica-Biloxi Indian Tribe; United Keetoowah Band of Cherokee Indians in Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma.

History and Description of the Remains

In 1955, human remains representing, at minimum, one individual were removed from site 3ST27, on the Ozark-St. Francis National Forests, by caver Roger Bottoms, in Stone County, AR. No known individuals were identified. No associated funerary objects are present.

In 1973, additional human remains representing, at minimum, two individuals were removed from sites 3ST12 and 3ST26, on private property, by Don Williams, USDA-Forest Service Geologist, also in Stone County, AR, and added to the human remains from site 3ST27. No known individuals were identified. No associated funerary objects are present.

The sites date from A.D. 165 to 1600. Sites 3ST27, 3ST12, and 3ST26 are located within the historical range of The Osage Nation and the Quapaw Tribe of Indians.

Determinations Made by the USDA Forest Service, Ozark-St. Francis National Forests

Officials of the USDA Forest Service, Ozark-St. Francis National Forests have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 3 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human

remains and associated funerary objects and The Osage Nation and the Quapaw Tribe of Indians.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should contact Judith L. Henry, Forest Supervisor, USDA Forest Service Ozark-St. Francis National Forests, Russellville, AR 72801, telephone (479) 964–7202, before December 17, 2012. Repatriation of the human remains and associated funerary objects to The Osage Nation and the Quapaw Tribe of Indians may proceed after that date if no additional claimants come forward.

The USDA Forest Service, Ozark-St. Francis National Forests, is responsible for notifying the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Quassarte Tribal Town; Caddo Nation of Oklahoma; Cherokee Nation; Chickasaw Nation; Choctaw Nation of Oklahoma; Delaware Nation, Oklahoma; Eastern Shawnee Tribe of Oklahoma; Jena Band of Choctaw Indians; Kialegee Tribal Town; Miami Tribe of Oklahoma; Mississippi Band of Choctaw Indians; Peoria Tribe of Indians of Oklahoma; Quapaw Tribe of Indians; Shawnee Tribe; The Muscogee (Creek) Nation; The Osage Nation (previously listed as the Osage Tribe); The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; Tunica-Biloxi Indian Tribe; United Keetoowah Band of Cherokee Indians in Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma, that this notice has been published.

Dated: October 12, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–27951 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–11491: 2200–1100–665]

Notice of Inventory Completion: U.S. Department of Agriculture, Forest Service, Ozark-St. Francis National Forests, Russellville, AR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture (USDA), Forest Service, Ozark-St. Francis National Forests has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects may contact the Ozark-St. Francis National Forests. Repatriation of the human remains and associated funerary objects to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains and associated funerary objects should contact the Ozark-St. Francis National Forests at the address below by December 17, 2012.

ADDRESSES: Judith L. Henry, Forest Supervisor, USDA Forest Service, Ozark-St. Francis National Forests, Russellville, AR 72801, telephone (479) 964–7202.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the possession of the Ozark-St. Francis National Forests. The human remains and associated funerary objects either were removed from lands on the Ozark-St. Francis National Forests or, as noted, were removed from private land and donated to the Ozark-St. Francis National Forests by private collectors.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Ozark-St. Francis National Forests professional staff in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Quassarte Tribal Town; Caddo Nation of Oklahoma; Cherokee Nation; Chickasaw Nation; Choctaw Nation of Oklahoma; Delaware Nation, Oklahoma; Eastern Shawnee Tribe of Oklahoma; Jena Band of Choctaw Indians; Kialegee Tribal Town; Miami Tribe of Oklahoma; Mississippi Band of Choctaw Indians; Peoria Tribe of Indians of Oklahoma; Quapaw Tribe of Indians; Shawnee Tribe; The Muscogee (Creek) Nation; The Osage Nation (previously listed as the Osage Tribe); The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; Tunica-Biloxi Indian Tribe; United Keetoowah Band of Cherokee Indians in Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma.

History and Description of the Remains

In 1978, human remains representing, at minimum, one individual were removed from site 3BE276 in Benton County, AR. The site was recorded in 1978 by Monroe Hutton and Gayle J. Fritz of the Arkansas Archeological Survey (AAS). Based on a close examination of the landlines in 2007, this site is located outside the Ozark-St. Francis National Forests, on private property adjacent to an Arkansas Highway Department right-of-way. The AAS transferred the remains to the Ozark-St. Francis National Forests Supervisor's Office in 1992. The human remains consist of a single human tibia. No known individuals were identified. No associated funerary objects are present. The site dates from 2000 B.C. to A.D. 1200. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1969, human remains representing, at minimum, four individuals were removed from site 3NW79 in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated the remains to the USDA Forest Service. The Gregoires identified human remains from one burial at the site, and the USDA Forest Service identified additional human remains in faunal collections from the site. No known individuals were identified. The two associated funerary objects from the identified burial are a lanceolate dart point and a soil sample. The site dates from 8000 B.C. to A.D. 1600. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1972, human remains representing, at minimum, two individuals were removed from site 3NW428 in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated the remains to the USDA Forest Service. The Gregoires identified human remains of a young adult female from one burial at the site, and determined that those remains had previously been excavated and reburied by unknown looters. The USDA Forest Service identified additional human remains in faunal collections from the site. No

known individuals were identified. The two associated funerary objects from the burial are a cane splint needle and a unifacial knife or scraper. The site dates from 5000 B.C. to A.D. 1200. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1986, human remains representing, at minimum, three individuals were removed from site 3NW623 in Newton County, AR, by John Slay, Forest Archeologist, Ozark-St. Francis National Forests. No known individuals were identified. No associated funerary objects are present. The site dates from the Early Archaic through Mississippi periods (7000 B.C.–A.D. 1600). The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1971, human remains representing, at minimum, one individual were removed from site 3NW405 in Newton County, AR, by Steve Erwin of the AAS. The site is located on USDA-Forest Service land. No known individuals were identified. No associated funerary objects are present. The site dates from 2000 B.C. to A.D. 1600. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1971, human remains representing, at minimum, two individuals were removed from site 3NW408 in Newton County, AR, by Steve Erwin of the AAS. The site is located on USDA-Forest Service land. No known individuals were identified. No associated funerary objects are present. The site dates from 2000 B.C. to A.D. 1600. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1967, human remains representing, at minimum, one individual were removed from site 3NW67 in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 500 B.C. to A.D. 1600. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1970, human remains representing, at minimum, one individual were removed from site 3NW77, on private property, in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 500 B.C. to A.D. 1600. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1967 and 1969, human remains representing, at minimum, one individual were removed from site 3NW122 in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 500 B.C. to A.D. 1600. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1967 and 1968, human remains representing, at minimum, one individual were removed from site 3NW129 in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 500 B.C. to A.D. 1600. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1971, human remains representing, at minimum, two individuals were removed from site 3NW136 in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 5000 B.C. to A.D. 1600. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1971, human remains representing, at minimum, one individual were removed from site 3NW161, on private property, in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from A.D. 500 to 900. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1971, human remains representing, at minimum, one individual were removed from site 3NW234, on private property, in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 500 B.C. to A.D. 900. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1969, human remains representing, at minimum, one individual were removed from site 3NW247, on private property, in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 2000 B.C. to A.D. 900. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1970, human remains representing, at minimum, one individual were removed from site 3NW267, on private property, in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. The six associated funerary objects are three shell beads, a bone pendant, a Langtry dart point, and a portion of a small mammal skeleton. The site dates from 2000 B.C. to A.D. 1000. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1970, human remains representing, at minimum, one individual were removed from site 3NW269, on private property, in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 500 B.C. to A.D. 900. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1970, human remains representing, at minimum, one individual were removed from site 3NW372 in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The USDA-Forest Service identified these human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 2000 B.C. to A.D. 900. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

In 1977, human remains representing, at minimum, three individuals were removed from site 3NW457, on private property, in Newton County, AR, by Thelma and Louis Gregoire of the AAS. In 1988, they donated their collection to the USDA-Forest Service. The Gregoires identified human remains from one burial from the site, and the USDA-Forest Service identified additional human remains in faunal collections from the site. No known individuals were identified. No associated funerary objects are present. The site dates from 5000 B.C. to A.D. 1600. The location of this site is within the historical range of the Caddo Nation of Oklahoma and The Osage Nation.

Determinations Made by the USDA Forest Service, Ozark-St. Francis National Forests

Officials of the USDA Forest Service, Ozark-St. Francis National Forests have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 28 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 10 objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Caddo Nation of Oklahoma and The Osage Nation.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should contact Judith L. Henry, Forest Supervisor, USDA Forest Service Ozark-St. Francis National Forests, Russellville, AR 72801, telephone (479) 964–7202, before December 17, 2012. Repatriation of the human remains and associated funerary objects to the Caddo Nation of Oklahoma and The Osage Nation may proceed after that date if no additional claimants come forward.

The USDA Forest Service, Ozark-St. Francis National Forests, is responsible for notifying the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Quassarte Tribal Town; Caddo Nation of Oklahoma; Cherokee Nation; Chickasaw Nation; Choctaw Nation of Oklahoma; Delaware Nation, Oklahoma; Eastern Shawnee Tribe of Oklahoma; Jena Band of Choctaw Indians; Kialegee Tribal Town; Miami Tribe of Oklahoma; Mississippi Band of Choctaw Indians; Peoria Tribe of Indians of Oklahoma; Quapaw Tribe of Indians; Shawnee Tribe; The Muscogee (Creek) Nation; The Osage Nation (previously listed as the Osage Tribe); The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; Tunica-Biloxi Indian Tribe; United Keetoowah Band of Cherokee Indians in Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma, that this notice has been published.

Dated: October 12, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–27949 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–11514; 2200–1100–665]

Notice of Inventory Completion: U.S. Department of Agriculture, Forest Service, Tongass National Forest, Juneau, AK, and the University of Alaska, Museum of the North, Fairbanks, AK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture (USDA), Forest Service, Tongass National Forest, and the University of Alaska, Museum of the North, have completed an inventory of human remains in consultation with the appropriate Indian tribe, and have determined that there is a cultural affiliation between the human remains and a present-day Indian tribe. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains may contact the Tongass National Forest. Repatriation of the human remains to the Indian tribe stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains should contact the Tongass National Forest at the address below by December 17, 2012.

ADDRESSES: Forrest Cole, Forest Supervisor, Tongass National Forest, 648 Mission St, Ketchikan, AK 99901, telephone (907) 228–6281.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the USDA Tongass National Forest and in the possession of the University of Alaska, Museum of the North, Fairbanks, AK. The human remains were removed from the Tongass National Forest, near Juneau, AK.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Museum of the North professional staff in consultation with representatives of Douglas Indian Association.

History and Description of the Remains

Sometime in 1964 or earlier, human remains representing, at minimum, two individuals were removed from the Taku Village Site, near Juneau, AK. The Taku Village site is located approximately 12 miles from Juneau, AK, on lands of the Tongass National Forest. The human remains consist of two skulls found in a grave at the extreme east end of the village, about 50 feet from the high water line of the beach. The grave was marked by a marble headstone and bore the inscription: ''Johnny Age 25 years, Died February 1895 Erected by his brother William.'' The second individual buried in the grave is likely a woman. The gravesite may be described as a buried house, including a wooden floor, log sides, and three layers of hand-sawed planks for a roof. About six inches of soil covered the top layer of planks. A fence surrounded the grave and the marble headstone. One individual was identified by the grave marker; the other

individual was not identified. No associated funerary objects are present.

The human remains are determined to be Native American due to the nature of the burial and the location within the graveyard of the Taku Village. The Taku Village site was one of the primary villages inhabited by the Taku Tlingit until about 1926, with graves at the cemetery dating from 1895 to 1926. The Taku Village site and cemetery is located within the traditional territory of the Taku Tlingit, represented today by the Douglas Indian Association. Oral traditions confirm the affiliation of the Taku Tlingit with the Taku Village site and cemetery, and support the culturally affiliation with present day Douglas Indian Association.

Determinations Made by the USDA Tongass National Forest and the Museum of the North

Officials of the USDA Tongass National Forest and the Museum of the North have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Douglas Indian Association.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains should contact Forrest Cole, Forest Supervisor, Tongass National Forest, 648 Mission St, Ketchikan, AK 99901, telephone (907) 228–6281, before December 17, 2012. Repatriation of the human remains to the Douglas Indian Association may proceed after that date if no additional claimants come forward.

The Tongass National Forest is responsible for notifying the Douglas Indian Association that this notice has been published.

Dated: October 16, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–27948 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–11439; 2200–1100–665]

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Control of Casa Grande Ruins National Monument, National Park Service, Coolidge, AZ; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the possession of the U.S. Department of the Interior, National Park Service, Casa Grande Ruins National Monument, Coolidge, AZ. The human remains and cultural items were removed from Pinal County, AZ.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the Superintendent, Casa Grande Ruins National Monument.

This notice corrects the minimum number of individuals and associated funerary objects for a Notice of Inventory Completion previously published in the **Federal Register** (61 FR 10009, March 12, 1996). A reassessment of the inventory prior to repatriation revealed that some of the human remains and cultural items were removed from tribal lands prior to 1979 and were therefore not in the possession or control of the National Park Service. The U.S. Department of the Interior, Bureau of Indian Affairs asserted control over the human remains and associated funerary objects from tribal land in 2012 and will publish a Notice of Inventory Completion addressing those remains and objects.

In the **Federal Register** (61 FR 10009, March 12, 1996), paragraphs three through five are corrected by substituting the following paragraphs:

The Monument's collection of human remains represents a minimum of 54 Native American individuals and 55 associated funerary objects recovered from Hohokam sites within the Monument.

Human remains recovered from Hohokam sites dating between 975–1400 A.D. within the Monument boundaries comprise a minimum of 31 individuals. No known individuals were identified. The 36 associated funerary objects are 21 jars, 5 bowls, 2 pitchers, 7 sherds, and 1 jar cover.

In addition, cremations, burials, and incomplete lots of human bone representing a minimum of 23 individuals whose archeological context are unknown have also been classified as Hohokam, primarily dating to the Classic Period (1150–1400 A.D.). No known individuals were identified. The 19 associated funerary objects are 15 jars, 2 bowls, 1 sherd, and 1 bag of beads.

In the **Federal Register** (61 FR 10009, March 12, 1996), the first two sentences of paragraph eight are corrected by substituting the following sentences:

Based on the above mentioned information, and the consultation with the above mentioned tribes, officials of the National Park Service have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of 54 individuals of Native American ancestry. National Park Service officials have determined that, pursuant to 25 U.S.C. 3001 (3)(A), the 55 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

Repatriation of the human remains and associated funerary objects occurred after the 30-day waiting period expired for the original March 12, 1996, Notice of Inventory Completion. For questions related to this notice, contact Karl Cordova, Superintendent, Casa Grande Ruins National Monument, 1100 W. Ruins Drive, Coolidge, AZ 85128, telephone (520) 723–3172.

Casa Grande Ruins National Monument is responsible for notifying the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and Zuni Tribe of the Zuni Reservation, New Mexico, that this notice has been published.

Dated: October 16, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–27947 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–11440; 2200–1100–665]

Notice of Inventory Completion: U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC, and U.S. Department of the Interior, National Park Service, Western Archeological and Conservation Center, Tucson, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior, Bureau of Indian Affairs, and U.S. Department of the Interior, National Park Service, Western Archeological and Conservation Center, have completed an inventory of human remains and associated funerary objects in consultation with the appropriate Indian tribes, and have determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes. Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects may contact the U.S. Department of the Interior, Bureau of Indian Affairs. Repatriation of the human remains and associated funerary objects to the Indian tribes stated below may occur if no additional claimants come forward.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the human remains and associated funerary objects should contact the U.S. Department of the Interior, Bureau of Indian Affairs at the address below by December 17, 2012.

ADDRESSES: Anna Pardo, Museum Program Manager/NAGPRA Coordinator, U.S. Department of the Interior, Indian Affairs, 12220 Sunrise Valley Drive, Room 6084, Reston, VA 20191, telephone (703) 390–6343.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC, and in the physical custody of the U.S. Department of the Interior, National Park Service, Western Archeological and Conservation Center, Tucson, AZ. The human remains and associated funerary objects were removed from sites on the Gila River Indian Reservation in Pinal County, AZ.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects.

Consultation

A detailed assessment of the human remains was made by National Park Service professional staff in consultation with representatives of the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and the Zuni Tribe of the Zuni Reservation, New Mexico (hereafter referred to as ''The Tribes''').

History and Description of the Remains

In 1916, human remains representing, at minimum, one individual were removed from an unnamed site on the Gila River Indian Reservation in Pinal County, AZ, during the excavation of the Indian Hospital foundation. The human remains and associated funerary object were given to the National Park Service in 1916. Ownership was transferred to the Bureau of Indian Affairs in 2012. No known individuals were identified. The one associated funerary object is a cremation jar.

Between 1931 and 1934, human remains representing, at minimum, 12 individuals were removed from unnamed sites on the Gila River Indian Reservation in Pinal County, AZ. The human remains and associated funerary objects were given to the National Park Service in 1934. Ownership was transferred to the Bureau of Indian Affairs in 2012. No known individuals were identified. The 22 associated funerary objects are 8 jars, 2 bowls, 1 plate, 1 shell bracelet, 8 unworked shell pieces, and 2 awls.

The sites date to A.D. 975–1400. Oral tradition, historical records, ethnography, history, archeological evidence, and a cultural affiliation study indicate that The Tribes all have cultural ties to the sites from which the human remains and associated funerary objects were removed.

Determinations Made by the U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC, and the U.S. Department of the Interior, National Park Service

Officials of the Bureau of Indian Affairs and the National Park Service have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 13 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 23 objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and The Tribes.

Additional Requestors and Disposition

Representatives of any Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should contact Anna Pardo, Museum Program Manager/NAGPRA Coordinator, U.S. Department of the Interior, Indian Affairs, 12220 Sunrise Valley Drive, Room 6084, Reston, VA 20191, telephone (703) 390–6343, before December 17, 2012. Repatriation of the human remains and associated funerary objects to The Tribes may proceed after that date if no additional claimants come forward.

The Bureau of Indian Affairs is responsible for notifying The Tribes that this notice has been published.

Dated: October 16, 2012.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2012–27944 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SERO–NCPTT–11571; PPWOCRADS2,PCU00RP14.R50000]

Notice of Meeting Preservation Technology and Training Board

AGENCY: National Park Service, Interior.

ACTION: Notice of Meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix (1988)), that the Preservation

Technology and Training Board (PTT Board) of the National Center for Preservation Technology and Training, National Park Service, will meet on Wednesday and Thursday, November 28–29, 2012, at the Presidio in San Francisco, California.

The PTT Board was established by Congress to provide leadership, policy advice, and professional oversight to the National Center for Preservation Technology and Training (NCPTT) in compliance with Section 404 of the National Historic Preservation Act of 1966, as amended, (16 U.S.C. 470x–2(e)).

The PTT Board will meet at the Presidio, Long Avenue, Building #989, San Francisco, CA 94129—telephone (318) 356–7444. The meeting will run from 9:00 a.m. to 5:00 p.m. on November 28, 2012, and from 9:00 a.m. to noon on November 29, 2012 (PACIFIC).

The PTT Board's meeting agenda will include: Review and comment on NCPTT FY2012 accomplishments and operational priorities for FY2013; FY2012 and FY2013 National Center budget and initiatives; recent research; and training programs.

The PTT Board meeting is open to the public. Facilities and space for accommodating members of the public are limited; however, visitors will be accommodated on a first-come, first-served basis. Any member of the public may file a written statement concerning any of the matters to be discussed by the PTT Board.

DATES: The Meeting Dates are: November 28, 2012, 9:00 a.m. to 5:00 p.m. and November 29, 2012, 9:00 a.m. to noon, San Francisco, CA 94129 (PACIFIC).

ADDRESSES: The meeting location is: The Presidio, Long Avenue, Building #989, San Francisco, CA 94129.

SUPPLEMENTARY INFORMATION: Persons wishing more information concerning this meeting, or who wish to submit written statements, may contact: Mr. Kirk A. Cordell, Executive Director, National Center for Preservation Technology and Training, National Park Service, U.S. Department of the Interior, 645 University Parkway, Natchitoches, LA 71457; telephone (318) 356–7444. In addition to U.S. Mail or commercial delivery, written comments may be sent by fax to Mr. Cordell at (318) 356–9119. 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. Minutes of the meeting will be available for public inspection no later than 90 days after the meeting at the office of the Executive Director, National Center for Preservation Technology and Training, National Park Service, U.S. Department of the Interior, 645 University Parkway, Natchitoches, LA 71457; telephone (318) 356–7444.

Dated: November 5, 2012.

Kirk A. Cordell,

Executive Director, National Center for Preservation Technology and Training.

[FR Doc. 2012–27823 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–11614;2200–1100–665]

Notice of Intent To Repatriate Cultural Items: The Museum of Indian Arts and Culture, Museum of New Mexico, Santa Fe, NM

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Museum of Indian Arts and Culture, Museum of New Mexico, in consultation with the appropriate Indian tribe, has determined that the cultural items meet the definition of unassociated funerary objects and repatriation to the Indian tribe stated below may occur if no additional claimants come forward. Representatives of any Indian tribe that believes itself to be culturally affiliated with the cultural items may contact the Museum of Indian Arts and Culture.

DATES: Representatives of any Indian tribe that believes it has a cultural affiliation with the cultural items should contact the Museum of Indian Arts and Culture at the address below by December 17, 2012.

ADDRESSES: Elena Sweeney, Acting Director, Museum of Indian Arts and Culture, P.O. Box 2087, Santa Fe, NM 87504, telephone (505) 690–1415.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the possession of the Museum of Indian Arts and Culture that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

Between 1928 and 1932, joint excavations by the University of New Mexico and the School of American Research removed human remains and funerary objects from the Unshagi site (LA 123), in Sandoval County, NM. Human remains from these burials are under the control of the Maxwell Museum of Anthropology at the University of New Mexico and the Peabody Museum of Harvard University. The Museum of Indian Arts and Culture has control over seven unassociated funerary objects from the site, including one worked glycimeris shell, three Jemez Black-on-white bowls, one Kuaua Glaze Polychrome bowl, one Glaze F bowl, and one necklace made of fish-vertebrae. The seven objects were removed from numbered burials, but it is not possible to link these funerary objects with specific human remains in the Maxwell Museum *or* Peabody Museum collections.

Between 1910 and 1913, excavations by the American Bureau of Ethnology and the School of American Research removed human remains and funerary objects from the Amoxiumqua site (LA 481), in Sandoval County, NM. Human remains from these burials are under the control of the Smithsonian Institution in Washington DC. The Museum of Indian Arts and Culture has control over three unassociated funerary objects from the site, including two Jemez Black-on-white bowls and one strand of Venetian glass beads. The objects were removed from numbered burials, but it is not possible to link these funerary objects with specific human remains in the Smithsonian collection.

In 1921, the School of American Research and the Laboratory of Anthropology removed human remains and funerary objects from the Guisewa site (LA 679), in Sandoval County, NM. Human remains from these burials are under the control of the Maxwell Museum of Anthropology at the University of New Mexico. The Museum of Indian Arts and Culture has control over five unassociated funerary objects from the site, including four Jemez Black-on-white bowls and one charred textile fragment. The objects were

removed from numbered burials, but it is not possible to link these funerary objects with specific human remains in the Maxwell Museum collection.

In 1937, the University of New Mexico archaeological field school removed human remains and funerary objects from the Guisewa site (LA 679), in Sandoval County, NM. Human remains from these burials are under the control of the Maxwell Museum of Anthropology at the University of New Mexico. The Museum of Indian Arts and Culture has control over three unassociated funerary objects from the site, including one small culinary bowl, one Jemez Black-on-white bowl, and one restorable Black-on-white bowl. The objects were removed from numbered burials, but it is not possible to link these funerary objects with specific human remains in the Maxwell Museum collection.

In 1965, the Museum of New Mexico removed human remains and funerary objects from the Guisewa site (LA 679), in Sandoval County, NM, prior to the installation of a new water line. Human remains from these burials are under the control of the Maxwell Museum of Anthropology at the University of New Mexico. The Museum of Indian Arts and Culture has control over three unassociated funerary objects from the site, including one corn, one lot of animal bones, and one small restorable utility ware bowl. The objects were removed from numbered burials, but it is not possible to link these funerary objects with specific human remains in the Maxwell Museum collection.

At an unknown date, an unknown individual removed human remains and funerary objects from an excavated burial at the Giusewa site (LA 679), in Sandoval County, NM. The location of human remains from this site is unknown, but they are presumed to be in the collections of the Maxwell Museum of Anthropology. The Museum of Indian Arts and Culture has control over one unassociated funerary object from the site. It is not possible to link this funerary object with specific human remains in the Maxwell Museum collection.

Based on material culture and associated architecture, the unassociated funerary objects listed in this notice have been identified as Native American. The burials from which these objects were removed can be identified as ancestral Jemez because they came from known Puebloan sites of the upper Jemez River drainage. Populations that inhabited these sites are linked by Native oral tradition, Euro-American records, and archeological evidence to members of the present-day Pueblo of Jemez, New Mexico.

Determinations Made by the Museum of Indian Arts and Culture

Officials of the Museum of Indian Arts and Culture have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the 22 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Pueblo of Jemez, New Mexico.

Additional Requestors and Disposition

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the unassociated funerary objects should contact Elena Sweeney, Acting Director, Museum of Indian Arts and Culture, P.O. Box 2087, Santa Fe, NM 87504, telephone (505) 690–1415, before December 17, 2012. Repatriation of the unassociated funerary objects to the Pueblo of Jemez, New Mexico, may proceed after that date if no additional claimants come forward.

The Museum of Indian Arts & Culture, Museum of New Mexico, is responsible for notifying the Pueblo of Jemez, New Mexico, that this notice has been published.

Dated: October 25, 2012.

David Tarler,

Acting Manager, National NAGPRA Program.

[FR Doc. 2012–27955 Filed 11–15–12; 8:45 am]

BILLING CODE 4312–50–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–861]

Certain Cases for Portable Electronic Devices; Institution of Investigation Pursuant to the Tariff Act of 1930, as Amended

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on September 26, 2012, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Speculative Product Design, LLC of Mountain View, California. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain cases for portable electronic devices by reason of infringement of certain claims of U.S. Patent No. 8,204,561 (''the '561 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2012).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 8, 2012, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain cases for portable electronic devices that infringe one or

more of claims 1–16 of the '561 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Speculative Product Design, LLC, 303 Bryant Street, Mountain View, California 94041.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Anbess Electronices Co. Ltd., 1F, Block B, Building 4, Cui Feng hao Yuan, ShuiJing, BuJi, LongGang, Shenzhen, GC, 518112, China.

BodyGlove International, LLC, 201 Herondo Street, Redondo Beach, California 90277.

Fellowes, Inc., 1789 Norwood Avenue, Itsaca, Illinois 60143.

ROCON Digital Technology Corp., Block 15, Fumin Industrial Zone, Shenzhen, China 518111.

SW-Box.com, aka Cellphonezone Limited, Flat A, 15/F Hillier Comm. Bldg, 65–67 Bonham Strand East, Sheung Wan, Hong Kong.

Trait Technology (Shenzhen) Co., Limited, dba Trait-Tech, 416–419RM, 305# Sufa Building, Huafa North Road, Futian District, Shenzhen, China 518031.

Hongkong Wexun Ltd, Wexun Tech (Hong Kong) Co., Ltd, Block 15, Fumin Industrial Zone, Pinghu Community Office, Longgang District, Guangdong, China 518111.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 9, 2012.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–27864 Filed 11–15–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–796]

Certain Electronic Digital Media Devices and Components Thereof; Notice of Request for Statements on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the presiding administrative law judge has issued a Final Initial Determination and Recommended Determination on Remedy and Bonding in the above-captioned investigation. The Commission is soliciting comments on public interest issues raised by the recommended relief, specifically a limited exclusion order against certain electronic digital media devices and components thereof imported by respondents Samsung Electronics Co, Ltd. of Korea; Samsung Electronics America, Inc. of Ridgefield Park, New Jersey; and Samsung Telecommunications America, LLC of Richardson, Texas (collectively ''Samsung''), and cease and desist orders against Samsung.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2392. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that if the Commission finds a violation it shall exclude the articles concerned from the United States:

> Unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is interested in further development of the record on the public interest in these investigations. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the administrative law judge's Recommended Determination on Remedy and Bonding issued in this investigation on November 7, 2012. Comments should address whether issuance of an exclusion order and/or cease and desist orders in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) Identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) Indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the recommended exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) Explain how the exclusion order and/or cease and desist orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on December 3, 2012.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–796'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and of sections 201.10 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50).

By order of the Commission.

Issued: November 13, 2012.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–27950 Filed 11–15–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–815]

Certain Projectors With Controlled-Angle Optical Retarders, Components Thereof, and Products Containing Same; Notice of Commission Determination Not To Review an Initial Determination Terminating the Investigation in Its Entirety

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 24) terminating the above-captioned in its entirety based on withdrawal of the complaint.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 25, 2011, based on a complaint filed on October 21, 2011, as supplemented on November 2, 2011, by Compound Photonics Ltd. of London, United Kingdom and Compound Photonics U.S. Corporation of Phoenix, Arizona (collectively ''Compound Photonics''). 76 *FR* 72722–23 (Nov. 25, 2011). The complaint alleges violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain projectors with controlled-angle optical retarders, components thereof, and products containing same by reason of infringement of claims of U.S. Patent No. 6,829,027. The complaint further alleges the existence of a domestic industry. The Commission's notice of investigation named as respondents Sony Corporation of Tokyo, Japan; Sony Corporation of America of New York, New York; and Sony Electronics Inc. of San Diego, California. The Office of Unfair Import Investigation was named as a participating party.

On October 17, 2012, Compound Photonics filed a motion to terminate the investigation in its entirety based on withdrawal of the complaint. The motion stated that the respondents do not oppose the motion. On October 19, 2012, the Commission investigative attorney filed a response in support of the motion.

On October 19, 2012, the ALJ issued the subject ID, granting Compound Photonics' motion pursuant to section 210.21(a)(1) of the Commission's Rules of Practice and Procedure (19 CFR 210.21(a)(1)). No petitions for review of this ID were filed.

The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.42).

By order of the Commission.

Issued: November 13, 2012.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–27914 Filed 11–15–12; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Delegation of Authority to the Principal Deputy Assistant Attorney General for the Civil Division

AGENCY: Department of Justice.

ACTION: Notice.

SUMMARY: On November 9, 2012, the Attorney General issued Attorney General Order No. 3350–2012, which delegates all of the power and authority of the Assistant Attorney General for the Civil Division to the Principal Deputy Assistant Attorney General for the Civil Division, unless any such power or authority is required by law to be exercised by the Assistant Attorney General for the Civil Division personally. With this delegation, the Assistant Attorney General for the Civil Division and the Principal Deputy Assistant Attorney General for the Civil

Division will each, concurrently, have the same set of delegated powers.

DATES: Attorney General Order No. 3350–2012 became effective November 9, 2012.

FOR FURTHER INFORMATION CONTACT: Rosemary Hart, Special Counsel, Office of Legal Counsel, Department of Justice, Washington, DC 20530; (202) 514–2027.

SUPPLEMENTARY INFORMATION: Pursuant to 28 U.S.C. 509, ''[a]ll functions of other officers of the Department of Justice and all functions of agencies and employees of the Department of Justice are vested in the Attorney General'' but for exceptions not applicable here. Pursuant to 28 U.S.C. § 510, the Attorney General has broad authority to ''authorize[e] the performance by any other officer, employee, or agency of the Department of Justice of any function of the Attorney General.'' Various powers and authorities have been delegated to the Assistant Attorney General for the Civil Division. *See, e.g.,* 28 CFR Ch. I, Pt. 0, Subpts. I, Y, App. to Subpt. Y; 28 CFR 15.4. This most recent delegation ensures that the Assistant Attorney General for the Civil Division and the Principal Deputy Assistant Attorney General for the Civil Division will each, concurrently, have the same set of delegated powers, thereby enhancing efficient management of Civil Division operations.

The delegation order is a matter of internal Department management. Accordingly, the requirements under the Administrative Procedure Act for notice and comment and a delay in effective date are not applicable. See 5 U.S.C. 553. Although publication is not required, the Department has chosen to publish this notice to advise the public of this recent delegation.

The order is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and accordingly it has not been reviewed by the Office of Management and Budget. In addition, the order will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b). Nor will it have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, this order does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment pursuant to Executive Order 13132.

Attorney General Order 3350–2012 reads as follows:

''By virtue of the authority vested in me by law, including 28 U.S.C. §§ 509 and 510, I hereby delegate to the Principal Deputy Assistant Attorney General for the Civil Division all the power and authority of the Assistant Attorney General for the Civil Division, unless any such power or authority is required by law to be exercised by the Assistant Attorney General for the Civil Division personally.''

Dated: November 13, 2012.

Rosemary Hart,

Special Counsel.

[FR Doc. 2012–27942 Filed 11–15–12; 8:45 am]

BILLING CODE 4410–12–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act (''CERCLA'')

On November 9, 2012, the Department of Justice lodged a proposed consent decree (''proposed Decree'') with the United States District Court for the Western District of Pennsylvania in the lawsuit entitled *United States and the Commonwealth of Pennsylvania Department of Environmental Protection* v. *Cast Parts, Inc, et al.,* Civil Action No. 12–1656.

The United States filed this lawsuit under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). The United States' complaint names Cast Parts, Inc., Energy Control Systems, Inc., Gutierrez Machine Corporation, Kirschbaum-Krupp Metal Corporation, K&K Metal Recycling, LLC., Lavigne Manufacturing Co., M.J. Metal, Inc., Marshalltown Company, Metal Mart International, Inc., Middletown Aerospace Corporation, Mid-State Investment Company, Mid-State Machine Company, LLC, National Machine Company, Premco, Inc., Rolls-Royce Corporation, Black & Decker (U.S.) Inc., Johns Hopkins University, Johns Hopkins University Applied Physics Laboratory, LLC, and Winter's Performance Products as defendants. The complaint requests recovery of costs that the United States incurred responding to releases of hazardous substances at the Remacor Superfund Site in West Pittsburg, Lawrence County, Pennsylvania. All defendants signed the consent decree, and collectively agree to pay $1,110,865.40 of the United States' response costs. In return, the United States agrees not to sue the defendants under sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607(a).

The publication of this notice opens a period for public comment on the proposed Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the Commonwealth of Pennsylvania Department of Environmental Protection* v. *Cast Parts, Inc. et al.,* D.J. Ref. No. 90–11–3–09682/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email ...	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $10.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2012–27874 Filed 11–15–12; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Exemptions From Certain Prohibited Transaction Restrictions

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Grant of Individual Exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code). This notice includes the following: D–11710, El Paso Corporation Retirement Savings Plan

(the Plan), 2012–19; and L–11688, Sharp HealthCare (Sharp), 2012–20.

SUPPLEMENTARY INFORMATION: The Department published notices in the **Federal Register** of the pendency of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in the applications for exemption and referred interested persons to the applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, DC. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No requests for a hearing were received by the Department. Public comments were received by the Department as described in the granted exemptions.

The notices of proposed exemptions were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011) [1] and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;

(b) The exemptions are in the interests of the plans and their participants and beneficiaries; and

(c) The exemptions are protective of the rights of the participants and beneficiaries of the plans.

[1] The Department has considered exemption applications received prior to December 27, 2011 under the exemption procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990).

El Paso Corporation Retirement Savings Plan (the Plan) Located in Houston, Texas

[Prohibited Transaction Exemption 2012–19; Exemption Application No. D–11710]

Exemption

Section I: Transactions

The restrictions of sections 406(a)(1)(A), 406(a)(1)(E), 406(a)(2), 406(b)(1), 406(b)(2), and 407(a)(1)(A) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) and 4975(c)(1)(E) of the Code,[2] shall not apply, in connection with a merger transaction (the Merger) between El Paso Corporation (El Paso) and Kinder Morgan, Inc. (KMI):

(a) To the acquisition by the individually directed accounts of the participants of the Plan (the Invested Participants) of certain publicly traded warrants (the Warrants) issued by KMI, which became a party in interest with respect to the Plan after the merger (the Merger); and

(b) To the holding of the Warrants by the accounts in the Plan of the Invested Participants; provided that the conditions, as set forth in Section II of this exemption, were satisfied at the time of the acquisition of the Warrants by the accounts in the Plan of such Invested Participants and throughout the duration of the holding of the Warrants in the accounts of such Invested Participants.

Section II: Conditions

The relief provided in this exemption is conditioned upon adherence to the material facts and representations described, herein, and as set forth in the application file and upon compliance with the conditions, as set forth in this exemption.

(a) The Warrants were acquired by the individually-directed accounts of the Invested Participants, all or a portion of whose accounts in the Plan hold the common stock of El Paso (the EP Stock);

(b) The exchange by the shareholders, including the Invested Participants, of the EP Stock for Warrants resulted from an independent act of El Paso and KMI, as corporate entities in connection with the Merger, and occurred automatically without any action or control on the part of such shareholders, including the Invested Participants;

(c) The acquisition of the Warrants by the Invested Participants occurred in connection with the Merger, and such Warrants were made available on the same terms to all shareholders of the EP Stock, including the Invested Participants;

(d) The decisions with regard to the holding and disposition of the Warrants were made by each of the Invested Participants in accordance with the provisions under the Plan for individually-directed accounts;

(e) The Warrants allocated to the accounts of the Invested Participants in the Plan may be exercised or sold at any time by such Invested Participants giving investment directions in accordance with the provisions of the Plan;

(f) The Invested Participants did not pay any fees or commissions in connection with the acquisition and holding of the Warrants, nor did the Invested Participants pay any fees on the exercise of the Warrants; and

(g) Prior to entering into the Merger, El Paso obtained all necessary approvals from any relevant state agencies and federal agencies, including, but not limited to the U.S. Department of Justice Antitrust Division, the Federal Energy Regulatory Commission, the Securities and Exchange Commission, and the Federal Trade Commission.

Effective Date: This exemption is effective, May 25, 2012, the closing date of the Merger.

[2] For purposes of this exemption, references to specific provisions of Title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the Code.

Written Comments

In the Notice, the Department invited all interested persons to submit written comments and requests for a hearing within sixty (60) days of the date of the publication of the Notice in the **Federal Register** on June 1, 2012. All comments and requests for hearing were due by July 31, 2012. During the comment period, the Department received no requests for hearing. However, the Department did receive a comment in a letter, dated July 5, 2012, from James E. Street (Mr. Street), Vice President, Human Resources and IT of KMI. As of the date of the Merger, KMI became an interested person with respect to the Plan.

In his letter, Mr. Street informed the Department that the Merger was effective on May 25, 2012. Accordingly, Mr. Street represents that the subject transactions were entered into on the effective date of the Merger for business expediency reasons before a final exemption could be obtained from the Department. As the subject transactions have already been consummated, Mr. Street, on behalf of KMI, requests that the Department grant a retroactive exemption, effective as of May 25, 2012, the date when the Merger closed.

The Department concurs, and accordingly, the final exemption has been amended to change the tense of the verbs to reflect that the subject transactions have been entered into, and to insert the following paragraph:

Effective Date: This exemption is effective, May 25, 2012, the closing date of the Merger.

In response to an inquiry by the Department, Mr. Street, on behalf of KMI, in a letter dated September 25, 2012, confirmed that, to the best of his knowledge and belief, the material facts presented and the representations made by El Paso in the original prohibited transaction exemption application (the Application) submitted to the Department on November 23, 2011, and in the supplemental submissions relating to the Application remain true and correct and that the conditions set forth in Section II of the Notice, as published in the **Federal Register** on June 1, 2012, were satisfied, as of May 25, 2012, the closing date of the Merger of El Paso and KMI, and thereafter.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the Notice of Proposed Exemption which was published on June 1, 2012, at 77 FR 32692.

FOR FURTHER INFORMATION CONTACT: Ms. Angelena C. Le Blanc of the Department, telephone (202) 693–8540. (This is not a toll-free number.)

Sharp HealthCare (Sharp), Located in San Diego, California

[Prohibited Transaction Exemption 2012–20; Exemption Application No. L–11688]

Exemption

Section I. Covered Transactions

A. The restrictions of sections 406(a)(1)(A), 406(a)(1)(D), 406(b)(1), and 406(b)(2) of the Act shall not apply, effective August 1, 2006 through and until November 15, 2012, to the purchase of health insurance by the Sharp HealthCare Health and Dental Plan (the Plan) from the Sharp Health Plan (the HMO), provided that the conditions of Section II have been met.

B. The restrictions of sections 406(a)(1)(A), 406(a)(1)(D), 406(b)(1), and 406(b)(2) of the Act shall not apply, effective as of November 16, 2012, to the purchase of health insurance by the Plan from the HMO, provided that the conditions of Section II and Section III are met.

Section II. General Conditions

(a) Sharp is the sole member of the HMO, and more than 50% of the appointment power for the HMO's Board of Directors is held by Sharp.

(b) Sharp is licensed to sell HMO coverage in the State of California.

(c) The HMO is certified by the California Department of Managed Health Care as being in compliance with the requirements for a licensed HMO within the last 18 months.

(d) The HMO has undergone a financial examination by the California Department of Managed Health Care within the past 5 years and will continue to undergo such financial examinations at least once every five years.

(e) The HMO has been, and will continue to be, examined by an independent certified public accountant annually.

(f) The amount the Plan pays to Sharp for HMO coverage is reasonable and does not exceed the amount the Plan would have paid for similar services in an arm's length transaction between unrelated parties.

(g) All HMO-offered health care providers meet all applicable licensure requirements and certifications.

(h) The HMO offers a sufficient number of non-Sharp affiliated health care providers to effectively allow Plan participants the opportunity to receive health care services from either Sharp or non-Sharp affiliated health care providers.

(i) No commissions are paid by the Plan with respect to the sale of HMO coverage.

(j)(i) With respect to the relief provided in section I. A., for each taxable year of the HMO, the gross premiums received in that taxable year by the HMO from the Plan did not exceed 50% of the gross premiums received by the HMO for all HMO coverage issued in that taxable year; or

(ii) with respect to the relief provided in section I. B., for each taxable year of the HMO, the gross premiums received in that taxable year by the HMO from the Plan will not exceed 50% of the gross premiums received by the HMO for all HMO coverage issued in that taxable year.

(k) Sharp maintains or causes to be maintained for a period of six years from the date of any covered transaction hereunder such records as are necessary to enable the persons described in paragraph (l)(i) below to determine whether the conditions of this exemption have been met, provided that (i) a separate prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of Sharp, the records are lost or destroyed prior to the end of the six-year period, and (ii) no party in interest other than Sharp shall be subject to a civil penalty that may be assessed under section 502(i) of the Act, if such records are not maintained, or are not available for examination as required by paragraph (l)(i) below.

(l)(i) Except as provided below in paragraph (l)(ii), and notwithstanding any provisions of subsections (a)(2) and (b) of section 504 of the Act, the records referred to above in paragraph (k) are unconditionally available at their customary location for examination during normal business hours by:

(A) Any duly authorized employee or representative of the Department,

(B) Any duly authorized representative of the California Department of Managed Health Care or any State or Federal governmental body responsible for regulatory oversight of Sharp or the HMO, and

(C) Any fiduciary of the Plan or the Plan's authorized representative; and

(ii) None of the persons described above in paragraph (l)(i)(C) shall be authorized to examine trade secrets of Sharp, or commercial or financial information which is privileged or confidential, and should Sharp refuse to disclose information on the basis that such information is exempt from disclosure, Sharp shall, by the close of the thirtieth (30th) day following the request, provide a written notice advising that person of the reasons for the refusal and that the Department may request such information.

Section III. Prospective Conditions

(a) Sharp retains annually the services of an independent third-party consultant to determine whether the amount employees and/or their dependents pay for coverage is reasonable and does not exceed the amount that would be paid for similar services in an arm's length transaction between unrelated parties, which amount includes the cost of co-payments and other out-of-pocket expenses for such coverage borne by participants and/or their dependents, and written copies of such determination are distributed to Plan participants along with summaries of health care costs for similar, competing health care providers.

(b) The Board of Directors of Sharp appoints a committee (the Plan Committee) consisting of the Senior Vice President and General Counsel, the Senior Vice President and Chief Financial Officer, and the Vice President, Compensation and Benefits, and such other representatives as the Board of Directors may deem appropriate. The Plan Committee will annually ascertain and certify in writing

that the above requirements of this exemption continue to be met.

Section IV. Effective Dates

Section I.A. of this exemption is effective as of August 1, 2006, through and until November 15, 2012, and Section I.B. of this exemption is effective as of November 16, 2012.

The Department invited all interested persons to submit written comments with respect to the proposed exemption on or before September 30, 2012. During the comment period, the Department received one email inquiry which generally concerned the individual's difficulty in understanding the notice of proposed exemption. However, the Department received no comments or requests for a hearing from interested persons.

Therefore, after giving full consideration to the entire record, the Department has decided to grant the exemption. For further information regarding the individual exemption, interested persons are encouraged to obtain copies of the exemption application file (Application No. L–11688) that the Department maintains with respect to the individual exemption. The complete application file, as well as supplemental submissions received by the Department, is made available for public inspection in the Public Documents room of the Employee Benefits Security Administration, Room N–1513, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210.

For a complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the proposed exemption published in the **Federal Register** on August 28, 2012 at 77 FR 52061.

FOR FURTHER INFORMATION CONTACT: Mr. Warren Blinder, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor, telephone (202) 693–8553. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Each exemption is supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of an exemption is subject to the express condition that the material facts and representations contained in the application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 9th day of November 2012.

Lyssa E. Hall,

Director of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2012–27848 Filed 11–15–12; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Proposed Exemptions From Certain Prohibited Transaction Restrictions

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Notice of Proposed Exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code). This notice includes the following proposed exemptions: D–11610, UBS Financial Services, Inc. D–11666, Central Pacific Bank 401(k) Retirement and Savings Plan (the Plan); D–11672, Studley, Inc. Section 401(k) Plan Profit Sharing Plan (the Plan); and D–11724, EquiLend Holdings LLC (EquiLend).

DATES: All interested persons are invited to submit written comments or requests for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this **Federal Register** Notice.

ADDRESSES: Comments and requests for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. All written comments and requests for a hearing (at least three copies) should be sent to the Employee Benefits Security Administration (EBSA), Office of Exemption Determinations, Room N–5700, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Attention: Application No._____, stated in each Notice of Proposed Exemption. Interested persons are also invited to submit comments and/or hearing requests to EBSA via email or FAX. Any such comments or requests should be sent either by email to: *moffitt.betty@dol.gov,* or by FAX to (202) 219–0204 by the end of the scheduled comment period. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue NW., Washington, DC 20210.

Warning: If you submit written comments or hearing requests, do not include any personally-identifiable or confidential business information that you do not want to be publicly-disclosed. All comments and hearing requests are posted on the Internet exactly as they are received, and they can be retrieved by most Internet search engines. The Department will make no deletions, modifications or redactions to the comments or hearing requests received, as they are public records.

SUPPLEMENTARY INFORMATION:

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform

interested persons of their right to comment and to request a hearing (where appropriate).

The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (76 FR 66637, 66644, October 27, 2011).[1] Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

UBS Financial Services Inc., Located in Weehawken, New Jersey

[Application No. D–11610]

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the following exemption under the authority of Code section 4975(c)(2), and in accordance with the procedures set forth in 29 CFR Part 2570, subpart B (76 FR 66637, October 27, 2011), as follows:

Section I: Covered Transactions

If the proposed exemption is granted, the sanctions resulting from the application of Code section 4975, by reason of Code section 4975(c)(1)(A) and (D)–(E), shall not apply, effective January 4, 2002, until December 9, 2005, to (1) principal trades by UBS Financial Services Inc. (the Applicant) with certain plans, subject to Code section 4975, but not subject to Title I of ERISA (the IRAs), which resulted in the IRAs purchasing or selling securities from the Applicant (collectively, the Transactions); and (2) compensation paid by the IRAs to the Applicant in connection with the Transactions (the Transaction Compensation).

This proposed exemption is subject to the conditions set forth below in Sections II and III.

Section II: Specific Conditions

(a) The Transactions and the Transaction Compensation were corrected (1) pursuant to the requirements set forth in the Department's Voluntary Fiduciary Correction Program (the VFC Program)[2] and (2) in a manner consistent with those transactions described in the Applicant's VFC Program application, dated March 5, 2010 (the VFC Program Application), that were substantially similar to the Transactions but that involved plans described in Code section 4975(e)(1) and subject to Title I of ERISA (the Qualified Plan Transactions).

(b) The Applicant received a ''no-action letter'' from the Department in connection with the Qualified Plan Transactions described in the VFC Program Application.

(c) An independent fiduciary confirmed that the methods utilized to correct the Transactions and Transaction Compensation were sufficient to return each affected IRA to at least the position that it would have been in had the Transactions and Transaction Compensation not occurred, and that the correction methods were properly applied to the Transactions and Transaction Compensation based on a review of a representative sample of the corrections, selected at random by the independent fiduciary.

For purposes of this exemption, a fiduciary is ''independent'' if it is independent of and unrelated to Applicant and its affiliates. In this regard, a fiduciary will not be deemed independent of Applicant and its affiliates if: (1) Such fiduciary directly or indirectly controls, is controlled by, or is under common control with Applicant or its affiliates, (2) such fiduciary directly or indirectly receives any compensation or other consideration in connection with any transaction described in this exemption, except that it may receive compensation for acting as an independent fiduciary from Applicant in connection with the transactions described herein, if the amount or payment of such compensation is not contingent upon, or in any way affected by such fiduciary's decision; or (3) the annual gross revenue received by the fiduciary, in any fiscal year, from Applicant or its affiliates exceeds one percent (1%) of the fiduciary's annual gross revenue from all sources (for federal income tax purposes) for its prior tax year.

(d) The terms of the Transactions and the Transaction Compensation were at least as favorable to the IRAs as the terms generally available in arm's-length transactions between unrelated parties.

(e) The Transactions and Transaction Compensation were not part of an agreement, arrangement or understanding designed to benefit a disqualified person, as defined in Code section 4975(e)(2).

(f) The Applicant did not take advantage of the relief provided by the VFC Program and Prohibited Transaction Exemption 2002–51[3] (PTE 2002–51) for three (3) years prior to the date of the Applicant's submission of the VFC Program Application.

Section III: General Conditions

(a) The Applicant maintains, or causes to be maintained, for a period of six (6) years from the date of any Transaction such records as are necessary to enable the persons described in Section III(b)(1) to determine whether the conditions of this exemption have been met, except that:

(1) A separate prohibited transaction shall not be considered to have occurred if, due to circumstances beyond the control of Applicant, the records are lost or destroyed prior to the end of the six-year period; and

(2) No disqualified person with respect to an IRA, other than Applicant, shall be subject to excise taxes imposed by Code section 4975, if such records are not maintained, or are not available for examination, as required by Section III(b)(1).

(b)(1) Except as provided in Section III(b)(2), the records referred to in Section III(a) are unconditionally available at their customary location for examination during normal business hours by:

(A) Any duly authorized employee or representative of the Department, the Internal Revenue Service, or the Securities and Exchange Commission;

(B) Any fiduciary of any IRA that engaged in a Transaction, or any duly authorized employee or representative of such fiduciary; or

(C) Any owner or beneficiary of an IRA that engaged in a Transaction or a representative of such owner or beneficiary.

(2) None of the persons described in Sections III(b)(1)(B) and (C) shall be authorized to examine trade secrets of Applicant, or commercial or financial information which is privileged or confidential.

[1] The Department has considered exemption applications received prior to December 27, 2011 under the exemption procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).

[2] 71 FR 20262 (April 19, 2006).

[3] 67 FR 70623 (Nov. 25, 2002), as amended, 71 FR 20135 (April 19, 2006).

(3) Should Applicant refuse to disclose information on the basis that such information is exempt from disclosure, Applicant shall, by the close of the thirtieth (30th) day following the request, provide a written notice advising that person of the reasons for the refusal and that the Department may request such information.

Effective Date: If granted, this proposed exemption will be effective from January 4, 2002, until December 9, 2005.

Summary of Facts and Representations

1. The Applicant is UBS Financial Services Inc., a wholly owned subsidiary of UBS AG. The Applicant is a large financial institution headquartered in Basel and Zurich, Switzerland. As of December 31, 2011, UBS AG had invested assets of 2,167 billion CHF.

2. From January 4, 2002, to December 9, 2005, contrary to the Applicant's policies, certain of Applicant's financial advisors (the FAs) caused Applicant to engage in a number of principal transactions involving IRAs for which the Applicant or the FA acted as an ERISA fiduciary. These principal transactions included: (a) 711 principal purchases of bonds from the Applicant, with an aggregate purchase price of $18,359,746 in 88 IRAs (the Bond Purchase Transactions) (b) 110 principal sales of bonds to the Applicant, with an aggregate sales price of $4,257,643 in 45 IRAs (the Bond Sale Transactions); (c) 128 principal purchases of stock from the Applicant, for an aggregate purchase price of $1,882,230 in 37 IRAs (the Stock Purchase Transactions); and (d) 1 principal sale of stock to the Applicant, for a sales price of less than $1 (the Stock Sale Transaction) (collectively, the Bond Purchase Transactions, the Bond Sale Transactions, the Stock Purchase Transactions and Stock Sale Transaction are referred to as the Transactions). A total of 105 IRAs were involved in the Transactions. (Some of the IRAs were involved in more than one type of transaction.)

3. The Transactions caused the payment of compensation to the Applicant (Transaction Compensation). With respect to Bond Purchase Transactions and Bond Sale Transactions, the Applicant was compensated through a ''mark-up'' of the bond price; the aggregate amount of such mark-ups was $115,363. With respect to the Stock Purchase Transactions and the Stock Sale Transaction, the Applicant was compensated through commissions totaling $44,964.

4. Upon discovering that certain of the FAs caused the Applicant to engage in the Transactions, the Applicant implemented changes to its policies and procedures to prohibit the opening of any brokerage accounts that would permit FAs to exercise discretion. The Applicant represents that the FAs can now only open accounts that would permit the exercise of discretion under a discretionary advisory program where principal trades are blocked.

5. The Applicant seeks relief with respect to the Transactions and with respect to the payment of the Transaction Compensation. Specifically, the Applicant believes that: (a) The purchase and sale of securities, both bonds and stocks, between the IRAs and the Applicant was prohibited by Code section 4975(c)(1)(A); (b) both the Transactions and the payment of Transaction Compensation were prohibited by Code section 4975(c)(1)(D); and (c) the Transactions and the receipt of Transaction Compensation were prohibited by Code section 4975(c)(1)(E). The Applicant believes that, if the proposed exemption is not granted, the IRAs would be subject to hardship resulting from the uncertainty of not having the prohibited transactions outlined herein resolved. Further, if the proposed exemption is not granted, the IRAs would be subject to additional hardship as a result of the resultant uncertainty regarding the correction methodology applied by the Applicant.

6. The Applicant represents that as soon as the Transactions and the Qualified Plan Transactions were discovered it began an investigation that led to the correction process. The Applicant corrected the Qualified Plan Transactions pursuant to the requirements set forth in the VFC Program. The Applicant filed a VFC Program Application, dated March 5, 2010, with respect to the Qualified Plan Transactions, and it received a no-action letter from the Department, dated February 4, 2011, with respect to the Qualified Plan Transactions.

7. While the Qualified Plan Transactions were properly corrected under the VFC Program, the Applicant was not able to similarly correct the Transactions and the Transaction Compensation. Despite being substantially similar to the Qualified Plan Transactions, the Transactions and the Transaction Compensation are ineligible for relief under the VFC Program and PTE 2002–51 because they involved IRAs which are not covered under Title I of ERISA. The Applicant, however, believes that granting relief pursuant to the proposed exemption is consistent with the Department's statement that ''[the VFC Program] does not foreclose its future consideration of individual exemption requests for transactions involving IRAs that are outside the scope of relief provided by both the VFC Program and the class exemption under circumstance when, for example, a financial institution received a no action letter applicable only to plans subject to [the VFC Program] for a transaction(s) that involved both plans and * * * IRAs.'' 71 FR 20135, 20137 (April 19, 2006).

8. The Applicant represents that the Transactions were corrected pursuant to the requirements set forth in the VFC Program and in a manner consistent with the Applicant's VFC Program Application, with such representation made in the Applicant's exemption application, dated March 5, 2010, under penalty of perjury. In this regard, the Applicant corrected the Transactions in the manner described below:

(a) With respect to the Bond Purchase Transactions, since bonds are debt instruments, the Applicant corrected the Bond Purchase Transactions, based on economic similarity to a loan transaction correction, under the procedures for loans made at a fair market interest rate in Section 7.2(a) of the VFC Program. The correction method for a loan, which is set forth in Section 7.2(a)(2) of the VFC program, is for the party in interest to pay back the loan in full, including any prepayment penalties. The Applicant represents that the Bond Purchase Transactions were conducted at fair market values (FMVs) because, among other things, the transactions were conducted using trading systems and procedures designed to result in trades being conducted at prices that are as favorable as possible to the IRAs under prevailing market conditions and were in fact conducted at prices not less favorable to the IRAs than the prices the FAs could have obtained for the IRAs by conducting the trades in arm's-length transactions with third-party market participants.

(b) With respect to the Bond Sale Transactions and the Stock Sale Transaction, the Applicant corrected these Transactions under the procedures for sale of an asset by a plan to a party in interest under Section 7.4(b) of the VFC Program. Section 7.4(b)(2)(i) of the VFC Program generally requires that the asset be repurchased from the party in interest at the lower of the price for which it originally sold the property or the FMV of the property at the time of correction. As an alternative, Section 7.4(b)(2)(ii) of the VFC Program provides that a plan may receive a cash

settlement of the ''Principal Amount,'' defined as the amount by which the FMV of the asset at the time of original sale exceeds the original sales price, plus the greater of ''Lost Earnings,'' which is generally defined as the approximate amount that would have been earned by a plan on the Principal Amount but for the prohibited transaction, or the ''Restoration of Profits,'' as described in Section 5(b) of the VFC Program, provided, that, an independent fiduciary determines that the applicable Plan would receive a greater benefit with such correction than by repurchase. The Applicant represents that ''Restoration of Profits,'' as defined under the VFC Program, did not apply with respect to the Transactions because no amounts were used for a specific purpose such that a profit was determinable. The Principal Amount for each of the Bond Sale Transactions and the Stock Sale Transaction was zero because the bond or the stock was sold at FMV.

It was impractical or impossible for the IRAs to repurchase most of the bonds in the Bond Sale Transactions because most of the bonds had been called, matured, were thinly traded or not in the inventory of the Applicant or its affiliates. For the remaining bonds in the Bond Sale Transactions, none of the IRAs elected to repurchase the bond from the Applicant despite the Applicant's offer to sell the bond back to the IRA at the lower of the price for which the IRA originally sold the bond or the FMV of the bond at the time of correction. Therefore, the Applicant corrected all of the Bond Sale Transactions by paying the IRAs the Transaction Compensation, if any, plus Lost Earnings on the Transaction Compensation from the time of the Transaction.

For the Stock Sale Transaction, it was impossible to repurchase the stock because the company had dissolved. Further, because no commissions were charged by the Applicant for the Stock Sale Transaction, no payment to the IRA with respect to compensation was necessary to correct the Stock Sale Transaction. Finally, since the Principal Amount with respect to the Stock Sale Transaction was zero, there were no Lost Earnings on the Principal Amount to pay to the IRA.

(c) With respect to the Stock Purchase Transactions, the Applicant corrected the Stock Purchase Transactions under the procedures for the purchase by a plan of an asset from a party in interest pursuant to Section 7.4(a) of the VFC Program. Section 7.4(a) generally requires that the asset be sold back to the party in interest who originally sold the asset to the plan or to a person who is not a party in interest for a price equal to the greater of (1) the FMV of the asset at the time of resale, without reduction for the costs of sale, plus restoration to the plan of the party in interest's investment return from the proceeds of the sale, to the extent they exceed the plan's net profits from owning the property, or (2) the plan's original purchase price, plus the greater of Lost Earnings on the plan's original purchase price or the Restoration of Profits, if any. As an alternative, the plan may retain the asset and receive (1) the greater of the Lost Earnings or the Restoration of Profits, if any, on the original purchase price, but only to the extent that such Lost Earnings or Restoration of Profits exceeds the difference between the FMV of the asset as of correction and the original purchase price and (2) the amount by which the original purchase price exceeded the FMV of the asset (at the time of the original purchase), plus the greater of Lost Earnings or Restoration of Profits, if any, on such excess; provided, an independent fiduciary determined that the plan will realize a greater benefit from this correction than it would from the resale described in section 7.4(a)(2)(i) of the VFC Program. The Applicant corrected the Stock Purchase Transactions under the alternative correction methodology, taking into account any prior disposition of the stock by an IRA subsequent to the original purchase.

9. With respect to the Applicant's correction of the Transactions, (a) the Applicant took into account all transaction costs (e.g., Transaction Compensation), if any, paid by the IRAs in calculating the corrective payments; and (b) the Applicant engaged an independent fiduciary, Evercore Trust Company. Evercore Trust Company stated that (x) the methods utilized to correct the Transactions were sufficient to return each affected IRA to at least the position that it would have been in had the Transactions not occurred, (y) the alternative correction method utilized for the Stock Purchase Transactions did not result in the affected IRAs being returned to more unfavorable financial positions than if the general correction method described in 7.4(a) of the VFC Program been used instead, and (z) the correction methods were properly applied to the Transactions based on a review of a representative sample of the corrections.

10. Evercore Trust Company confirmed to the Applicant that (a) during the period beginning with the date on which the earliest Transaction occurred and ending with the date Evercore Trust Company completed its engagement as an independent fiduciary with respect to the Transactions and the Transaction Compensation, it was not an entity that was directly or indirectly controlling, controlled by, or under common control with, the Applicant or its affiliates, (b) the compensation received by Evercore Trust Company from the Applicant for its services as an independent fiduciary with respect to the Transactions and the Transaction Compensation was not contingent upon, or in any way affected by, Evercore Trust Company's determination, and Evercore Trust Company did not, and will not, directly or indirectly receive any other compensation or consideration from the Applicant in connection with the Transactions or Transaction Compensation, and (c) for any fiscal year of Evercore Trust Company, during which, or during part of which, it acted as an independent fiduciary with respect to the Transactions or Transaction Compensation, or received any compensation from the Applicant for its services as an independent fiduciary with respect to the Transactions or Transaction Compensation (Subject Fiscal Year), the annual gross revenue received by Evercore Trust Company and its affiliates from the Applicant or its affiliates for the Subject Fiscal Year did not exceed one percent (1%) of the annual gross revenue received by Evercore Trust Company and its affiliates from all sources (for federal income tax purposes) for their most recent fiscal years that ended prior to the Subject Fiscal Year.

11. The Applicant represents that it credited, or issued a check to, each IRA to which a corrective payment was due.

12. The Applicant believes that the Transactions were inadvertent and resulted in the IRAs paying no more than the market price with respect to the Bond Purchase Transactions and the Stock Purchase Transactions, and receiving at least the market price with respect to the Bond Sale Transactions and the Stock Sale Transaction, because the Transactions were conducted using trading systems and procedures designed to result in trades being conducted at prices that are as favorable as possible to the IRAs under prevailing market conditions and were in fact conducted at prices not less favorable to the IRAs than the prices the FAs could have obtained for the IRAs by conducting the trades in arm's-length transactions with third-party market participants.

13. The Applicant represents that it has not taken advantage of the relief provided by the VFC Program and PTE 2002–51 for the three (3) years prior to

the date of the Applicant's submission of the VFC Program Application, and that the Transactions were not part of an agreement, arrangement or understanding designed to benefit a disqualified person.

14. The Applicant represents that the proposed exemption is: (a) Administratively feasible because the Applicant has corrected the Transactions pursuant to the requirements set forth in the VFC Program; has obtained relief under the VFC Program for the Qualified Plan Transactions; has put procedures in place to ensure that no similar Transactions occur in the future; and has obtained an opinion from an independent fiduciary, Evercore Trust Company, confirming that the methods utilized to correct the Transactions and Transaction Compensation were sufficient to return each affected IRA to at least the position that it would have been in had the Transactions and Transaction Compensation not occurred, and that the correction methods were properly applied to the Transactions and Transaction Compensation based on a review of a representative sample of the corrections, selected at random by the independent fiduciary; (b) in the interests of the affected IRAs and their owners and beneficiaries because the Transactions have been corrected pursuant to the procedures set forth in the VFC Program, which are designed to ensure that the corrections are made in a manner that is in the interests of the IRAs and their owners and beneficiaries; and (c) protective of the rights of the owners and beneficiaries of the IRAs because the requested relief is only with respect to past transactions, which the Applicant believes were conducted at prices no less favorable to the IRAs than prices the IRAs could have paid or received in arm's-length transactions with third party market participants, that have already been effectively unwound pursuant to the requirements set forth in the VFC Program.

15. In summary, the Applicant represents that the Transactions and the Transaction Compensation satisfy the statutory criteria for an administrative exemption contained in Code section 4975(c)(2) because, among other things: (a) The Transactions and Transaction Compensation were substantially similar to the Qualified Plan Transactions; (b) the Transactions and Transaction Compensation were corrected pursuant to the requirements set forth in the VFC Program and in a manner similar to those described in the Applicant's VFC Program Application; (c) the Applicant received a ''no-action letter'' from the Department in connection with Applicant's VFC Program Application; (d) the Applicant obtained an opinion from an independent fiduciary, Evercore Trust Company, confirming that the methods utilized to correct the Transactions and Transaction Compensation were sufficient to return each affected IRA to at least the position that it would have been in had the Transactions and Transaction Compensation not occurred, and that the correction methods were properly applied to the Transactions and Transaction Compensation based on a review of a representative sample of the corrections, selected at random by the independent fiduciary; (e) the terms of the Transactions and the Transaction Compensation were at least as favorable to the IRAs as the terms generally available in arm's-length transactions between unrelated parties; (f) the Transactions and Transaction Compensation were not part of an agreement, arrangement or understanding designed to benefit a disqualified person; and (g) the Applicant did not take advantage of the relief provided by the VFC Program and PTE 2002–51 for three (3) years prior to the date of the Applicant's submission of the VFC Program Application.

FOR FURTHER INFORMATION CONTACT: Mr. Brian Shiker of the Department, telephone (202) 693–8552. (This is not a toll-free number.)

Central Pacific Bank 401(k) Retirement and Savings Plan (the Plan), Located in Honolulu, HI

[Application No. D–11666]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990).

Section I: Transactions

If the proposed exemption is granted, effective for the period beginning April 11, 2011 and ending May 6, 2011, the restrictions of sections 406(a)(1)(A), 406(a)(1)(E), 406(a)(2), 406(b)(1), 406(b)(2), and 407(a)(1)(A) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) and 4975(c)(1)(E) of the Code,[4] shall not apply:

(a) To the acquisition of certain subscription right(s) (the Right or Rights) by the individually-directed account(s) (the Account or Accounts) of certain participant(s) in the Plan in connection with an offering (the Offering) of shares of common stock (the Stock) of Central Pacific Financial Corporation (CPFC) by CPFC, a party in interest with respect to the Plan; and

(b) To the holding of the Rights received by the Accounts during the subscription period of the Offering; provided that the conditions, as set forth in Section II of this proposed exemption were satisfied for the duration of the acquisition and holding.

Section II: Conditions

The relief provided in this proposed exemption is conditioned upon adherence to the material facts and representations described, herein, and as set forth in the application file, and upon compliance with the conditions, as set forth in this proposed exemption.

(a) The receipt of the Rights by the Accounts occurred in connection with the Offering, and the Rights were made available by CPFC to all shareholders of the Stock of CPFC, including the Accounts;

(b) The acquisition of the Rights by the Accounts resulted from an independent corporate act of CPFC;

(c) Each shareholder of the Stock, including each of the Accounts, received the same proportionate number of Rights, and this proportionate number of Rights was based on the number of shares of Stock held by each such shareholder;

(d) The Rights were acquired pursuant to, and in accordance with, provisions under the Plan for individually-directed investment of the Accounts by the individual participants in the Plan, all or a portion of whose Accounts in the Plan held the Stock (the Invested Participant(s));

(e) The decision with regard to the holding and disposition of the Rights by an Account was made by the Invested Participant whose Account received the Rights;

(f) If any of the Invested Participants failed to give instructions as to the exercise of the Rights received in the Offering, such Rights were sold in blind transactions on the New York Stock Exchange (NYSE) and the proceeds from such sales were distributed *pro-rata* to the Accounts in the Plan of such Invested Participants;

(g) No brokerage fees, no commissions, and no fees or expenses

[4] For purposes of this proposed exemption, references to specific provisions of Title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the Code.

were paid by the Plan or by the Accounts to any related broker in connection with the sale of any of the Rights or in connection with the exercise of any of the Rights, and no brokerage fees, no commissions, no subscription fees, and no other charges were paid by the Plan or by the Accounts with respect to the acquisition and holding of the Stock; and

(h) Based on the difference ($1.13) between the average proceeds per Right ($6.05) received by other holders who sold Rights during the Offering and the average proceeds per Right ($4.92) received by Invested Participants whose Accounts sold Rights, between April 26, 2011 and May 3, 2011, CPFC will make a corrective payment to the Plan in the amount of $30,618.48 ($1.13 x 27,096 Rights sold), plus a lost earnings component on such amount, calculated at a 2.83% annual rate of interest for the period from May 6, 2011 to the date of the grant of this proposed exemption, and will distribute such corrective payment, and the lost earnings component, *pro rata* to the Accounts of each of the 186 Invested Participants whose Accounts in the Plan sold the 27,096 Rights.

Effective Date: This proposed exemption, if granted, will be effective for the period beginning on April 11, 2011, the commencement date of the Offering, and ending on May 6, 2011, the close of the Offering.

Summary of Facts and Representations

1. The Plan is a defined contribution 401(k) retirement saving plan which provides for a cash and deferred arrangement. The Plan was adopted, effective as of November 1, 1985.[5] The Plan obtained its latest determination letter from the Internal Revenue Service (the IRS) in 2002. Although the Plan has been amended since receiving the determination letter from the IRS, the administrator of the Plan and the tax counsel for the Plan believe that the Plan is designed and is currently being operated in compliance with the applicable requirements of the Code.

As of April 11, 2011, there were 1,115 participants in the Plan. The Plan is a participant directed account plan designed and operated to comply with the requirements of section 404(c) of the Act.

The Plan is funded by elective employee contributions, as well as employer matching contributions, and discretionary employer profit sharing contributions in cash to the ESOP. It is represented that no discretionary contributions were made in 2008, 2009, and 2010. The fair market value of the total assets of the Plan, as of April 11, 2011, was $85,827,254. As of August 30, 2012, the fair market value of the Plan's assets was $90,594,733. 2. CPFC is the sponsor of the Plan. CPFC is a bank holding company, incorporated in the State of Hawaii on February 1, 1982, as ''CPB Inc.'' CPFC's principal place of business is Honolulu, Hawaii.

CPFC, a parent company, through its subsidiaries, offers full-service commercial banking throughout the State of Hawaii and offers limited commercial banking services in certain areas of California. CPFC does not employ any persons other than the officers of the Central Pacific Bank (the Bank) and from time to time the support staff of the Bank. It is represented that substantially all of the activities of CPFC are conducted through the Bank.

According to the Form 10–Q, as of March 3, 2012, on a consolidated basis, CPFC and its subsidiaries had total assets of $4,158,288,000, total liabilities of $3,680,848,000, and total stockholders' equity of $477,440,000.

3. The Bank is a wholly-owned subsidiary of CPFC. The Bank is a full-service commercial bank incorporated in the State of Hawaii on March 16, 1982, with 34 branches and 120 ATMs located throughout the State of Hawaii. The Bank also has an office in California. The Bank offers a broad range of products and services, including accepting time and demand deposits, and originating commercial, construction, and consumer loans, and commercial and residential mortgages. All employees of the Bank, its subsidiaries, and certain other affiliated companies are covered by the Plan.

4. Vanguard Fiduciary Trust Company (Vanguard) is the third party administrator, the trustee, and the custodian of the Plan. Vanguard, as trustee, has the responsibility of investing, holding, collecting, distributing, and accounting for the assets of the Plan in the trust.

5. The Plan is administered by a committee (the Committee), which is composed of certain appointed employees of the Bank. The Committee has the responsibility of selecting the investment options of the trust into which the participants of the Plan can direct their contributions.

6. Participants in the Plan are permitted to self-direct the investments in their Accounts based on certain options held under the Plan. Among the investment options offered to participants are various types of securities, including shares of the Stock held in the CPFC stock fund (the Stock Fund). Investment in the Stock Fund by the Accounts of participants in the Plan is entirely voluntary. It is represented that neither CPFC nor its subsidiaries contribute any capital Stock to the Plan. Instead all employer contributions are made in cash, and the Stock is acquired by the Accounts in the Plan only as a result of participant-directed investment decisions.

The Plan provides that participants are entitled to direct the voting of the Stock held in their Accounts in the Plan. Vanguard, as trustee, has the responsibility of carrying out such directions. As of December 31, 2009, and December 31, 2010, respectively, the Plan investments included 938,180 shares and 893,122 shares of the Stock held in the Stock Fund.

7. The Stock of CPFC is publicly-traded on the NYSE under the symbol ''CPF.'' The Stock has no par value. It is represented that the Stock is the same class of shares available to other investors. The Stock is a ''qualifying employer security,'' as defined under section 407(d)(5) of the Act and 4975(e) of the Code.

Background

8. On February 2, 2011, CPFC effected a one-for-twenty reverse stock split (the Reverse Stock Split) of the outstanding shares of Stock. As a result of the Reverse Stock Split, the outstanding shares of Stock decreased from 30,539,999 shares to 1,528,935 shares.

As part of its recapitalization plan to raise $325 million from accredited investors in a private placement (the Private Placement), CPFC, on February 18, 2011, entered into subscription agreements with affiliates of the Carlyle Group and the Anchorage Capital Group, LLC and with various other investors. In this regard, CPFC sold 32,500,000 shares of Stock at a price of $10 per share.

On the same day, February 18, 2011, CPFC entered into an exchange agreement (the Exchange Agreement) with the United States Department of the Treasury (Treasury), pursuant to which the Treasury agreed, subject to the terms and conditions in the Exchange Agreement, to exchange 135,000 shares of CPFC's preferred stock designated as Fixed Rate Cumulative Preferred Stock, having a liquidation amount of $1,000 per share, held by the Treasury and accrued and unpaid dividends thereon for 5,620,117 shares of CPFC's Stock, and amended a warrant held by the Treasury to reduce the

[5] Effective July 1, 2003, December 31, 2004, December 31, 2006, and July 26, 2007, respectively, the Central Pacific Bank Employee Stock Ownership Plan, the CB Bancshares, Inc. Profit Sharing Retirement Saving Plan, the CB Bancshares, Inc. ESOP, and the Hawaii HomeLoans, Inc. 401(k) Retirement Savings Plan were merged into the Plan.

number of shares of Stock issuable upon exercise of the warrant from 1,585,748 to 79,288 (the TARP Exchange).

Following the closing of the Private Placement and the TARP Exchange, CPFC had 39,649,052 shares of Stock outstanding, as of April 11, 2011. CPFC commenced the Offering whereby shareholders of record, as of 5 p.m. EST on the February 17, 2011 (the Record Date), would receive the Rights. CPFC represents that it conducted the Offering, because it wanted to provide existing shareholders and other investors, including the Accounts of Invested Participants in the Plan, who could not participate in the Private Placement, with the opportunity to purchase the Stock at the same price per share paid by the investors in the Private Placement.

9. The Offering commenced on April 11, 2011, and closed on May 6, 2011. It is represented that 2,000,000 shares of Stock were subscribed for by all shareholders. In this regard, the Offering was fully subscribed. There were valid exercises to purchase an aggregate of 1,325,230 shares, pursuant to directions from holders of the basic Rights. The remaining 674,770 shares available to be issued in the Offering were allocated *pro rata* among the holders entitled to exercise the over-subscription privilege. It is represented that the exercise of the Rights resulted in gross proceeds for CPFC of $20,000,000.

10. At the close of business on April 11, 2011, the date of the Offering, the Stock was trading on the NYSE at $19.43 per share. The closing price of the Stock on the ending date of the Offering on May 6, 2011, was $13.70.

11. Under the terms of the Offering, all shareholders of the Stock, including the Accounts of Invested Participants in the Plan, automatically received the Rights, at no charge. Each of the Rights entitled the shareholders of the Stock, including the Accounts of Invested Participants in the Plan, to purchase, through the exercise of such Rights, the Stock issued by CPFC in connection with the Offering. With respect to the Rights, under the terms of the Offering, one (1) Right was issued for each whole share of the Stock held by each shareholder, including the Accounts of Invested Participants in the Plan, on the Record Date.

12. The Rights entitled the holders thereof to a basic right to subscribe for their *pro rata* share of $20 million dollars' worth of Stock issued by CPFC, as well as an over-subscription privilege to subscribe for additional shares of Stock, subject to certain limitations and allocation procedures, up to the number of shares of Stock that were not subscribed for by the other holders of the Rights, pursuant to their basic Rights.

However, the over-subscription privilege was conditioned on each shareholder first exercising their basic Rights in full. Because the Accounts of Invested Participants in the Plan did not exercise all of their basic Rights in full and, because, as a practical matter it was unlikely that all of the Accounts of Invested Participants in the Plan would do so, given the number of Invested Participants in the Plan whose Accounts held the Stock, the over-subscription privilege was not available to Rights attributable to the Accounts of Invested Participants in the Plan.

13. All shareholders of the Stock, including the Accounts of Invested Participants in the Plan, held the Rights until such Rights were exercised, or such Rights were sold. With regard to the exercise of the Rights, it is represented that the Rights could only be exercised in whole numbers. Upon exercise, each of the Rights permitted a shareholder of the Stock, including each of the Accounts of Invested Participants in the Plan, to purchase 1.3081 shares of Stock at a subscription price of $10.00 per share (such amount is represented to take into account the Reverse Stock Split that occurred on February 2, 2011). Fractional shares of Stock resulting from the exercise of basic Rights on an aggregate basis as to any holder of such Rights, including the Accounts of Invested Participants in the Plan, were rounded down to the nearest whole number.

A shareholder, including each of the Accounts of Invested Participants in the Plan, had the right to choose to exercise some, all, or none of its Rights. The election to exercise, some, all or none of its Rights had to be received by 5 p.m. EST on April 29, 2011, by the tabulation agent, Wells Fargo Bank, NA Shareowner Services (WFSS), in order to allow sufficient processing time. The election to exercise any of the Rights was irrevocable.

14. With regard to the sale of the Rights, it is represented that the Rights were transferable. Further, it is represented that the Rights were traded on the NYSE. Any Rights that were not exercised either as a result of a partial exercise or as a result of insufficient assets in an Account to cover an exercise (excluding the assets in the Stock Fund), or as a result of a failure to timely return the election form were automatically sold on the NYSE to unrelated third parties by Vanguard, as trustee, acting on behalf of each such Account. The proceeds from such sale were credited *pro rata* to the Plan Accounts of Invested Participants.

15. The Invested Participants were notified of the issuance of the Rights in a news release, in a posting on the CPFC's Web site, and in various letters and email communications from CPFC during the month of April 2011. In addition, each of the Invested Participants was also provided detailed information regarding the Rights Offering, including a copy of the prospectus which described the Offering, a document providing frequently asked questions and answers regarding the Offering, an election form, a return envelope addressed to WFSS, the tabulating agent, and a statement indicating the number of shares of Stock each such Invested Participant held in his/her Account in the Plan, as of the Record Date.

16. In order to exercise some or all of the Rights, an Invested Participant [6] had to complete an election form and to submit such election form to WFSS by the close of business on the fifth (5th) business day (April 29, 2011, at 5 p.m. EST), prior to the expiration of the Offering on May 6, 2011.[7]

Each Invested Participant who submitted an election form was required to indicate on such election form a sufficient amount of current investments in the Account of such Invested Participant in the Plan (other than the assets in the Stock Fund) to be liquidated on a pro-rated basis to cover the purchase of Stock in connection with the exercise of the Rights. The pro-rated funds were segregated from the other investments within the Invested Participant's Account into a separate holding fund (the Rights Fund) at Vanguard which was established in anticipation of the Offering. Vanguard placed the order to purchase the Stock with the subscription agent, Wells Fargo Bank, N.A. (Wells Fargo Bank), a registered broker-dealer that is unrelated

[6] It is represented that the Accounts of the Invested Participants in the Plan rely on the relief provide by the statutory exemption, pursuant to section 408(e) of the Act for the exercise of the Rights.

The Department is offering no view, as to whether the requirements of the statutory exemption provided in section 408(e) of the Act have been satisfied. Further, the Department, herein, is not providing any relief with respect to the exercise of the Rights.

[7] It is represented that the extra five (5) business days were required to provide sufficient time to process all such elections by the Accounts of Invested Participants in the Plan to exercise their Rights, tabulate and confirm the results, liquidate each such Invested Participant's funds, confirm the orders and the availability of such funds, and remit payment to purchase the shares. It is represented that non-Plan shareholders were also required to submit their election forms five (5) days prior to the expiration of the Offering.

to CPFC and the Plan. It is represented that the Rights Fund was liquidated, and cash equal to the necessary subscription payment was transferred to the Wells Fargo Bank. Following the closing of the Offering, the purchased shares of Stock were then converted back to the equivalent number of units of the Plan's Stock Fund and credited to the Account of the Invested Participant.

17. As of the Record Date, February 17, 2011, 287 Accounts of Invested Participants in the Plan held the Stock. As of the Record Date, the approximate percentage of the fair market value of the total assets of the Plan invested in the Stock was two percent (2%). Also, as of the Record Date, the shares of Stock held in the Accounts of Invested Participants in the Plan constituted approximately three percent (3%) of the shares of Stock outstanding.

18. It is represented that based on the ratio of one (1) Right for each share of Stock held by the Accounts of Invested Participants, the Plan acquired 46,327 Rights as a result of the Offering. Of the Rights received by the Plan on behalf of Accounts of the Invested Participants, all such Rights were either exercised or sold. None of the Rights expired.

Of the 46,327 Rights received by the Accounts of Invested Participants as a result of the Offering, it is represented that 19,231 Rights held by 102 Accounts of Invested Participants in the Plan were exercised for Stock. It is represented that on May 19, 2011, the Accounts of the Invested Participants in the Plan received the Stock purchased as a result of the exercise of the Rights. It is further represented that the Stock purchased in connection with the Offering was eligible for trading on NYSE by the Accounts of the Invested Participants in the Plan on May 19, 2011.

Unlike the other holders of the Rights, the Invested Participants whose Accounts in the Plan received the Rights were not permitted to sell the Rights throughout the period April 11–25, 2012, due to Plan administrative constraints. However, of the 46,327 Rights received by the Accounts of Invested Participants as a result of the Offering, it is represented that over the period from April 26, 2011 to May 3, 2011, the Invested Participants of 186 Accounts sold 27,096 Rights on the NYSE. On May 9, 2011, the Accounts of those Invested Participants received the proceeds from the sales of such Rights totaling $133,339.44.

Based on the difference ($1.13) between the average proceeds per Right ($6.05) received by other holders who sold Rights during the Offering and the average proceeds per Right ($4.92) received by Invested Participants whose Accounts sold Rights, between April 26, 2011 and May 3, 2011, CPFC will make a corrective payment to the Plan in the amount of $30,618.48 ($1.13 × 27,096 Rights sold). Further, CPFC proposes to include a lost earnings component on the amount of the corrective payment calculated at a 2.83% annual rate of interest for the period from May 6, 2011, to the date of the grant of this proposed exemption. It is represented that the interest rate on the lost earnings component was calculated taking the greater of the weighted average return for all investment funds available under the Plan and the average return for the Retirement Savings Trust (the stable value fund under the Plan in which the proceeds from the sale of the Rights were distributed). CPFC will distribute such corrective contribution, plus the lost earnings component, *pro rata* to each of the 186 Invested Participants whose Accounts in the Plan sold Rights.

19. No brokerage fees, no commissions, no subscription fees, and no other charges were paid by the Plan or by any of the Accounts of Invested Participants in the Plan with respect to the acquisition and holding of the Stock and no brokerage fees, no commissions, and no fees or expenses were paid by the Plan or by any of the Accounts of Invested Participants in the Plan to any related broker in connection with the sale of the Rights or in connection with the exercise of the Rights.

Requested Relief

20. The application was filed on behalf of CPFC. In this regard, CPFC has requested an exemption: (a) For the acquisition of the Rights by the Accounts of the Invested Participants in the Plan in connection with the Offering of Rights by CPFC; and (b) for the holding of the Rights by the Accounts of the Invested Participants in the Plan during the subscription period of the Offering.

It is represented that the Rights acquired by the Accounts of Invested Participants in the Plan satisfy the definition of ''employer securities,'' pursuant to section 407(d)(1) of the Act. However, as the Rights were not stock or a marketable obligation, such Rights do not meet the definition of ''qualifying employer securities,'' as set forth in section 407(d)(5) of the Act. Accordingly, the subject transactions constitute an acquisition and holding on behalf of the Accounts of Invested Participants in the Plan, of employer securities which are not qualifying employer securities, in violation of section 407(a) of the Act, for which CPFC has requested relief from sections 406(a)(1)(A), 406(a)(1)(E), 406(a)(2), and 407(a)(1)(A) of the Act. CPFC has also requested relief from the prohibitions of section 406(b)(1) and 406(b)(2) of the Act.

21. It is represented that the subject transactions have already been consummated. In this regard, the Accounts of Invested Participants in the Plan acquired the Rights pursuant to the Offering on April 11, 2011, and held such Rights pending the closing of the Offering on May 6, 2011, when such Rights either were exercised or sold. As there was insufficient time between the dates when the Accounts of Invested Participants in the Plan acquired the Rights and when such Rights were exercised or sold, to apply for and be granted an exemption, CPFC is seeking a retroactive exemption to be granted, effective from April 11, 2011, the date that the Accounts of Invested Participants in the Plan acquired the Rights, to May 6, 2011, the closing date of the Offering.

22. CPFC represents that the proposed exemption is administratively feasible. In this regard, the acquisition and holding of the Rights by the Accounts of Invested Participants in the Plan were one-time transactions that involved an automatic distribution of the Rights to all shareholders. It is represented that it is customary for corporations to make a rights offering available to all shareholders.

23. CPFC represents that the transactions which are the subject of this proposed exemption are in the interest of the Accounts of Invested Participants in the Plan, because the subject transactions represented a valuable opportunity to such Accounts to buy the Stock at a discount or to sell the Rights. It is represented that this discount could be realized by the Accounts of Invested Participants in the Plan by selling the Stock immediately after the exercise of the Rights and investing the proceeds from such sale of the Stock in other investment options under the Plan.

24. CPFC represents that the proposed exemption provides sufficient safeguards for the protection of the Accounts of Invested Participants in the Plan and the beneficiaries of such Accounts. In this regard, participation in the Offering protected the Accounts of the Invested Participants in the Plan from having their interests in CPFC diluted as a result of the Offering.

It is further represented that the interests of the Accounts of Invested Participants in the Plan were adequately protected in that such Accounts acquired and held the Rights automatically as a result of the Offering. In addition, CPFC made the Rights

available on the same terms to all shareholders of the Stock, including the Accounts. In this regard, each shareholder of the Stock, including each of the Accounts, received the same proportionate number of Rights, and this proportionate number of Rights was based on the number of shares of Stock held by such shareholder.

The Accounts of Invested Participants in the Plan were protected against economic loss by exercising the Rights or by selling the Rights. It is represented that the closing price of the Stock on May 6, 2011, was $13.70 per share which was in excess of the strike price of $10.00 per share.

25. In summary, CPFC represents that the subject transactions satisfy the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because:

(a) The receipt of the Rights by the Accounts occurred in connection with the Offering, and the Rights were made available by CPFC to all shareholders of the Stock of CPFC, including the Accounts;

(b) The acquisition of the Rights by the Accounts resulted from an independent corporate act of CPFC;

(c) Each shareholder of the Stock, including each of the Accounts, received the same proportionate number of Rights, and this proportionate number of Rights was based on the number of shares of Stock held by such shareholder;

(d) The Rights were acquired pursuant to, and in accordance with, provisions under the Plan for individually-directed investment of the Accounts by the Invested Participants, all or a portion of whose Accounts in the Plan held the Stock;

(e) The decision with regard to the holding and disposition of the Rights by an Account was made by the Invested Participant whose Account received the Rights;

(f) If any of the Invested Participants failed to give instructions as to the exercise of the Rights received in the Offering, such Rights were sold in blind transactions on the NYSE and the proceeds from such sales were distributed *pro-rata* to the Accounts in the Plan of such Invested Participants;

(g) No brokerage fees, no commissions, and no fees or expenses were paid by the Plan or by the Accounts to any related broker in connection with the sale of any of the Rights or in connection with the exercise of any of the Rights, and no brokerage fees, no commissions, no subscription fees, and no other charges were paid by the Plan or by the Accounts with respect to the acquisition and holding of the Stock; and

(h) Based on the difference ($1.13) between the average proceeds per Right ($6.05) received by other holders who sold Rights during the Offering and the average proceeds per Right ($4.92) received by Invested Participants whose Accounts sold Rights, between April 26, 2011 and May 3, 2011, CPFC will make a corrective payment to the Plan in the amount of $30,618.48 ($1.13 × 27,096 Rights sold), plus a lost earnings component on such amount calculated at a 2.83% annual rate of interest for the period from May 6, 2011 to the date of the grant of this proposed exemption, and will distribute such corrective payment, and the lost earnings component, *pro rata* to the Accounts of each of the 186 Invested Participants whose Accounts in the Plan sold Rights.

Notice to Interested Persons

The persons who may be interested in the publication in the **Federal Register** of the Notice of Proposed Exemption (the Notice) include all Invested Participants whose Accounts in the Plan were invested in the Stock at the time of the Offering.

It is represented that all such interested persons will be notified of the publication of the Notice by first class mail, to each such interested person's last known address within fifteen (15) days of publication of the Notice in the **Federal Register**. Such mailing will contain a copy of the Notice, as it appears in the **Federal Register** on the date of publication, plus a copy of the Supplemental Statement, as required, pursuant to 29 CFR 2570.43(a)(2), which will advise all interested persons of their right to comment and to request a hearing. All written comments and/or requests for a hearing must be received by the Department from interested persons within 45 days of the publication of this proposed exemption in the **Federal Register**.

All comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines.

FOR FURTHER INFORMATION CONTACT: Ms. Angelena C. Le Blanc of the Department, telephone (202) 693–8551. (This is not a toll-free number.)

Studley, Inc. Section 401(k) Profit Sharing Plan (the Plan), Located in New York, NY

[Application No. D–11672]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR Part 2570 Subpart B (55 FR 32836, 32847, August 10, 1990). If the proposed exemption is granted, the restrictions of section 406(a)(1)(A) and (D) and section 406(b) of the Act, and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A), (D), (E) and (F) of the Code, shall not apply to the sale (the Sale) of an 8.828121% partnership interest (the Interest) in the Julien J. Studley N Street Partnership, a general partnership (the JJS Partnership), by the Plan to Studley, Inc. (the Employer), a party in interest with respect to the Plan, provided that the following conditions are satisfied:

(a) The Sale is a one-time transaction for cash;

(b) The terms and conditions of the Sale are at least as favorable to the Plan as those that the Plan could obtain in an arm's length transaction with an unrelated third party;

(c) The Interest is sold for $900,000;

(d) The Sale is consummated within two weeks after the date a final exemption regarding the Sale is published in the **Federal Register**;

(e) If, (1) within seven years of the date of the Sale of the Interest to the Employer, (i) the Employer sells the Interest, (ii) JJS Partnership sells its interest in N19 Associates LLC (N19 Associates), or (iii) N19 Associates sells its building on N Street, Washington, DC, and (2) the net amount realized by the Employer in respect of the Interest upon and by reason of such sale, exceeds the sum of (i) the $900,000 price paid for the Interest, and (ii) any capital contributed by the Employer to the JJS Partnership in respect of the Interest after the date of the Sale and any other funds paid or advanced by the Employer to, or on behalf of, the JJS Partnership in respect of the Interest after the date of the Sale, the Employer will contribute such excess amount to the Plan within two weeks of its receipt by the Employer;

(f) The Plan pays no commissions, fees, or other expenses in connection with the Sale; and

(g) The Plan has not waived or released and does not waive or release any claims, demands, and/or causes of

action that the Plan may have against the Employer or the Plan fiduciaries in connection with the acquisition and holding of the Interest or Sale of the Interest to the Employer.

Summary of Facts and Representations

1. The Studley, Inc. Section 401(k) Profit Sharing Plan (the Plan) is sponsored by Studley, Inc. (the Employer or the Applicant), located in New York, New York. Julien Studley (Mr. Studley) was the founder of the Employer. Pursuant to a buyout, all of his shares in the Employer not held in an employee benefit plan were purchased on December 12, 2002, by the Employer, at which time Mr. Studley resigned as a voting member from the Employer's Board of Directors. He remained a non-voting member until June 2004. Since then, Mr. Studley has not held any position with, or interest in, the Employer (other than shares held in employee benefit plans). The Employer is in the business of providing commercial real estate advisory, brokerage and related services.

The Plan had 61 participants and beneficiaries, as of November 14, 2011. Based on the most recently available audited financial statements, the total value of the Plan's assets was $26,830,211, as of December 31, 2010. The Plan's trustee is T. Rowe Price Trust Company. The trust agreement indicates that the trustee takes direction from the named fiduciary (the Named Fiduciary), which is the Employer. The Plan has a non-participant directed profit sharing component in which it holds real estate investments, as well as a 401(k) component which is participant directed.

2. Among the assets of the Plan is an 8.828121% interest (the Interest) in the Julien J. Studley N Street Partnership (JJS Partnership), a general partnership in which the Employer and the Plan are both general partners. The Applicant represents that there are currently eight other members in the JJS Partnership in addition to the Employer and the Plan. No other employee benefit plans are members of the JJS Partnership.

The managing partners of the JJS Partnership are Mr. Studley and Mr. Peter Speier, and neither the Plan nor the Employer has management responsibilities. The JJS Partnership was formed and capitalized on or about December 28, 1976. The Applicant represents that the Interest was acquired by the Plan in 1982 for $45,000 and is held under an ancillary trust agreement (the Ancillary Trust Agreement), with Mitchell Steir and Michael Colacino as trustees.[8] Mr. Steir is the Chairman of the Board and Chief Executive Officer of the Employer while Mr. Colacino is the President of the Employer. Under the Ancillary Trust Agreement, the trustees are subject to the direction of the Employer, as Named Fiduciary, with respect to the investment and disposition of the trust fund assets.

3. The Applicant represents that the JJS Partnership was formed for the purpose of holding an interest in an entity known as N19 Associates. The JJS Partnership holds a 32% interest in N19 Associates, which owns a building on N Street in Washington, DC (the Building). The Plan's effective interest in the Building is 2.825%, which is 8.828121% of 32%.

4. The NYRO opened an investigation of the Plan and found that the Plan's interest in the JJS Partnership is an illiquid and hard-to-value asset.[9] The Plan has been unable, in at least two instances, to make requested distributions to Plan participants because of the Plan's investment in the Interest. In addition, certain recent annual reports (Forms 5500) filed for the Plan have not reflected a current valuation for the Interest.[10] The NYRO and the Applicant agreed that the Plan should liquidate its investment in the JJS Partnership in order to be able to make the distributions to eligible participants. Because the Interest is an illiquid asset, Studley is requesting an exemption that, if granted, would permit Studley to purchase the Interest from the Plan.

5. The Applicant represents that N19 Associates is controlled by Melvin and Edward Lenkin, who are not affiliated with the Employer or the JJS Partnership. The JJS Partnership has commenced litigation against the Lenkins based, in part, upon their refusal to provide current information regarding the Building. Due to the disagreement among the parties, the Applicant represents, among other things, that JJS Partnership has been unable to obtain and provide to the Plan the information that would enable the Plan to obtain a current appraisal of the Interest by an independent appraiser. The most recently available independent appraisal assigns the Interest a value of $670,000, as of November 3, 2006, which reflects a 25% minority discount by reason of the Plan's holding a minority, non-controlling interest. This was the value for the Interest used in the Plan's audited financial statements as of December 31, 2010.

6. The Applicant represents that the most recent expression of interest from an unrelated party [i.e., Goldstar Real Estate Fund II, LP (Goldstar)] in purchasing the Building received by the JJS Partnership on August 2, 2010 was $45 million. However, the potential sale of the Building to Goldstar could not be consummated in the absence of a current independent appraisal of the Building, which is currently not obtainable due to the lack of cooperation among the parties, as described in Representation 5, above. Therefore, the Employer proposes to purchase the Interest from the Plan for $900,000 on the following basis: After deducting N19 Associates' mortgage and other liabilities and expenses associated with the sale, a $45 million purchase price for the Building would result in $900,000 of net proceeds to the Plan in respect of the Interest. It is represented that this price is very favorable to the Plan because it does not reflect any discount for the fact that the JJS Partnership and the Plan hold only minority, non-controlling interests, and the discounting of minority, non-controlling interests is a recognized principle of valuation.[11] Assuming a sale (the Sale) of the Interest for $900,000, the Applicant represents that the Plan will achieve an average annual rate of return of approximately 11.5% per annum, based on Plan records of cash amounts received or paid by the Plan during the term of this investment (except for two years[12] for which no records are available). This calculation includes capital calls paid by the Plan.

The Applicant represents that according to its available records, the Plan has received approximately $167,690 in cash distributions from the JJS Partnership during the time it has

[8] Pursuant to the Ancillary Trust Agreement, a separate trust was established to hold the Plan's real estate investments. As part of its investigation (see Representation 4, below), the Department's New York Regional Office (NYRO) inquired whether the Plan's acquisition of the Interest was a purchase or a contribution by the Employer. The Plan's records are incomplete on this matter.

[9] The reasons for these characterizations are discussed in Representation 5, below.

[10] The Internal Revenue Service (the IRS) examined the Plan and determined that prohibited transactions had been entered into involving loans to the Plan from the Employer for the years 2002 through 2006. The prohibited transactions were corrected on December 22, 2006 and the Employer filed Forms 5330 for the years 2002 through 2006 and paid the resulting excise taxes.

[11] This representation was made by the Applicant to both the Department's Office of Exemption Determinations and the NYRO.

[12] Although no records are available for the years 1982 and 2001, the NYRO reviewed the available pertinent records and concluded that the Sale, based upon the terms described herein, would enable the NYRO to close its investigation.

held the Interest.[13] Specifically, according to the Applicant, the Plan has historically received a portion of the rental income generated by the Building. However, this source of revenue has been retained pending completion of the litigation described above. The Applicant requests that the scope of relief contained in this proposed exemption include relief from section 406(b)(3) of ERISA (as well as section 406(a)(1)(A) and (D) and section 406(b)(1) and (2) of ERISA) since the Employer may receive from the Partnership, subsequent to the Sale, the Plan's current share of the undistributed revenue. According to the Applicant, such amount is not currently quantifiable due to the litigation and other factors that are outside of the control of Studley. The Applicant stresses that it is in the best interests of the Plan to consummate the Sale as soon as possible in order to provide liquidity to the Plan, rather than to delay the date of the Sale until after the litigation is resolved. The Applicant reiterates that the amount of the Sale represents the best price the Plan may be expected to receive for the Interest.

7. In addition, the Employer has included in the terms of the proposed Sale a ''true-up'' provision that the Employer will contribute an additional amount to the Plan if (a) within seven years of the date of the Sale of the Interest to the Employer, (i) the Employer sells the Interest, (ii) JJS Partnership sells its interest in N19 Associates, or (iii) N19 Associates sells the Building, and (b) the net amount realized by the Employer in respect of the Interest upon and by reason of such Sale, exceeds the sum of (i) the $900,000 price paid for the Interest, and (ii) any capital contributed by the Employer to the JJS Partnership in respect of the Interest after the date of the Sale and any other funds paid or advanced by the Employer to, or on behalf of, the JJS Partnership in respect of the Interest after the date of the Sale. The Employer will contribute such excess amount to the Plan within two weeks of its receipt by the Employer. Such contribution will be allocated to the Plan accounts of participants who were invested in the Interest at the time of the Sale.[14] The Applicant also represents that if, within seven years of the date of the Sale of the Interest by the Plan to the Employer, the Employer, in its sole discretion, elects to fund any capital call in respect of its own interest (that it owned prior to the subject Sale) in the JJS Partnership, then, and only then, will the Employer be obligated to the Plan to fund such capital call in respect of the Interest.

8. The Applicant represents that the requested exemption for the Sale of the Plan's Interest to the Employer is in the interest of the Plan because it will enable the participants and beneficiaries to realize the value of the Interest and receive requested distributions in respect of their investment therein. The Applicant also represents that the requested exemption is also protective of the rights of the participants and beneficiaries of the Plan because the Sale price reflects the best information available to the Employer of the Interest's current fair market value, with no discount taken for a minority, non-controlling interest. Moreover, according to the Applicant, the ''true-up'' provision gives the participants and beneficiaries of the Plan protection against a down market and allows their full participation in any up market for the next seven years.

The Applicant also represents that the Sale of the Interest will be a one-time transaction for cash, and the Plan will incur no fees, commissions, or other expenses in connection with the Sale. Further, the Employer will bear the costs of the exemption application and notification of interested persons.

9. In consideration of the following conditions, the Department has tentatively determined that the Sale will satisfy the statutory criteria for an exemption under section 408(a) of the Act: (a) The Sale will be a one-time transaction for cash; (b) the terms and conditions of the Sale will be at least as favorable to the Plan as those that the Plan could obtain in an arm's length transaction with an unrelated third party; (c) the Interest will be sold for $900,000; (d) the Sale will be consummated within two weeks after the date a final exemption regarding the Sale is published in the **Federal Register**; (e) If, (1) within seven years of the date of the Sale of the Interest to the Employer, (i) the Employer sells the Interest, (ii) JJS Partnership sells its interest in N19 Associates LLC (N19 Associates), or (iii) N19 Associates sells its building on N Street, Washington, DC, and (2) the net amount realized by the Employer in respect of the Interest upon and by reason of such sale, exceeds the sum of (i) the $900,000 price paid for the Interest, and (ii) any capital contributed by the Employer to the JJS Partnership in respect of the Interest after the date of the Sale and any other funds paid or advanced by the Employer to, or on behalf of, the JJS Partnership in respect of the Interest after the date of the Sale, the Employer will contribute such excess amount to the Plan within two weeks of its receipt by the Employer; (f) the Plan will pay no commissions, fees, or other expenses in connection with the Sale; and (g) the Plan has not waived or released and does not waive or release any claims, demands, and/or causes of action that the Plan may have against the Employer or the Plan fiduciaries in connection with the acquisition and holding of the Interest or Sale of the Interest to the Employer.

Notice to Interested Persons

All comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines.

FOR FURTHER INFORMATION CONTACT: Mr. Eric A. Raps of the Department, telephone (202) 693–8532. (This is not a toll-free number.)

EquiLend Holdings LLC (EquiLend), Located in New York, New York

[Application No. D–11724]

Proposed Amendment to Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the following amendment to Prohibited Transaction Exemption 2002–30 (67 FR 39069) under the authority of ERISA section 408(a), section 8477(c)(3) of the Federal Employees' Retirement System Act of 1986 (FERSA) and Code section 4975(c)(2), and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (76 FR 66637, 66644, October 27, 2011), as follows:

Section I. Sale of Equilend Products to Plans

If the proposed exemption is granted, the restrictions of ERISA section 406(a)(1)(A) and (D) and the sanctions resulting from the application of Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) and (D), shall not apply, effective October 1, 2012, to the sale or licensing of certain data and/or analytical tools to a plan by EquiLend, a party in interest with respect to such plan.

[13] The Applicant also represents that the Plan has paid approximately $18,645 in capital calls. Thus, based on the available figures, the Plan has received a net distribution of $149,045.

[14] It is represented that the Plan's recordkeeper T. Rowe Price will determine the affected Plan accounts in connection with both the Sale of the Interest to the Employer and any future additional contribution by the Employer per the true-up provision of the Purchase and Sale Agreement.

This exemption, if granted, would be subject to the following conditions:

(a) The terms of any such sale or licensing are at least as favorable to the plan as the terms generally available in an arm's-length transaction involving an unrelated party;

(b) Any data sold/licensed to the plan will be limited to:

(1) Current and historical data related to transactions, whether or not proposed or occurring on EquiLend's electronic securities lending platform (the Platform) or,

(2) Data derived from current and historical data using statistical or computational techniques; and

(c) Each analytical tool sold/licensed to the plan will be an objective statistical or computational tool designed to permit the evaluation of securities lending activities.

Section II. Use of Platform by Owner Lending Agent/Sale of Equilend Products to Plans Represented by Owner Lending Agent/Provision of Securities Lending Data Involving Plans to Equilend by Owner Lending Agent

If the proposed exemption is granted, the restrictions of ERISA sections 406(a)(1)(A) and (D) and 406(b), FERSA section 8477(c)(2), and the sanctions resulting from the application of Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) and (D) through (F), shall not apply, effective October 1, 2012, to: (1) The participation in the Platform by an equity owner of EquiLend (an Equity Owner), in its capacity as a securities lending agent for a plan (an Owner Lending Agent); (2) the sale or licensing of certain data and/or analytical tools by EquiLend to a plan for which an Equity Owner acts as a securities lending agent; and (3) the provision by an Owner Lending Agent to EquiLend of securities lending data based on off-Platform securities lending transactions conducted by an Owner Lending Agent on behalf of a plan.

This proposed exemption, if granted, would be subject to the following conditions:

(a) In the case of participation in the Platform on behalf of a plan, to the extent an applicable exemption is required, the securities lending transactions conform to the provisions of Prohibited Transaction Class Exemption (PTE) 2006–16 (71 FR 63786 (Oct. 31, 2006)) (or its successor), and/or any applicable individual exemption;

(b) None of the fees imposed by EquiLend for securities lending transactions conducted through the use of the Platform at the direction of an Owner Lending Agent will be charged to a plan;

(c) Each securities lender and securities borrower participating in a securities lending transaction through EquiLend will be notified by EquiLend as to its responsibilities with respect to compliance, as applicable, with ERISA, the Code, and FERSA. This requirement may be met by including such notification in the participation, subscription or other user agreement required to be executed by each participant in EquiLend;

(d) EquiLend will not act as a principal in any securities lending transaction involving plan assets;

(e) Each Owner Lending Agent will provide prior written notice to its plan clients of its intention to participate in EquiLend;

(f)(1) Except as otherwise provided in paragraph (i), the arrangement pursuant to which the Owner Lending Agent utilizes the services of EquiLend on behalf of a plan for securities lending:

(A) Is subject to the prior written authorization of an independent fiduciary (an authorizing fiduciary) as defined in paragraph (b) of Section III). For purposes of subparagraph (f)(1), the requirement that the authorizing fiduciary be independent shall not apply in the case of an Equity Owner Plan;

(B) May be terminated by the authorizing fiduciary, without penalty to the plan, within the lesser of: (i) The time negotiated for such notice of termination by the plan and the Owner Lending Agent, or (ii) five business days. Notwithstanding the foregoing, the requirement for prior written authorization will be deemed satisfied in the case of any plan for which the authorizing fiduciary has previously provided written authorization to the Owner Lending Agent pursuant to PTE 2006–16 (or any predecessor or successor thereto), unless such authorizing fiduciary objects to participation in the Platform in writing to the Owner Lending Agent within 30 days following disclosure of the information described in paragraphs (e) and (g) of this Section to such authorizing fiduciary;

(2) Except as otherwise provided in paragraph (i), each purchase or license of a securities lending-related product from EquiLend on behalf of a plan by an Owner Lending Agent:

(A) Is subject to the prior written authorization of an authorizing fiduciary. For purposes of subparagraph (f)(2), the requirement for prior written authorization shall not apply to any purchase or licensing of an EquiLend securities lending-related product by an Equity Owner Plan if the fee or cost associated with such purchase or licensing is not paid by the Equity Owner Plan; and

(B) May be terminated by the authorizing fiduciary within: (i) The time negotiated for such notice of termination by the plan and the Owner Lending Agent; or (ii) five business days, whichever is lesser, in either case without penalty to the plan, provided that, such authorizing fiduciary shall be deemed to have given the necessary authorization in satisfaction of this subparagraph (f)(2) with respect to each specific product purchased or licensed pursuant thereto unless such authorizing fiduciary objects to the Owner Lending Agent within 15 days after the delivery of information regarding such specific product to the authorizing fiduciary in accordance with paragraph (g) of this exemption; and

(3) Except as otherwise provided in paragraph (i), provision by an Owner Lending Agent to EquiLend of securities lending data based on off-Platform securities lending transactions conducted on behalf of a plan:

(A) Is subject to the prior written authorization of an authorizing fiduciary; and

(B) May be terminated by the authorizing fiduciary with respect to the future provision of data within the lesser of (i) the time negotiated for such notice of termination by the plan and the Owner Lending Agent or (ii) five business days, in either case without penalty to the plan. Notwithstanding the foregoing, the requirement for prior written authorization will be deemed satisfied unless such authorizing fiduciary objects to provision by the Owner Lending Agent to EquiLend of such data in writing to the Owner Lending Agent within 30 days following disclosure of the information described in paragraph (g) of this Section to such authorizing fiduciary.

(g) The authorization(s) described in paragraph (f) of this Section shall not be deemed to have been made unless the Owner Lending Agent has furnished the authorizing fiduciary with any reasonably available information that the Owner Lending Agent reasonably believes to be necessary for the authorizing fiduciary to determine whether such authorization should be made, and any other reasonably available information regarding the matter that the authorizing fiduciary may reasonably request. This includes, but is not limited to: (1) a statement that the Equity Owner, as securities lending agent, has a financial interest in the successful operation of EquiLend, (2) a

statement, provided on an annual basis, that the authorizing fiduciary may terminate the arrangement(s) described in (f) above at any time, and (3) a statement that the Owner Lending Agent intends to provide to EquiLend securities lending data based on off-Platform securities lending transactions conducted by the Owner Lending Agent on behalf of the plan;

(h) Any purchase or licensing of data and/or analytical tools with respect to securities lending activities by a plan pursuant to this Section complies with the relevant conditions of Section I and will be authorized in advance by an authorizing fiduciary in accordance with the applicable procedures of paragraphs (f), (g) and (i);

(i) In the case of a pooled separate account maintained by an insurance company qualified to do business in a state or a common or collective trust fund maintained by a bank or trust company supervised by a state or federal agency (Commingled Investment Fund), the requirements of paragraph (f) of this Section shall not apply, provided that—

(1) The information described in paragraph (g) (including information with respect to any material change in the arrangement) of this Section and a description of the operation of the Platform (including a description of the fee structure paid by securities lenders and borrowers), shall be furnished by the Owner Lending Agent to the authorizing fiduciary (described in paragraph (b) of Section III) with respect to each plan whose assets are invested in the account or fund, not less than 30 days prior to implementation of any such arrangement or material change thereto, or, not less than 15 days prior to the purchase or license of any specific securities lending-related product, and, where requested, upon the reasonable request of the authorizing fiduciary. For purposes of this subparagraph, the requirement that the authorizing fiduciary be independent shall not apply in the case of an Equity Owner Plan;

(2) In the event any such authorizing fiduciary notifies the Owner Lending Agent that it objects to participation in the Platform, or to the purchase or license of any EquiLend securities lending-related tool or product, or to the further provision by an Owner Lending Agent to EquiLend of securities lending data based on off-Platform securities lending transactions conducted on behalf of the plan, the plan on whose behalf the objection was tendered is given the opportunity to terminate its investment in the account or fund, without penalty to the plan, within such time as may be necessary to effect the withdrawal in an orderly manner that is equitable to all withdrawing plans and to the non-withdrawing plans. In the case of a plan that elects to withdraw pursuant to the foregoing, such withdrawal shall be effected prior to the implementation of, or material change in, the arrangement or purchase or license, but any existing arrangement need not be discontinued by reason of a plan electing to withdraw; and

(3) In the case of a plan whose assets are proposed to be invested in the pooled account or fund subsequent to the implementation of the arrangements and which has not authorized the arrangements in the manner described in paragraphs (i)(1) and (i)(2), the plan's investment in the account or fund shall be authorized in the manner described in paragraph (f)(1)(A), (f)(2)(A), and (f)(3)(A);

(j) The Equity Owner, together with its affiliates (as defined in Section III(a)), does not own at the time of the execution of a securities lending transaction on behalf of a plan by the Equity Owner (i.e., in its capacity as Owner Lending Agent) through EquiLend or at the time of the purchase, or commencement of licensing, of data and/or analytical tools by the plan, more than 20% of:

(1) If EquiLend is a corporation, including a limited liability company taxable as a corporation, the combined voting power of all classes of stock entitled to vote or the total value of shares of all classes of stock of EquiLend, or

(2) If EquiLend is a partnership, including a limited liability company taxable as a partnership, the capital interest or the profits interest of EquiLend;

(k) Any information, authorization, or termination of authorization may be provided by mail or electronically; and

(l) No Equity Owner Plan, as defined in Section III(e), will participate in the Platform, other than through a Commingled Investment Fund in which the aggregate investment of all Equity Owner Plans at the time of the transaction constitutes less than 20% of the total assets of such fund. Notwithstanding the foregoing, this prohibition shall not apply to the participation by an Equity Owner Plan as of the date that the aggregate loan balance of all securities lending transactions entered into through EquiLend by all participants outstanding on such date (excluding transactions entered into on behalf of Equity Owner Plans) is equal to or greater than $10 billion; provided that if such aggregate loan balance is later determined to be less than $10 billion, no additional participation by an Equity Owner Plan (other than through a Commingled Investment Fund) shall occur until such time as the $10 billion threshold amount is again met.

Section III. Definitions

For purposes of this proposed exemption:

(a) An ''affiliate'' of another person means:

(1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(2) Any officer, director, partner, employee, relative (as defined in ERISA section 3(15)) of such other person; and

(3) Any corporation or partnership of which such other person is an officer, director or partner.

For purposes of this paragraph, the term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(b) The term ''authorizing fiduciary'' means, with respect to an Owner Lending Agent, a plan fiduciary who is independent of such Owner Lending Agent. In this regard, an authorizing fiduciary will not be considered independent of an Owner Lending Agent if:

(1) Such fiduciary directly or indirectly controls, is controlled by, or is under common control with the Owner Lending Agent; or

(2) Such fiduciary directly or indirectly receives any compensation or other consideration from the Owner Lending Agent or an affiliate for his or her own personal account in connection with any securities lending transaction described herein; provided that Commingled Investment Funds and Equity Owner Plans maintained by such Owner Lending Agent or an affiliate will not be deemed affiliates of such Owner Lending Agent for purposes of this subparagraph (2).

For purposes of Section II, no Equity Owner or any affiliate may be an authorizing fiduciary except in the case of an Equity Owner Plan. Notwithstanding the foregoing, the requirements for consent by an authorizing fiduciary with respect to participation in the Platform, and the annual right of such fiduciary to terminate such participation, shall be deemed met to the extent that the Owner Lending Agent's proposed utilization of the services of EquiLend on behalf of a plan for securities lending has been approved by an order of a United States district court.

(c) The term ''Owner Lending Agent'' means an Equity Owner in its capacity as a fiduciary of a plan acting as securities lending agent in connection with the loan of plan assets that are securities.

(d) The term ''Equity Owner'' means an entity that either directly or through an affiliate owns an equity ownership interest in EquiLend.

(e) The term ''Equity Owner Plan'' means a plan which is established or maintained by an Equity Owner of EquiLend as an employer of employees covered by such plan, or by its affiliate.

(f) The terms ''plan'' means:

(1) An ''employee benefit plan'' within the meaning of ERISA section 3(3), subject to Part 4 of Subtitle B of Title I of ERISA,

(2) A ''plan'' that is within the meaning of Code section 4975(e)(1) and subject to Code section 4975, or

(3) The Federal Thrift Savings Fund.

Effective Date: The proposed exemption would be effective October 1, 2012 with respect to arrangements entered into on or after that date. The provisions of PTE 2002–30 shall continue to apply to arrangements entered into before October 1, 2012.

Summary of Facts and Representations

1. The applicant is EquiLend, a Delaware limited liability company established on May 16, 2001. As of March 15, 2012, the equity owners of EquiLend were as follows: BlackRock, Credit Suisse, JP Morgan Clearing Corp., JP Morgan Chase, Merrill Lynch, Morgan Stanley, State Street, Goldman Sachs, Northern Trust and UBS, or affiliates of the foregoing entities. The applicant represents that, as of March 15, 2012, each equity owner owned 10 percent of EquiLend.

2. The applicant submitted a request that Prohibited Transaction Exemption 2002–30 (67 FR 39069) (PTE 2002–30) be amended. PTE 2002–30 was originally promulgated on June 6, 2002, and it permits: (1) The sale or licensing of certain data and/or analytical tools to an employee benefit plan by EquiLend; (2) participation in the Platform by an equity owner of EquiLend (an Equity Owner), in its capacity as a securities lending agent for the plan (an Owner Lending Agent); and (3) the sale or licensing of certain data and/or analytical tools by EquiLend to a plan for which an Equity Owner acts as an Owner Lending Agent. Unless otherwise noted, the facts and representations of PTE 2002–30, are integrated herein.[15]

3. The applicant represents that, as permitted under Section I of PTE 2002–30, EquiLend currently sells and/or licenses certain data to plans. Consistent with the terms of the individual exemption, this data is: (A) Historical in nature and relates to transactions proposed or occurring on the system; or (B) derived from current and historical data utilizing statistical or computational techniques. In this regard, the applicant notes that Section I(b) of PTE 2002–30 requires that, with respect to the sale or licensing of certain data and/or analytical tools to an employee benefit plan by EquiLend:

> (b) Any data sold/licensed to the plan will be limited to: (1) current and historical data related to transactions proposed or occurring on the Platform or, (2) data derived from current and historical data using statistical or computational techniques.

4. The applicant is seeking to amend Section I(b) of PTE 2002–30, effective October 1, 2012. The applicant notes that Section I(b) of PTE 2002–30 limits the types of data that may be licensed or sold by EquiLend. Specifically, Section I(b) precludes the sale or licensing of data to a plan by Equilend where such data sold/licensed involves the use of current or historical data related to transactions that are proposed or occurring off the Platform. The applicant believes, however, that access to off-Platform securities lending data by plans will further enhance EquiLend's existing client service functionality via the Platform by expanding the information that is available to plans. The applicant states that the addition of additional data to the Platform enhances the ability of a plan to evaluate the performance of lending agents and the returns on lending portfolios.

5. The applicant, therefore, requests that the Department revise Section I(b) of PTE 2002–30 in a manner that would permit, effective October 1, 2012, EquiLend to use, sell or license data relating to transactions occurring off the Platform to plans. If this proposed amendment is granted, Section I(b) of PTE 2002–30 will provide that:

> (b) Any data sold/licensed to the plan will be limited to:
>
> (1) Current and historical data related to transactions, whether or not proposed or occurring on EquiLend's electronic securities lending platform (the Platform) or,
>
> (2) Data derived from current and historical data using statistical or computational techniques.

6. In the applicant's view, affected plans would be adequately protected with respect to the sale and licensing by EquiLend of this off-Platform data. In this regard, the applicant notes that Section I(b) of PTE 2002–30 limits the type of data that may be sold and licensed by EquiLend to current and historical data related to securities lending transactions, or data derived from current and historical data using statistical or computational techniques. Further, the applicant notes that the terms of any sale or licensing of data must be at least as favorable to the plan as the terms generally available in an arm's-length transaction involving an unrelated party. The applicant represents that these limitations/conditions are sufficient to ensure that plans would be adequately protected to the extent Section I(b) of PTE 2002–30 is revised to include any current and historical data related to transactions proposed occurring off the Platform.[16]

7. The applicant also seeks to amend Section II of PTE 2002–30, effective October 1, 2012. Section II presently permits: (1) Participation in the Platform by an Equity Owner, in its capacity as an Owner Lending Agent; and (2) the sale or licensing of certain data and/or analytical tools by EquiLend to a plan for which an Equity Owner acts as an Owner Lending Agent. The applicant notes that Section II of the individual exemption does not permit the provision by an Owner Lending Agent to EquiLend of securities lending data based on off-Platform securities lending transactions conducted by an Owner Lending Agent on behalf of a plan.

8. However, for the same reasons stated above, the applicant believes that access to off-Platform securities lending data by plans will further enhance EquiLend's existing client service functionality via the Platform by expanding the information that is available to plans. The applicant, therefore, requests that the Department amend PTE 2002–30 to permit, effective October 1, 2012, the provision by an Owner Lending Agent to EquiLend of securities lending data based on off-Platform securities lending transactions conducted by an Owner Lending Agent on behalf of a plan. The applicant notes that, if this proposed amendment is adopted, the three categories of transactions covered by Section II would be: (1) The participation in the Platform by an Equity Owner, in its capacity as an Owner Lending Agent; (2) the sale or licensing of certain data and/

[15] The applicant represents that, to the best of its knowledge, EquiLend has complied with all applicable conditions set forth in PTE 2002–30.

[16] The proposed amended exemption does not provide relief under Section I from ERISA section 406(a)(1)(C) with respect to the use of the Platform on behalf of a plan by a lending fiduciary which is not an Equity Owner. In this regard, the applicant and the lending fiduciaries intend to rely on ERISA section 408(b)(2) to the extent any such relief is necessary.

or analytical tools by EquiLend to a plan for which an Equity Owner acts as a securities lending agent; and (3) the provision by an Owner Lending Agent to EquiLend of securities lending data based on off-Platform securities lending transactions conducted by an Owner Lending Agent on behalf of a plan.

9. The applicant believes that affected plans would be adequately protected with respect to the proposed amendment to Section II. In this regard, a new condition is proposed in Section II that would be applicable to the new category of transactions that would be covered therein. To the extent an Owner Lending Agent provides to EquiLend data based on off-Platform securities lending transactions conducted on behalf of plans, prior to such provision of data, each Owner Lending Agent will disclose to a plan's authorizing fiduciary who is independent of the Owner Lending Agent and EquiLend (other than in case of an Equity Owner Plan) that such Owner Lending Agent intends to provide to EquiLend data based on off-Platform securities lending transactions conducted on behalf the plan. Thereafter, the plan's authorizing fiduciary must consent to provision of such data by the Owner Lending Agent to EquiLend (such authorizing fiduciary will be deemed to have given the required authorization unless such authorizing fiduciary objects in writing to the provision to EquiLend of data based on off-Platform securities lending transactions conducted on behalf of the plan to the Owner Lending Agent within 30 days after disclosure of such information). This authorization may be terminated with respect to the future provision of data by the authorizing fiduciary without penalty to the plan, within the lesser of: (i) The time negotiated for such notice of termination by the plan and the Owner Lending Agent, or (ii) five business days.[17]

10. The applicant notes that Section II of PTE 2002–30 contains other conditions that are designed to ensure that plans are adequately protected with respect to this amendment, if adopted. Specifically, conditions (a) through (j) of the individual exemption require that:

(A) In the case of participation in the Platform on behalf of a plan, to the extent applicable the procedures regarding the securities lending activities conform to the provisions of PTE 2006–16 (or its successor), and/or any applicable individual exemption;

(B) None of the fees imposed by EquiLend for securities lending transactions conducted through the use of the Platform at the direction of an Owner Lending Agent will be charged to a plan;

(C) Each securities lender and securities borrower participating in a securities lending transaction through EquiLend will be notified by EquiLend as to its responsibilities with respect to compliance, as applicable, with ERISA, the Code, and FERSA;

(D) Equilend will not act as a principal in any security lending transaction involving plan assets;

(E) Each Equity Owner will provide prior written notice to its plan clients of its intention to participate in EquiLend;

(F) The arrangement pursuant to which the Equity Owner utilizes the services of EquiLend on behalf of a plan:

(1) Is subject to the prior written authorization of an authorizing fiduciary;

(2) May be terminated by the authorizing fiduciary, without penalty to the plan, within the lesser of: (i) The time negotiated for such notice of termination by the plan and the Equity Owner, or (ii) five business days;

(G) With certain limited exceptions, each purchase or license of a securities lending-related product from EquiLend is subject to the prior authorization of an authorizing fiduciary;

(H) The Equity Owner will furnish each authorizing fiduciary with any reasonably available information which the Equity Owner reasonably believes to be necessary to determine whether such authorization should be made or renewed;

(I) The provision by an Owner Lending Agent to EquiLend of data based on off-Platform securities lending transactions conducted on behalf of a plan:

(1) Is subject to the prior authorization of an authorizing fiduciary ;

(2) May be terminated by the authorizing fiduciary with respect to the future provision of data, without penalty to the plan, within the lesser of: (i) The time negotiated for such notice of termination by the plan and the Equity Owner, or (ii) five business days; and

(J) The Equity Owner, together with its affiliates, does not own at the time of the execution of a securities lending transaction on behalf of a plan by the Equity Owner through EquiLend or at the time of the purchase, or commencement of licensing, of data and/or analytical tools by the plan, more than 20% of EquiLend.

11. In summary, the applicant represents that this proposed amendment to PTE 2002–30 satisfies the statutory criteria for an administrative exemption contained in ERISA section 408(a) and Code section 4975(c)(2) because, among other things: (a) The proposed amendment to Section I and Section II of PTE 2002–30 will be administratively feasible and protective of and in the best interests of the plans and their participants and beneficiaries because of the conditions set forth originally and for the same reasons as set forth originally in PTE 2002–30; and (b) the proposed amendment to Section II of PTE 2002–30 will be additionally protective of the rights of participants and beneficiaries because each Owner Lending Agent will disclose to a plan's authorizing fiduciary who is independent of the Owner Lending Agent and EquiLend (other than in case of an Equity Owner Plan) that such Owner Lending Agent intends to provide to EquiLend data based on off-Platform securities lending transactions conducted on behalf a plan. Further, the plan's authorizing fiduciary must consent to the provision of such data by the Owner Lending Agent to EquiLend.

Notice to Interested Parties

The applicant represents that the potentially interested participants and beneficiaries cannot all be identified and therefore the only practical means of notifying such participants and beneficiaries of this proposed exemption is by the publication of this notice in the **Federal Register**. Comments and requests for a hearing must be received by the Department not later than 30 days from the date of publication of this notice of proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Brian Shiker of the Department, telephone (202) 693–8552. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section

[17] The Department notes that ERISA's general standards of fiduciary conduct also would apply. In this regard, ERISA section 404 requires, among other things, a fiduciary to discharge his duties respecting a plan solely in the interest of the plan's participants and beneficiaries and in a prudent manner. Accordingly, an independent plan fiduciary must act prudently with respect to: (1) The decision to enter into the described arrangement; and (2) the negotiation of the terms of such arrangement including any payment of compensation. The Department further emphasizes that it expects plan fiduciaries, prior to entering into any of the proposed arrangements, to fully understand the extent of the services to be provided, the fee structure and the risks associated with these types of arrangements following disclosure by the service provider of all relevant information. In addition, the Department notes that such plan fiduciaries are responsible for periodically monitoring the services provided.

4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries, and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 9th day of November, 2012.

Lyssa E. Hall,

Director of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2012–27849 Filed 11–15–12; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2012–0031]

Standard on 4,4'—Methylenedianiline in Construction; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Standard on 4,4'—Methylenedianiline in Construction (29 CFR 1926.60).

DATES: Comments must be submitted (postmarked, sent, or received) by January 15, 2013.

ADDRESSES: *Electronically:* You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2012–0031, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number (OSHA–2012–0031) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (e.g., copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (i.e., employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The information collection requirements specified in the 4,4'-Methylenedianiline Standard for Construction (the ''MDA Standard'') (29 CFR 1926.60) protect workers from the adverse health effects that may result from their exposure to MDA, including cancer, liver and skin disease. The major paperwork requirements specify that employers must perform initial, periodic, and additional exposure

monitoring; notify each worker in writing of their results, as soon as possible but no longer than 5 days after receiving exposure monitoring results; and routinely inspect the hands, face, and forearms of each worker potentially exposed to MDA for signs of dermal exposure to MDA. Employers must also: establish a written compliance program; institute a respiratory protection program in accordance with 29 CFR 1910.134 (OSHA's Respiratory Protection Standard); and develop a written emergency plan for any construction operation that could have an emergency (i.e., an unexpected and potentially hazardous release of MDA).

Employers must label any material or products containing MDA, including containers used to store MDA-contaminated protective clothing and equipment. They also must inform personnel who launder MDA-contaminated clothing of the requirement to prevent release of MDA, while personnel who launder or clean MDA-contaminated protective clothing or equipment must receive information about the potentially harmful effects of MDA. In addition, employers are to post warning signs at entrances or accessways to regulated areas, as well as train workers exposed to MDA at the time of their initial assignment, and at least annually thereafter.

Other paperwork provisions of the MDA Standard require employers to provide workers with medical examinations, including initial, periodic, emergency and follow-up examinations. As part of the medical surveillance program, employers must ensure that the examining physician receives specific written information, and that they obtain from the physician a written opinion regarding the worker's medical results and exposure limitations.

The MDA Standard also specifies that employers are to establish and maintain exposure monitoring and medical surveillance records for each worker who is subject to these respective requirements, make any required record available to OSHA compliance officers and the National Institute for Occupational Safety and Health (NIOSH) for examination and copying, and provide exposure monitoring and medical surveillance records to workers and their designated representatives.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The Agency is requesting that it retain its previous burden hour request of 1,029 hours. As reported by the Consumer Price Index (CPI) there was a 9.1% inflation from 2007 to 2010. Therefore, there is an overall increase in capital costs of $5,640 (from $62,838 to $68,478). This adjustment is a result of an increase in the estimated cost of medical examinations from $168 to $183. Also, there is an increase in the estimated cost of laboratory airborne sample analysis from $107 to $117.

The Agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements contained in the Standard.

Type of Review: Extension of a currently approved collection.

Title: 4,4'- Methylenedianiline in Construction Standard (29 CFR 1926.60).

OMB Control Number: 1218–0183.

Affected Public: Business or other for-profits; Not-for-profit organizations; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 330.

Total Responses: 2,631.

Frequency: On occasion.

Average Time per Response: Varies from 5 minutes (.08 hour) for employers to provide information to the physician to 2 hours for initial monitoring.

Estimated Total Burden Hours: 1,029.

Estimated Cost (Operation and Maintenance): $68,478.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2012–0031). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627). Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (e.g., copyrighted material) is not publicly available to read or download through this Web site.

All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available through the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on November 13, 2012.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2012–27856 Filed 11–15–12; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Sunshine Act Meeting of the National Museum and Library Services Board

AGENCY: Institute of Museum and Library Services (IMLS), NFAH.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the agenda of the forthcoming meeting of the National Museum and Library Services Board. This notice also describes the function of the Board. Notice of the meeting is required under the Sunshine in Government Act.

DATE: Wednesday, November 14 and Thursday, November 15, 2012.

AGENDA: Twenty-Sixth Meeting of the National Museum & Library Service Board Meeting:

November 14, 2012

12:00 p.m.–2:00 p.m. Executive Session
(Closed to the Public)

November 15, 2012

9:00 a.m.–12:00 p.m. Public Session
I. Welcome
II. Approval of Minutes
III. Introduction of New Members
IV. Board Program: Libraries, Museums, and Early Learning
V. Financial Update
VI. Legislative Update
VII. Program Update
VIII. Adjourn
(Open to the Public)

PLACE: The meeting will be held at the Institute of Museum and Library Services. 1800 M Street NW., 9th Floor, Washington, DC, 20036. Telephone: (202) 653–4676.

FOR FURTHER INFORMATION CONTACT: Elizabeth Lyons, Program Coordinator for Special Events and Board Liaison, Institute of Museum and Library Services, 1800 M Street NW., 9th Floor, Washington, DC 20036. Telephone: (202) 653–4676.

SUPPLEMENTARY INFORMATION: The National Museum and Library Services Board is established under the Museum and Library Services Act, 20 U.S.C. Section 9101 *et seq.* The Board advises the Director of the Institute on general policies with respect to the duties, powers, and authorities related to Museum and Library Services.

The Executive Session from 12:30 p.m. until 2:00 p.m. on Wednesday, November 14, 2012, will be closed pursuant to subsections (c)(4) and (c)(9) of section 552b of Title 5, United States Code because the Board will consider information that may disclose: Trade secrets and commercial or financial information obtained from a person and privileged or confidential; and information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action. The Session from 9:00 a.m. until 12:00 p.m. on Thursday, November 15, 2012 is open to the public.

If you need special accommodations due to a disability, please contact: Institute of Museum and Library Services, 1800 M Street NW., 9th Fl., Washington, DC 20036. Telephone: (202) 653–4676; TDD (202) 653–4614 at least seven (7) days prior to the meeting date.

Dated: November 1, 2012.

Nancy Weiss,

General Counsel.

[FR Doc. 2012–27738 Filed 11–13–12; 8:45 am]

BILLING CODE 7036–01–M

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings; Notice

The National Science Board's *ad hoc* Committee on Honorary Awards, pursuant to NSF regulations (45 CFR Part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings for the transaction of National Science Board business, as follows:

DATE AND TIME: Friday, November 16, 2012, at 1:30 p.m. EST, Tuesday, November 20, 2012, at 1:30 p.m. EST.

SUBJECT MATTER: Discussion of candidates for the 2013 Vannevar Bush Award and 2013 National Science Board Public Service Award.

STATUS: Closed.

These meetings will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201Wilson Blvd., Arlington, VA 22230.

Please refer to the National Science Board Web site (*www.nsf.gov/nsb*) for information or schedule updates, or contact: Ann Ferrante, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292–7000.

Suzanne Plimpton,

Management Analyst.

[FR Doc. 2012–28055 Filed 11–14–12; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits 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 27, 2012, the National Science Foundation published a notice in the **Federal Register** of a permit application received. A permit was issued on November 9, 2012 to:

Permit No. 2013–018

Philip R. Kylel

Nadene G. Kennedy,

Permit Officer.

[FR Doc. 2012–27804 Filed 11–15–12; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0279; IA–12–044]

Mr. Brandon D. Neff, [HOME ADDRESS DELETED UNDER 10 CFR 2.390]; Order Prohibiting Involvement in NRC-Licensed Activities

I

Mr. Brandon D. Neff was formerly employed as a contract Condenser Replacement Project Superintendent at Energy Northwest's Columbia Generating Station (CGS or Licensee). The Licensee holds License NPF–21 issued by the U.S. Nuclear Regulatory Commission (NRC) pursuant to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), which was issued on April 13, 1984, and renewed on May 22, 2012. The license authorizes the operation of Columbia Generating Station in accordance with the

conditions specified therein. The facility is located on the Licensee's site in Richland, Washington.

II

The NRC's Office of Investigations, Region IV, initiated an investigation from June 3, 2011, through May 14, 2012, at Columbia Generating Station, Richland, Washington. The purpose of the investigation was to review the circumstances surrounding a fitness-for-duty (FFD) matter that occurred at CGS on June 2, 2011. The incident involved Mr. Brandon D. Neff's willful attempt to subvert a FFD drug test. During the investigation, several individuals including: Ms. Hansen, FFD Laboratory Technician II; Ms. Witt, FFD Leader; and Mr. Gloyn, Supervisor of Security Compliance, informed the investigator that on June 2, 2011, Mr. Neff submitted a synthetic urine sample as specimen Y22362385, and documented in writing on the Licensee's Federal Drug Testing Custody and Control Form that the specimen collected was not adulterated in any manner. Through Mr. Neff's own testimony, he admitted to taking prescription medication during the 2011 Memorial Day holiday weekend and that the medication had been prescribed to another individual.

Furthermore, Mr. Neff admitted that he knew the ramifications of taking another individual's medication because he was familiar with the regulatory requirements under 10 CFR part 26, and the licensee's site-wide procedure SWP–FFD–01, ''Fitness for Duty Program Requirements'' that relate to FFD and drug use. As a result of his decision to take another individual's prescription medication, Mr. Neff took several coordinated steps in an attempt to circumvent a FFD drug test in the event he was selected.

Based on the statements of Mr. Brandon D. Neff and the results of the investigation, it was determined that Mr. Neff had deliberately submitted a synthetic urine sample as a specimen for a FFD drug test and deliberately provided false information by signing the Licensee's Federal Drug Testing Custody and Control Form attesting that the specimen collected was not adulterated in any manner.

In a letter dated September 14, 2012, the NRC provided Mr. Neff the results of the investigation, which was initiated by the NRC's Office of Investigations. The letter informed Mr. Neff that the NRC was considering escalated enforcement action against him for an apparent violation due to failure to provide complete and accurate information to CGS when attesting that the specimen collected during the FFD drug test was not adulterated in any manner. As part of the letter, the NRC offered Mr. Neff a choice to attend a Predecisional Enforcement Conference or to request Alternative Dispute Resolution (ADR) through the use of mediation to resolve any possible disagreement over: (1) Whether the violation occurred; and (2) the appropriate enforcement action. Mr. Neff initially responded that he would like ADR. Mr. Neff, however, did not respond to any NRC staff's subsequent communication attempts.

III

The NRC concluded that Mr. Neff violated 10 CFR 50.5(a)(2) by deliberately submitting to the Licensee information that he knew to be incomplete and inaccurate in some respect material to the NRC. The NRC concluded that Mr. Neff's actions were deliberate and that he took several coordinated steps to subvert a FFD test in the event that he was selected for a FFD drug test, as a result of his decision to take another individual's prescription medication.

The NRC must be able to rely upon the Licensee, its employees, and contractors to comply with the NRC requirements, including the requirement to maintain a drug-free workplace and a workplace free of the effects of such substances, and to provide information and maintain records that are complete and accurate in all material respects. Mr. Neff's actions, in violating 10 CFR 50.5 and his misrepresentations to the licensee, have raised serious doubts as to whether he can be relied upon to comply with the NRC requirements and to provide complete and accurate information to the NRC or its licensees.

Consequently, I lack the requisite reasonable assurance that Mr. Neff can conduct NRC-licensed activities in compliance with the NRC's requirements, and that the health and safety of the public will be protected if Mr. Neff were permitted at this time to be involved in NRC-licensed activities. Therefore, the public health, safety, and interest require that Mr. Neff be prohibited from any involvement in NRC-licensed activities for a period of 3 years from the effective date of this Order. Additionally, Mr. Neff is required to notify the NRC of his employment in NRC-licensed activities for a period of 1 year following the prohibition period.

IV

Accordingly, pursuant to Sections 103, 161b, 161i, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR 50.5, and 10 CFR 150.20. *It is hereby ordered that:*

1. Mr. Brandon D. Neff is prohibited for 3 years, from the effective date of this Order, from engaging in NRC-licensed activities. NRC-licensed activities are those activities that are conducted pursuant to a specific or general license issued by the NRC, including, but not limited to, those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.

2. This Order shall be effective 30 days following its publication in the **Federal Register** and shall remain in effect until the condition of Item 1 has been met.

3. If Mr. Neff is currently involved with an NRC licensee other than Columbia Generating Station, or engaged in any other NRC-licensed activities, he must immediately cease those activities, and inform the NRC of the name, address, and telephone number of the employer, and provide a copy of this order to the employer.

4. For a period of 1 year after the 3-year period of prohibition has expired, Mr. Neff shall, within 20 days of acceptance of his first employment offer involving NRC-licensed activities or his becoming involved in NRC-licensed activities, as defined in paragraph IV.1 above, provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, of the name, address, and telephone number of the employer or the entity where he is, or will be, involved in the NRC-licensed activities. In the notification, Mr. Neff shall include a statement of his commitment to compliance with regulatory requirements and the basis why the Commission should have confidence that he will now comply with applicable NRC requirements.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Brandon D. Neff of good cause.

V

In accordance with 10 CFR 2.202, Mr. Brandon D. Neff must, and any other person adversely affected by this Order may, submit an answer to this Order within 30 days of its publication in the **Federal Register.** In addition, Mr. Neff and any other person adversely affected by this Order may request a hearing on this Order within 30 days of its publication in the **Federal Register.** Where good cause is shown, consideration will be given to extending the time to answer or request a hearing. A request for extension of time must be

made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

All documents filed in the 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 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 the 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 Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email at *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 the 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.

If a person other than Mr. Brandon D. Neff requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d).

If a hearing is requested by Mr. Neff or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained. In the absence of any request for hearing or ADR, or written approval of an extension of time in which to request a hearing, the provisions

specified in Section IV above shall be final 30 days from the date this Order is published in the **Federal Register** without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. If a hearing or ADR is requested, the effective date of this Order shall be determined in accordance with the hearing or ADR process.

Dated at Rockville, Maryland, this 6th day of November, 2012.

For the Nuclear Regulatory Commission.

Roy P. Zimmerman,

Director, Office of Enforcement.

[FR Doc. 2012–27930 Filed 11–15–12; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30259; 812–14006]

Highland Associates, Inc. and Financial Investors Trust; Notice of Application

November 9, 2012.

AGENCY: Securities and Exchange Commission (the ''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940, as amended (the ''Act''), for an exemption from section 15(a) of the Act and rule 18f–2 under the Act.

SUMMARY: *Summary of Application:* Applicants request an order that would permit them to enter into and materially amend subadvisory agreements without shareholder approval.

APPLICANTS: Highland Associates, Inc. (the ''Adviser'') and Financial Investors Trust (the ''Trust''), on behalf of the Redmont Resolute Fund I and Redmont Resolute Fund II (the ''Redmont Funds'').

DATES: *Filing Dates:* The application was filed on February 2, 2012, and amended on July 17, 2012, and October 16, 2012.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 4, 2012, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Elizabeth M. Murphy, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: c/o JoAnn Strasser, Thompson Hine LLP, 41 South High Street, 17th Floor, Columbus OH 43215.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Senior Counsel, at (202) 551–6876, or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust, a Delaware statutory trust, is registered under the Act as an open-end management investment company and is comprised of individual series, including the Redmont Funds, each with its own investment objective, policies and restrictions.[1] The Adviser, an Alabama corporation, is, and each other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940, as amended (the ''Advisers Act''). The Adviser serves as the investment adviser of the Redmont Funds and will serve as investment adviser to the future Funds. The Redmont Funds have entered into an investment advisory agreement with the Adviser (the ''Advisory Agreement''),[2] approved by the Trust's board of trustees (the ''Board''),[3] including a majority of the trustees who are not ''interested persons,'' as defined in section 2(a)(19) of the Act, of the Trust or the Adviser (the ''Independent Trustees''), and by shareholders representing a majority of each Redmont Fund's shares.

2. Under the terms of the Advisory Agreement, the Adviser is responsible for the overall management of each Redmont Fund's business affairs and selecting investments according to their respective investment objectives, policies and restrictions. For the investment management services that it provides to a Redmont Fund, the Adviser receives the fee specified in the Advisory Agreement. The Advisory Agreement also permits the Adviser to retain one or more subadvisers for the purpose of managing the investments of all or a portion of the assets of the Redmont Funds. Pursuant to this authority, the Adviser may enter into investment subadvisory agreements with unaffiliated investment subadvisers (''Subadvisers'') to provide investment advisory services to the Redmont Funds (each, a ''Subadvisory Agreement'' and together, the ''Subadvisory Agreements'').[4] Each Subadviser will be registered as an investment adviser under the Advisers Act. The Adviser will supervise, evaluate and allocate assets to the Subadvisers, and make recommendations to the Board about their hiring, retention or release, at all times subject to the authority of the Board. The Adviser will compensate each Subadviser out of the fees paid to the Adviser under the Advisory Agreement.

3. Applicants request an order to permit the Adviser, subject to Board approval, to enter into and materially amend Subadvisory Agreements without obtaining shareholder approval.

[1] Applicants also request relief with respect to any existing or future series of the Trust and any other existing or future registered open-end management investment company or series thereof that: (a) Is advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser or its successors (included within the term ''Adviser''); (b) uses the manager of managers structure (the ''Manager of Managers Structure'') described in the application; and (c) complies with the terms and conditions of the application (together with the Redmont Funds, the ''Funds'' and each, individually, a ''Fund''). For purposes of the requested order, ''successor'' is limited to any entity or entities that result from a reorganization of the Adviser into another jurisdiction or a change in the type of business organization. The only existing registered open-end investment company that currently intends to rely on the order is named as an applicant. The Redmont Funds are the only Funds that currently intend to rely on the requested order. If the name of any Fund contains the name of a Subadviser (as defined below), the name of the Adviser will precede the name of the Subadviser.

[2] The Adviser will enter into substantially similar investment advisory agreements to provide investment management services to future Funds (''Future Advisory Agreements''). The terms of Future Advisory Agreements will comply with section 15(a) of the Act and Future Advisory Agreements will be approved by shareholders and by the Board, including a majority of the Independent Trustees, in the manner required by sections 15(a) and 15(c) of the Act and rule 18f–2 thereunder. References to any Advisory Agreement include Future Advisory Agreements as they pertain to future Funds.

[3] The term ''Board'' also includes the board of trustees or directors of a future Fund, if different.

[4] The Redmont Funds do not currently employ Subadvisers, but each anticipates doing so in the future.

The requested relief will not extend to any subadviser that is an affiliated person, as defined in section 2(a)(3) of the Act, of the Trust, a Fund or the Adviser, other than by reason of serving as a subadviser to one or more of the Funds (an ''Affiliated Subadviser'').

4. Funds will inform shareholders of the hiring of a new Subadviser pursuant to the following procedures (''Modified Notice and Access Procedures''): (a) Within 90 days after a new Subadviser is hired for any Fund, that Fund will send its shareholders either a Multi-manager Notice or a Multi-manager Notice and Multi-manager Information Statement; [5] and (b) the Fund will make the Multi-manager Information Statement available on the Web site identified in the Multi-manager Notice no later than when the Multi-manager Notice (or Multi-manager Notice and Multi-manager Information Statement) is first sent to shareholders, and will maintain it on that Web site for at least 90 days. In the circumstances described in the application, a proxy solicitation to approve the appointment of new Subadvisers provides no more meaningful information to shareholders than the proposed Multi-manager Information Statement. Moreover, as indicated above, the Board would comply with the requirements of sections 15(a) and 15(c) of the Act before entering into or amending Subadvisory Agreements.

Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in relevant part, that it is unlawful for any person to act as an investment adviser to a registered investment company except pursuant to a written contract that has been approved by the vote of a majority of the company's outstanding voting securities. Rule 18f–2 under the Act provides that each series or class of securities in a series investment company affected by a matter must approve that matter if the Act requires shareholder approval.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or from any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that the requested relief meets this standard.

3. Applicants assert that the shareholders expect the Adviser and the Board to select the Subadvisers for the Funds that are best suited to achieve each Fund's investment objective. Applicants assert that, from the perspective of the investor, the role of the Subadvisers is substantially equivalent to that of the individual portfolio managers employed by the Adviser. Applicants state that requiring shareholder approval of each Subadvisory Agreement would impose costs and unnecessary delays on the Funds, and may preclude the Adviser from acting promptly in a manner considered advisable by the Board. Applicants note that the Advisory Agreement and any Subadvisory Agreement with an Affiliated Subadviser will remain subject to section 15(a) of the Act and rule 18f-2 under the Act, including the requirement for shareholder voting.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Fund may rely on the requested order, the operation of the Fund in the manner described in the application will be approved by a majority of the Fund's outstanding voting securities, as defined in the Act, or in the case of a Fund whose public shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the initial shareholder(s) before offering shares of that Fund to the public.

2. Each Fund relying on the requested order will disclose in its prospectus the existence, substance, and effect of any order granted pursuant to the application. Each Fund will hold itself out to the public as utilizing the Manager of Managers Structure. The prospectus will prominently disclose that the Adviser has ultimate responsibility (subject to oversight by the Board) to oversee the Subadvisers and recommend their hiring, termination, and replacement.

3. Funds will inform shareholders of the hiring of a new Subadviser within 90 days after the hiring of the new Subadviser pursuant to the Modified Notice and Access Procedures.

4. The Adviser will not enter into a subadvisory agreement with any Affiliated Subadviser without such agreement, including the compensation to be paid thereunder, being approved by the shareholders of the applicable Fund.

5. At all times, at least a majority of the Board will be Independent Trustees, and the nomination of new or additional Independent Trustees will be placed within the discretion of the then-existing Independent Trustees.

6. Whenever a subadviser change is proposed for a Fund with an Affiliated Subadviser, the Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the applicable Board minutes, that such change is in the best interests of the Fund and its shareholders, and does not involve a conflict of interest from which the Adviser or the Affiliated Subadviser derives an inappropriate advantage.

7. The Adviser will provide general management services to each Fund, including overall supervisory responsibility for the general management and investment of each Fund's assets and, subject to review and approval of the Board, will: (a) Set each Fund's overall investment strategies; (b) evaluate, select and recommend Subadvisers to manage all or a part of each Fund's assets; (c) allocate and, when appropriate, reallocate each Fund's assets among one or more Subadvisers; (d) monitor and evaluate the performance of Subadvisers; and (e) implement procedures reasonably designed to ensure that the Subadvisers comply with each Fund's investment objective, policies and restrictions.

8. No trustee or officer of the Trust or a Fund, or director, manager, or officer of the Adviser, will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by such person), any interest in a Subadviser, except for (a) ownership of interests in the Adviser or any entity that controls, is controlled by, or is under common control with the Adviser, or (b) ownership of less than 1% of the outstanding securities of any class of equity or debt of any publicly traded company that is either a Subadviser or an entity that controls, is controlled by, or is under common control with a Subadviser.

[5] A ''Multi-manager Notice'' will be modeled on a Notice of Internet Availability as defined in rule 14a-16 under the Securities Exchange Act of 1934 (''Exchange Act''), and specifically will, among other things: (a) Summarize the relevant information regarding the new Subadviser; (b) inform shareholders that the Multi-manager Information Statement is available on a Web site; (c) provide the Web site address; (d) state the time period during which the Multi-manager Information Statement will remain available on that Web site; (e) provide instructions for accessing and printing the Multi-manager Information Statement; and (f) instruct the shareholder that a paper or email copy of the Multi-manager Information Statement may be obtained, without charge, by contacting the Funds.

A ''Multi-manager Information Statement'' will meet the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the Exchange Act for an information statement. Multi-manager Information Statements will be filed electronically with the Commission via the EDGAR system.

9. In the event the Commission adopts a rule under the Act providing substantially similar relief to that in the order requested in the application, the requested order will expire on the effective date of that rule.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27875 Filed 11–15–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Wednesday, November 14, 2012 at 9:30 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A)(i) and (ii), and 17 CFR 200.402(a)(4), (8), (9)(A)(i) and (ii), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Walter, as duty officer, voted to consider the item listed for the Closed Meeting in a closed session, and determined that no earlier notice was possible.

The subject matter of the Closed Meeting will be an examination of a financial institution.

At times, changes in Commission priorities require alterations in the scheduling of meeting item.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary at (202) 551–5400.

Dated: November 13, 2012.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–28048 Filed 11–14–12; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68202; File Nos. SR–Phlx–2012–27; SR–Phlx–2012–54]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing of Amendments No. 1, and Order Granting Accelerated Approval for Proposed Rule Changes as Modified by Amendments No. 1 Relating to Complex Order Fees and Rebates for Adding and Removing Liquidity in Select Symbols

November 9, 2012.

I. Introduction

On March 1, 2012 and April 23, 2012, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'') [1] and Rule 19b–4 thereunder,[2] two proposed rule changes relating to the transaction fees for certain complex order (''Complex Order'') transactions.[3] The notice of filing of Phlx–2012–27 was published for comment in the **Federal Register** on March 15, 2012,[4] and the notice of filing of Phlx–2012–54 was published for comment in the **Federal Register** on May 4, 2012.[5]

On April 30, 2012, the Commission suspended the proposals and instituted proceedings to determine whether to approve or disapprove the proposals.[6] Following the institution of the proceedings, the Commission received a letter from the Exchange in support of its proposals.[7] On September 11, 2012, the Commission issued a notice of designation of a longer period for Commission action on the proceedings to determine whether to disapprove the proposed rule changes.[8] On October 24, 2012, the Exchange filed Amendment No. 1 to each of the proposed rule changes. In the amendments, the Exchange proposed to put certain of the fees (for Complex Order executions by Directed Participants [9] and Market Makers) [10] on a one-year pilot program, and stated that the proposed fees would be operative on December 3, 2012. The Exchange committed to provide publicly available data and data analyses of those fees to the Commission during the pilot.[11] The Exchange also represented that, prior to and at the time of a complex order transaction, Market Makers, including Directed Participants, are unaware of the identity of the contra-party to the transaction. The Exchange stated that Rule 707 is intended to prohibit coordinated actions between Directed Participants and order flow providers (''OFPs''), and that the Exchange proactively conducts surveillance for, and enforces against, such violations.[12]

The Commission received no comment letters on the proposals. This order approves the proposed rule changes, as modified by Amendments No. 1, and approves, as a one-year pilot program, those fees which the Exchange proposes to implement on a pilot basis.

II. Description of the Proposals

The Exchange's first proposal amended Complex Order fees and rebates for adding and removing liquidity in its Select Symbols.[13] Specifically, Phlx's proposal: (1) Increased the customer rebate for adding liquidity from $0.30 per contract to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A Complex Order is any order involving the simultaneous purchase and/or sale of two or more different options series in the same underlying security, priced at a net debit or credit based on the relative prices of the individual components, for the same account, for the purpose of executing a particular investment strategy. A Complex Order may also be a stock-option order, which is an order to buy or sell a stated number of units of an underlying stock or exchange-traded fund (''ETF'') coupled with the purchase or sale of options contract(s). *See* Exchange Rule 1080, Commentary .08(a)(i).

[4] *See* Securities Exchange Act Release No. 66551 (March 9, 2012), 77 FR 15400 (SR–Phlx–2012–27) (''Notice I'').

[5] *See* Securities Exchange Act Release No. 66883 (April 30, 2012), 77 FR 26591 (SR–Phlx–2012–54) (''Notice II'').

[6] *See* Securities Exchange Act Release No. 66884 (April 30, 2012), 77 FR 26595 (May 4, 2012) (''Order Instituting Proceedings''). The Order Instituting Proceedings suspended the fees adopted in SR–Phlx–2012–27 and SR–Phlx–2012–54. Consequently, these fees were in effect for only two months, from March 1, 2012 to April 30, 2012.

[7] *See* Letter from Joan C. Conley, Senior Vice President and Corporate Secretary, Nasdaq OMX, to Elizabeth M. Murphy, Secretary, Commission, dated July 26, 2012 (''Response'').

[8] *See* Securities Exchange Act Release No. 67825 (September 11, 2012), 77 FR 57168 (September 17, 2012).

[9] The term ''Directed Participant'' applies to transactions for the account of a Specialist, Streaming Quote Trader (''SQT'') or Remote Streaming Quote Trader (''RSQT'') resulting from a Customer order that is (1) directed to the Specialist, SQT or RSQT by an order flow provider, and (2) executed by that Specialist, SQT or RSQT electronically on Phlx XL II. *See* Phlx Fee Schedule at 3.

[10] A ''Market Maker'' includes Specialists (*see* Exchange Rule 1020) and Registered Options Traders (''ROTs'') (see Exchange Rule 1014(b)(i) and (ii), which includes SQTs (*see* Exchange Rule 1014(b)(ii)(A)) and RSQTs (*see* Exchange Rule 1014(b)(ii)(B)).

[11] *See* Amendment No. 1 to SR–Phlx–2012–27 and SR–Phlx–2012–54, filed October 24, 2012.

[12] *See* Amendment No. 1 to each filing, *supra* note 11.

[13] The Select Symbols are listed in Section I of the Phlx Fee Schedule.

$0.32 per contract; (2) created a new rebate for removing liquidity of $0.06 per contract for each contract of liquidity removed by an order designated as a customer Complex Order; (3) amended the fee for removing liquidity for all participants who are assessed such a fee; and (4) created a volume incentive for certain market participants that transact significant volumes of Complex Orders on the Exchange.

Phlx's proposal to amend the Fee for Removing Liquidity increased the Complex Order Fees for Removing Liquidity for the Directed Participant, Market Maker, Firm, Broker-Dealer, and Professional [14] categories of market participants. The fee for Directed Participant transactions increased from $0.30 to $0.32 per contract; the fee for Market Makers increased from $0.32 to $0.37 per contract; and the fee for Firms, Broker-Dealers, and Professionals increased from $0.35 to $0.38 per contract.

The proposal also provided a new volume incentive to Market Makers. The Exchange has four categories of Market Makers—Specialists,[15] ROTs,[16] SQTs [17]and RSQTs[18]—that would all be eligible to receive the volume incentive. Under this proposal, if a Market Maker executes more than 25,000 contracts of Complex Orders each day in a given month, the fees charged for all of that Market Maker's transactions in Complex Orders that remove liquidity, both as a Directed Participant and as a Market Maker, would be reduced by $0.01 per contract for that month.

In its second proposal, the Exchange did not propose to amend any of the fees for the Complex Order Directed Participant and Market Maker Fees for Removing Liquidity in Select Symbols. Rather, the Exchange provided further justification for the differential between the fees paid by Directed Participants and Market Makers.

As discussed more fully below, in its proposals and in its subsequent letter in support of its proposals, the Exchange advanced several arguments as to why the proposal to increase the fee for removing liquidity for Complex Orders to $0.32 per contract for Directed Participants, and to $0.37 per contract for non-directed Market Makers, and the corresponding increase in the differential between these two fees from $0.02 to $0.05 per contract, was not unreasonable or unfairly discriminatory. First, the Exchange stated that Directed Participants enter into payment for order flow agreements (''PFOF'') with OFPs so that OFPs will direct order flow to them to execute against.[19] According to the Exchange, the reduced fee for Directed Participants recognizes the cost that such Market Makers incur by entering into such PFOF agreements, and the fact that such arrangements bring additional order flow to the Exchange, to the benefit of all Exchange market participants. The Exchange also argued that Directed Participants have higher quoting obligations, and that unlike in the leg markets (*i.e.,* the market for the individual orders that make up a complex order) they do not have a guaranteed allocation for Complex Orders, and that these facts justify the fees. Second, the Exchange stated that the frequency with which Directed Participants execute against orders that are directed to them is such that the effective fee actually paid by such Market Makers is closer to the higher Market Maker rate.[20] Third, the Exchange stated that the proposed increase in the fee differential from $0.02 to $0.05 per contract will have a negligible impact on Directed Participants and non-directed Market Makers, given the average level of price improvement for customer Complex Orders. Fourth, the Exchange argued that a higher fee differential currently exists on another options exchange that is directly comparable to the Directed Participant/Market Maker differential at issue here. Finally, the Exchange argued that, given the stated policies of the Commission and applicable case law, the Commission should allow competition to determine whether the fees are fair and reasonable.

In its order suspending the two proposals and instituting proceedings to determine whether to approve or disapprove the proposals, the Commission noted several areas of concern. For example, the Commission questioned whether discrimination on the basis of whether a Market Maker has an off-exchange arrangement to pay an OFP to direct its orders to that Market Maker is a ''fair'' basis for discrimination among exchange members with respect to the fees charged by the Exchange, and whether a flat $0.05 fee differential appropriately reflects potential differences that may exist in payment for order flow arrangements between Market Makers and OFPs.[21] The Commission also questioned whether the proposed fees and fee differential would have an impact on competition, especially as between Directed Participants and Market Makers.[22] Finally, the Commission questioned whether the proposed fee changes will affect the quality of execution of customer Complex Orders or broader market quality, and, if so, how and what type of impact will they have.[23]

During the course of the proceedings, the Exchange amended its filings to implement the fee for removing liquidity for Directed Participants and other Market Makers on a one-year pilot basis, and to state that the proposed fees would be operative on December 3, 2012. The Exchange also represented that it would provide the Commission with certain publicly available data and data analyses, on a monthly basis, over the course of the pilot program that would enable the Commission to better evaluate the effects of the fee proposals. As part of the amendment, the Exchange also represented that, prior to and at the time of a complex order transaction, Market Makers, including Directed Participants, are unaware of the identity of the contra-party to the transaction. The Exchange stated that Rule 707 is intended to prohibit coordinated actions between Directed Participants and OFPs, and that the Exchange proactively

[14] The term ''Professional'' means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Exchange Rule 1000(b)(14).

[15] A Specialist is an Exchange member who is registered as an options specialist pursuant to Exchange Rule 1020(a).

[16] A ROT includes a SQT, a RSQT and a Non-SQT ROT, which by definition is neither a SQT nor a RSQT, and therefore cannot generate and submit quotes electronically. A Registered Option Trader is defined in Rule 1014(b) as a regular member of the Exchange located on the trading floor who has received permission from the Exchange to trade in options for his own account. *See* Exchange Rule 1014(b)(i) and (ii).

[17] An SQT is defined in Exchange Rule 1014(b)(ii)(A) as an ROT who has received permission from the Exchange to generate and submit option quotations electronically in options to which such SQT is assigned.

[18] An RSQT is defined Exchange Rule in 1014(b)(ii)(B) as an ROT that is a member or member organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in options to which such RSQT has been assigned. An RSQT may only submit such quotations electronically from off the floor of the Exchange.

[19] The PFOF agreements at issue here differ from PFOF fees charged pursuant to Exchange rules, in that the PFOF agreements here were entered into outside of the purview of the Exchange.

[20] A Market Maker that has order flow directed to it will be assessed the lower Directed Participant fee rate only if it actually executes against such order flow; otherwise, it will be assessed the higher Market Maker rate.

[21] *See* Order Instituting Proceedings, *supra* note 6, 77 FR 26598.

[22] *Id.*

[23] *Id.*

conducts surveillance for, and enforces against, such violations.[24]

III. Discussion and Commission Findings

After careful consideration, and as discussed below, the Commission finds that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange. In particular, the Commission finds that the proposals are consistent with Section 6(b)(4) of the Act, which requires that the rules of a national securities exchange ''provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities;''[25] Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange not be ''designed to permit unfair discrimination between customers, issuers, brokers, or dealers;''[26] and Section 6(b)(8) of the Act, which requires that the rules of a national securities exchange ''not impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Exchange Act].''[27] The Commission has also considered, pursuant to Section 3(f) of the Act, the proposals' impact on efficiency, competition and capital formation.[28]

Phlx argues in part that the Commission should rely on competitive forces to determine whether the proposed fees are reasonable and not unfairly discriminatory. Phlx states that competition should determine fee changes, noting that the ''Congress directed that exchanges' fee changes be deemed immediately effective for the expressed purpose of promoting price competition between markets.'' [29] In support of this argument, Phlx states that the Commission has ''a statutory duty to promote competition, including price competition.'' [30] Phlx also notes that the DC Circuit Court of Appeals has ''blessed'' the Commission practice of relying on competitive forces, where possible, to assess the reasonableness of proposed rules,[31] and that intervention here would contravene the Commission's ''stated policy'' in this respect.[32]

Phlx represents that the options markets operate in an intensely competitive environment, and that it and the other options exchanges are engaged in an intense competition on price (and other dimensions of competition) to attract order flow from directed and other order flow providers.[33] As an example, the Exchange notes that it and the Nasdaq Options Market (''NOM,'' a sister exchange) have modified options trading fees monthly or even bi-monthly to attract new order flow, retain existing order flow, and regain order flow lost to competitor's price cuts.[34] Phlx further states that price incentives are the essence of competition, in that they encourage market participants to provide attractive offerings to consumers, they benefit market participants who trade on the Exchange, and, in turn, they benefit consumers who enjoy greater price transparency and execution at lower prices.[35]

Phlx asserts that, in vibrant markets such as the options markets, participants who view one pricing scheme as unpalatable are free to move to another market or markets with favorable pricing.[36] Phlx states that, given the competitive nature of the options markets, no one exchange has sufficient market power to ''raise prices for competitively-traded options in an unreasonable or unfairly discriminatory manner in violation of the* * * Act.'' [37] According to Phlx, it is the member firms that have market power, as these market participants control the order flow that the options markets compete to attract.[38]

The Commission disagrees with the Exchange's assertion that the existence of competition alone is adequate to determine whether the fees are reasonable, not unfairly discriminatory, and an equitable allocation of fees among members under the Exchange Act. The Commission's market-based approach to evaluating whether certain market data fees are consistent with the Exchange Act incorporates two parts.[39] First, the Commission examines whether the exchange making the proposal was subject to significant competitive forces in setting the terms of its proposal, including the level of any fees. If the exchange was subject to significant competitive forces in setting the terms of a proposal, the Commission will approve the proposal unless it determines that there is a substantial countervailing basis to find that the terms nevertheless fail to meet an applicable requirement of the Exchange Act or the rules thereunder. The Commission has cited an unfair or unreasonably discriminatory proposal as an example of one such countervailing basis.

Applying this approach to the Exchange's proposal, the Commission finds under the first part of the analysis that the Exchange was subject to significant competitive forces in setting the terms of its proposal. There currently are ten registered national securities exchanges that trade listed options. The Commission has previously found that there is significant competition for order flow in the options markets.[40] The Exchange provided representations and data supporting the existence of intense competition for order flow among the options exchanges. In particular, the Exchange stated that the trading of options is a highly competitive environment, and that the ability to attract order flow is driven largely by price competition.[41] The Exchange also stated that member firms control the order flow that options markets compete to attract, and that exchange members, rather than the exchanges, drive competition.[42] The Exchange produced data showing the market share, based on contract volume, among the options exchanges, which, as of 2012, ranged from approximately less than 1% to 22% for equity options.[43] Similarly, monthly volume data published by the

[24] *See* Amendment No. 1 to each filing, *supra* note 11.

[25] 15 U.S.C. 78f(b)(4).

[26] 15 U.S.C. 78f(b)(5).

[27] 15 U.S.C. 78f(b)(8).

[28] *See* 15 U.S.C. 78c(f).

[29] *See* Response, *supra* note 7, at 12.

[30] *Id.* at 12.

[31] *Id.* at 11 (citing *NetCoalition* v. *SEC,* 615 F.3d 525 (DC Cir. 2010)).

[32] *Id.* at 10.

[33] *Id.* at 1, 2, 11.

[34] *Id.* at 11. The Exchange represents that in 2011 it and NOM filed 71 execution fee changes and all of the options exchanges together filed 173 fee changes (excluding market data, connectivity, colocation, and other fees). *Id.*

[35] *Id.* at 1–2.

[36] *Id.* at 12.

[37] *Id.* at 12.

[38] *Id.* at 12.

[39] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (SR–NYSEArca-2006–21); vacated and remanded, *NetCoalition* v. *SEC,* 615 F.3d 525 (DC Cir. 2010)). In the *NetCoalition* decision, the court held that the Commission's market-based approach to the market data fees in question was consistent with the Exchange Act, but reversed because the Commission had not adequately explained how competition would adequately constrain pricing in the particular case before it and that the record in the case did not contain sufficient evidence to support the Commission's conclusions.

[40] *See* Securities Exchange Act Release No. 61317 (January 8, 2010), 75 FR 2915 (January 19, 2010) (SR–ISE–2009–103) (finding that the exchange was subject to significant competitive forces in setting the terms of its proposal, including fees, and noting that ''the Exchange has a compelling need to attract order flow to maintain its share of trading volume, imposing pressure on the Exchange to act reasonably in establishing fees for these data offerings'').

[41] *See* Response, *supra* note 7, at 11.

[42] *Id.* at 12.

[43] *See* Response, *supra* note 7, at 12.

Options Clearing Corporation indicates that market share for equity options for September 2012 ranged from 0.70% (for NOBO) to 22.97% (for Phlx).[44] Further, six of the ten options exchanges have rules that provide for the trading of complex orders.[45] The Exchange produced data regarding market share among the options exchanges for complex orders on a monthly basis from November 2011 to June 2012. For June 1, 2012, the Exchange stated that the market share for complex orders ranged from 3.39% for NYSE Arca, which had 74,486 complex order trades, to 43.79% for ISE, which had 961,040 complex order trades.[46] Moreover, the volume for complex orders has been increasing over the past few years.[47] Further, the Commission's finding is based on the representation by the Exchange that the fees at issue apply only to the Select Symbols, which are all equity options that are able to be listed and traded on more than one options exchange, and are therefore subject to competition among the market for order flow.[48]

Under the second part of the analysis, the Commission does not at this time find that there is a substantial countervailing basis to find that the terms of the fees and fee differential fail to meet the requirements of the Exchange Act or the rules thereunder. The Commission notes that it received no comments in opposition to the proposed rule changes. The fees for removing liquidity as proposed distinguish between Directed Participants and all other Market Makers (or other members), and would provide the Directed Participants a lower fee than other Market Makers when the Directed Participants interact with order flow that has been directed to them. The Exchange argues in part that Directed Participants that execute against order flow in the complex market that has been directed to them do not have a 40% guaranteed allocation, unlike in the leg market,[49] and that the reduced fee for Directed Participants is an attempt to confer an additional benefit on Directed Participants for the value they provide in bringing order flow to the Exchange. The Exchange also argues that increased order flow provides better execution quality on the Exchange because customers enjoy greater price transparency and executions at lower prices, and that Market Makers to whom order flow is directed still must compete with other Exchange participants to interact with that order flow to receive the benefits of such arrangements.[50] According to the Exchange, this increased order flow, and corresponding greater execution quality, benefits all market participants.[51]

The Commission has previously approved as consistent with the Act rules of exchanges that provide directed Market Makers a 40% guaranteed allocation when they interact with directed order flow, based upon their status as directed Market Makers.[52] Likewise, pursuant to the proposals at issue here, Directed Participants on Phlx would be charged a lower fee when they interact with order flow directed to them, based on their status as Directed Participants.

When approving the proposals that provided a guaranteed allocation to directed market makers, the Commission found that the guaranteed allocation for directed market makers would not affect the incentives of the trading crowd to compete aggressively for orders based on price.[53] Here, the Commission believes that the potential impact of a guaranteed allocation on competition may be distinguished from the potential impact of the reduced transaction fee on competition. Specifically, the guaranteed allocation does not provide directed market makers an explicit subsidy—in the form of lesser per contract fees—over other market makers that are competing to execute against the same order flow. Rather, the guaranteed allocation scheme allocates portions of orders to other Market Makers who are at the same price as the directed market maker, thus protecting the incentive of other market makers to compete with directed market makers on price. In contrast, assessing a lesser transaction fee on Directed Participants than other Market Makers when the Directed Participants interact with order flow directed to them may allow Directed Participants to execute against Complex Orders at more aggressive prices than other market makers, which may reduce the incentive and ability of such other market makers to compete with Directed Participants on price.

The Commission has carefully considered the potential impact of the fees for removing liquidity on Directed Participants and other Market Makers and the $0.05 fee differential on competition between Directed Participants and other Market Makers that are competing to execute against the same order flow, and on the extent of price improvement provided to directed customer Complex Orders. The data provided by Phlx does not show any statistical significant adverse impact of the proposed fee and fee differential on the competitiveness of the market for directed customer Complex Orders on Phlx, or the extent of price improvement for directed customer Complex Orders.[54]

[44] *See* Options Clearing Corporation, Options Volume by Exchange, September 2012, at *http://www.optionsclearing.com/webapps/exchange-volume.*

[45] *See* C2 Rule 6.13; CBOE Rules 6.42, 6.45, 6.53C; ISE Rule 722; NYSE Arca Rules 6.62(e), 6.91; NYSE MKT Rules 900.3NY(e), 963NY, 980NY.

[46] *See* Phlx Supporting Data, at *http://www.sec.gov/comments/sr-phlx-2012–27/phlx201227–2.pdf.* Similarly, market share for complex orders in November 2011 ranged from 1.64% for C2, which had 33,406 trades, to 39.50% for ISE, which had 804,845 trades. Market share for complex orders in February 2012 ranged from 2.78% for NYSE Arca, which had 69,498 trades, to 37.97% for ISE, which had 950,368 trades.

[47] *See* Complex Orders Surge, Traders Magazine, March 2012 (noting increase in use of customer orders by customers at one broker-dealer in 2011); *see also* BATS February 2012 Options Market Update, at *http://www.batstrading.com/resources/fee_schedule/2012/BATS-February-2012–US-Market-Update.pdf* (noting that more volume is being done through complex strategies, and that volume in the complex order book has increased).

[48] *See* Response, *supra* note 7, at 11.

[49] *See* Response, *supra* note 7, at 17. Orders in the leg market are allocated pursuant to Exchange Rule 1014. Specifically, Directed Orders that are executed electronically are allocated first to customer limit orders resting on the limit order book at the execution price. For orders involving Directed Specialists, the contracts remaining in the Directed Order, if any, shall be allocated automatically as follows: The Directed Specialist shall be allocated a number of contracts that is the greater of: (a) The proportion of the aggregate size at the NBBO associated with such Directed Specialist's quote, SQT and RSQT quotes, and non-SQT ROT limit orders entered on the book at the disseminated price represented by the size of the Directed Specialist's quote; (b) the Enhanced Specialist Participation as described in Rule 1014(g)(ii); or (c) 40% of the remaining contracts. *See* Exchange Rule 1014(g)(viii).

For orders involving Directed RSQTs or SQTs, the contacts remaining in the Directed Order, if any, shall be allocated automatically as follows: The Directed RSQT or SQT shall be allocated a number of contracts that is the greater of the proportion of the aggregate size at the NBBO associated with such Directed SQT or RSQT's quote, the specialist's quote, other SQT and RSQT quotes, and non-SQT ROT limit orders entered on the book via electronic interface at the disseminated price represented by the size of the Directed RSQT or SQT's quote at the NBBO, or 40% of the remaining contracts. *See* Exchange Rule 1014(g)(viii).

[50] *See* Notice I, *supra* note 4, at 15404 and Response, *supra* at note 7, at 2.

[51] *See* Notice I, *supra* note 4, at 15404.

[52] *See, e.g.,* Securities Exchange Act Release No. 51759 (May 27, 2005), 70 FR 32860 (June 6, 2005) (order approving SR–Phlx–2004–91). In that order, the Commission noted that the Directed Participant would have to be quoting at the NBBO at the time the directed order was received to capitalize on the guarantee, and that Directed Participants have greater quoting obligations than other Phlx Market Makers that cannot be Phlx Directed Participants. *Id.*

[53] *Id. See also* Securities Exchange Act Release No. 34606 (August 26, 1994), 59 FR 45741 (September 2, 1994) (SR–Phlx–94–12) (approving 40% specialist guarantee).

[54] For purposes of studying the competitive impact of the fees for Directed Participants and

Continued

other Market Makers, Phlx provided data on the rate of interaction with directed customer Complex Orders by both Directed Participants and non-directed Market Makers. This data was provided, on a weekly basis, for the twelve months prior to the time the suspended fees were in effect, in addition to the two months the suspended fees were in place. Phlx also provided data on rates of price improvement for directed customer Complex Orders that received price improvement by both Directed Participants and non-directed markers. This data was provided for the four months prior to the time the suspended fees were in effect, in addition to the two months the suspended fees were in place. Phlx also produced data on the percentage of directed and non-directed customer Complex Orders that received price improvement, and the average price improvement for such orders. This data was provided for the four months prior to the time the suspended fees were in effect, in addition to the two months the suspended fees were in place.

With respect to rates of customer Complex Order interaction, for the period prior to the introduction of the new fees (March 2011–February 2012), the average order interaction by Directed Participants was 14.98%. For March and April 2012, when the lower Directed Participant (as compared to the fee assessed to other Market Makers) fee was in effect, the statistics show that order interaction by Directed Participants averaged 14.02% and 15.64%, respectively. These figures reflect the rates of Complex Order interaction as averaged among Directed Participants, i.e., the rate of Complex Order interaction for any given Directed Participant could, in fact, be much higher.

With respect to price improvement data, Phlx produced data for directed customer Complex Orders receiving price improvement, showing the breakdown by contra side participant type, and the average amount of price improvement for such order flow, also by contra side participant type. This data was produced for November 2011 to May 2012, using the week before the standard expirations in each month. The data that has been submitted shows that, for directed customer Complex Orders that received price improvement, Directed Participants interacted with those orders 7.8% of the time, and provided average price improvement of $7.90 per contract, during the time that the suspended fees were not in effect (November 2011–February 2012, and May 2012), and 11.8% of the time, with an average price improvement amount of $4.70 per contract, during the time that the suspended fees were in effect (March–April 2012). For directed customer Complex Orders that received price improvement, other Market Makers interacted with those orders 86.74% during the time that the suspended fees were not in effect (November 2011–February 2012, and May 2012) and 7.8% of the time during the time that the suspended fees were in effect (March–April 2012), and provided average price improvement of $6.14 and $5.15 per contract, respectively, for the same respective time periods.

Phlx also produced data showing the percentage of directed and non-directed customer Complex Orders that received price improvement, and the average amount of price improvement. This data was produced for November 2011 to May 2012, using the week before the standard expirations in each month. The data that has been submitted shows that non-directed customer Complex Orders received price improvement 17.2% of the time while the suspended fees were not in effect (November 2011–February 2012, and May 2012), with an average price improvement of $3.29 per contract. During the time the suspended fees were in effect (March–April 2012), non-directed Customer Complex orders received price improvement 13% of the time, with an average price improvement of $3.39 per contract. Directed customer Complex Orders received price improvement 29.6% of the time while the suspended fees were not in effect (November 2011–February 2012, and May 2012), with an average price improvement of $6.26 per contract. During the time the suspended fees were in effect (March–April 2012), directed Customer Complex orders received price improvement 30.5% of the time, with an average price improvement of $5.10 per contract.

In providing this data, Phlx used a definition of price improvement that compared the execution price with the limit price of the incoming order. In the data to be provided by Phlx as part of the pilot, Phlx will measure price improvement by comparing the Phlx best bid or offer at the time of the incoming order to the execution price of the order.

However, the suspended fees that are at issue were only in place for two months and thus were only analyzed over that period.[55] Phlx has filed an amendment to its filing to, among other things, specify that the portion of the proposed rule change relating to execution fees for Complex Orders for Directed Participants and other Market Makers, and the accompanying $0.05 fee differential, will be operative on a one-year pilot basis, and that such fees will be operative on December 3, 2012. Phlx also has committed to provide the Commission, on a monthly basis, with publicly available data and data analyses studying the impact of the fees for removing liquidity for complex orders for Directed Participants and other Market Makers upon inter and intra-market competition, and upon market quality. The Exchange has represented that it would provide such information as the Commission may request regarding this fee pilot, including information with respect to rates of order interaction by Directed Participants and Market Makers with Customer Complex Orders and rates of price improvement for Complex Orders.

This data and analysis will allow the Exchange and the Commission to further evaluate during the course of the pilot program the impact of the fees for removing liquidity for Directed Participants and other Market Makers and the $0.05 fee differential on competition between Directed Participants and other Market Makers and the extent of price improvement for Complex Orders over a longer time period with a larger data set.[56] For these reasons, the Commission finds that the proposed rule changes, each as modified by Amendment No. 1, are consistent with the Act. The Commission's finding takes into account that Directed Participants are subject to heightened quoting obligations compared to other Market Makers that are not Directed Participants,[57] and that the fact that whether a customer Complex Order is a directed order or not is not known to any Market Maker, including Directed Participants, prior to execution.[58]

In its original filing, the Exchange also pointed to the existence of non-exchange sponsored PFOF arrangements as a basis for the fees and fee differential. Specifically, Phlx argued that the fee differential is fair, equitable and not unfairly discriminatory because it is intended ''to * * * reflect the increased costs that are incurred by such Market Makers that enter into order flow arrangements at a cost and without the benefit of a guaranteed allocation.'' [59]

In support of its argument, Phlx has represented that it is aware that non-exchange-sponsored PFOF arrangements exist, and that the rates paid by Market Makers under these arrangements, in many cases, ''exceed [Phlx's] own exchange-sponsored payment for order flow fee and also exceed the rebates that [Phlx] provides for adding or removing liquidity from the exchange.'' [60] However, Phlx also represented that it ''does not compile data on the exact prices that Market Makers pay third-party order flow providers for directed order flow * * *.'' [61] Phlx has not produced any data with respect to non-exchange-sponsored payment for order flow arrangements, and has represented to Commission staff that it does not have such data.[62]

[55] *See supra* note 6.

[56] *See* Securities Exchange Act Release No. 66278 (January 30, 2012), 77 FR 5590 (SR–BX–2011–046) (approving a fee change to the BX Price Improvement Period (''PIP'') upon finding, in part, that the data provided by the exchange did not ''suggest any significant adverse impact of the proposed PIP fee change on the competitiveness of the PIP auction or the extent of price improvement for orders executed in the PIP in those series.'').

[57] The Commission recognizes that, given the structure of the Complex Order market on Phlx, there currently are no quoting obligations on Phlx specific to Complex Orders. However, quotations in the leg markets are relevant to the Complex Order market, as Complex Orders are priced based on the leg markets, and executions on the Complex Order market must take into account the prices in the leg markets. Additionally, Directed Participants must be at the best price for a complex order to execute against the Complex Order.

[58] Phlx Rule 707 prohibits Directed Participants and order flow providers from coordinating actions involving Directed Orders. *See also* Securities Exchange Act Release No. 51759 May 27, 2005), 70 FR 32860 (June 6, 2005) (SR–Phlx–2004–91) (noting the applicability of Rule 707 to this scenario). Thus, an order flow provider cannot let a Directed Participant know when it is sending a directed customer Complex Order to Phlx, or that it has such an order resting on Phlx's Complex Order book. In Amendment No. 1 to the proposals, Phlx noted that Rule 707 is intended to prohibit coordinated actions between Directed Participants and OFPs, and that the Exchange proactively conducts surveillance for, and enforces against, such violations. *See* Amendment No. 1 to SR–Phlx–2012–27 and SR–Phlx–2012–54, *supra* note 11.

[59] *See* Notice I, 77 FR 15402.

[60] *See* Response, *supra* note 7, at 14.

[61] *Id.*

[62] Phlx did provide links to the Web sites of two order flow providers, Interactive Brokers and

The Commission does not believe that this argument provides a reasonable basis to find that the fees and fee differential are consistent with the Act. As outlined above, pursuant to this argument, Phlx would be setting its fees, and discriminating among market participants, based on the existence of non-exchange sponsored PFOF arrangements. The record, however, does not contain any representations regarding the amounts of payments made by Directed Participants pursuant to such arrangements or whether such payments are made, whether these off-exchange PFOF arrangements are standardized, and whether the terms and amounts are the same between different OFPs and Directed Participants. As such, the Exchange has not substantiated the details of such off-exchange PFOF arrangements. The Commission believes it is likely that the terms of such arrangements could vary considerably between different Directed Participants and OFPs. Essentially, pursuant to this argument, Phlx could be discriminating in its fees for a specified amount based on payments potentially made off-exchange that may vary widely. The Commission therefore does not believe that this argument provides a basis to support a finding that the fees and fee differential are reasonable, equitably allocated, and not unfairly discriminatory. Nevertheless, for the reasons discussed above, the Commission finds that the proposed rule changes are consistent with 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 Numbers SR–Phlx–2012–27 and SR–Phlx–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 Numbers SR–Phlx–2012–27 and SR-Phlx-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 the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Numbers SR–Phlx–2012–27 and SR–Phlx–2012–54 and should be submitted on or before December 7, 2012.

V. Accelerated Approval of Proposed Rule Changes, as Modified by Amendments No. 1

Amendments No. 1 revised the proposed rule changes to, among other things, specify that the portion of the proposed rule change relating to fees for removing liquidity for Complex Orders for Directed Participants and other Market Makers, and the accompanying $0.05 fee differential, will be operative on a one-year pilot basis, and that such fees would be operative on December 3, 2012. Phlx also committed to provide the Commission, on a monthly basis, with publicly available data and data analyses studying the impact of the fees for removing liquidity for complex orders for Directed Participants and other Market Makers upon inter and intra-market competition, and upon market quality. The Exchange represented that it would provide such information as the Commission may request regarding this fee pilot, including information with respect to rates of order interaction with Customer Complex Orders and rates of price improvement. Receiving data and analysis from the Exchange during the duration of the pilot period will allow the Commission (and the Exchange) to continue to assess the impact, if any, of the proposed rule changes during the pilot period. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[63] for approving the proposed rule changes, as modified by Amendments No. 1, prior to the 30th day after the date of publication of notice in the **Federal Register.**

VI. Conclusion

For the foregoing reasons, the Commission finds that the proposed rule changes, as modified by Amendments No. 1, are consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with Sections 6(b)(4), 6(b)(5), and 6(b)(8) of the Act.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[64] that the proposed rule changes (SR–Phlx–2012–27 and SR–Phlx–2012–54), as modified by Amendments No. 1, be, and hereby are, approved. With respect to the fees for executions of Complex Orders by Directed Participants and Market Makers, such fees are approved on a one-year pilot basis, with such fees being operative on December 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[65]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27819 Filed 11–15–12; 8:45 am]

BILLING CODE 8011–01–P

Wedbush. The Interactive Brokers link generally describes its PFOF practices, and states that it receives PFOF payments from Timber Hill ''consistent with SEC-approved'' PFOF plans. Since the Commission does not approve non-exchange-sponsored PFOF arrangements, this sentence presumably refers to exchange-sponsored PFOF payments, which are not relevant here. The Wedbush link notes that PFOF payments with respect to the options exchanges range from $0–$0.75 per contract.

[63] 15 U.S.C. 78s(b)(2).

[64] 15 U.S.C. 78s(b)(2).

[65] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68204; File No. SR–BATS–2012–043]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Fees for Use of BATS Exchange, Inc.

November 9, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 1, 2012, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change 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 Exchange proposes to amend the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to BATS Rules 15.1(a) and (c). Changes to the fee schedule pursuant to this proposal will be effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the ''Options Pricing'' section of its fee schedule effective immediately, in order to: (i) Increase the TCV improvement requirements for the Grow with Us pricing plan; (ii) modify the rebates provided by the Exchange for Customer[6] orders that add liquidity to the Exchange's options platform (''BATS Options'') in options classes subject to the penny pilot program as described below (''Penny Pilot Securities'');[7] (iii) modify the fees charged by the Exchange for Customer orders that remove liquidity from BATS Options in Penny Pilot Securities; (iv) modify the rebates paid by the Exchange for Professional,[8] Firm, and Market Maker[9] orders that add liquidity to BATS Options in Penny Pilot Securities; (v) modify the fees charged by the Exchange for Professional, Firm, and Market Maker orders that remove liquidity from BATS Options in Penny Pilot Securities; (vi) modify the rebates paid by the Exchange under the BATS Options NBBO Setter Program;[10] (vii) modify the fees charged by the Exchange for Professional, Firm, and Market Maker orders that remove liquidity from BATS Options in non-Penny Pilot Securities; (viii) modify the rebates paid by the Exchange for orders that add liquidity to BATS Options in non-Penny Pilot Securities; (ix) eliminate the Enhanced NBBO Setter Rebate; and (x) modify pricing with respect to orders that are executed on away options exchanges. In addition to these changes, the Exchange proposes to re-number certain footnotes contained within the fee schedule.

(i) Grow With Us Pricing Program

The Exchange currently offers its Grow with Us pricing program to certain orders that add or remove liquidity, as further explained below, by providing a Member with enhanced rebates (and lower execution fees) to the extent such Member shows a minimum of 5 basis points of total consolidated volume (''TCV'')[11] improvement over the Member's previous highest monthly TCV on BATS Options, or ''High Water Mark.'' The Exchange has defined High Water Mark as the greater of a Member's fourth quarter 2011 TCV or a Member's best monthly TCV on BATS Options thereafter.

The Exchange has found that normal variance in trading behavior can cause an improvement of greater than 5 basis points from its Members. As such, the Exchange proposes to increase the requirement for the minimum improvement from 5 basis points of TCV to a more significant improvement of 10 basis points of TCV.

(ii) Customer Rebates for Adding Liquidity in Penny Pilot Securities

The Exchange currently provides rebates for Customer orders that add liquidity to the BATS Options order book in Penny Pilot Securities pursuant to a tiered pricing structure, as described below. In order to make a broader based and more inclusive rebate structure, the Exchange proposes to modify this tiered pricing structure and the rebates associated therewith as well as modify the rebates associated with the Grow with Us pricing program.

The Exchange currently provides a rebate of $0.30 per contract for Customer orders that add liquidity to the BATS Options order book to the extent a Member of BATS Options does not qualify for a higher rebate based on their average daily volume (''ADV'').[12] The Exchange also currently provides Members with an ADV equal to or

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A Member is any registered broker or dealer that has been admitted to membership in the Exchange.

[6] As defined on the Exchange's fee schedule, a ''Customer'' order is any transaction identified by a Member for clearing in the Customer range at the Options Clearing Corporation (''OCC''), except for those designated as ''Professional''.

[7] The Exchange currently charges different fees and provides different rebates depending on whether an options class is an options class that qualifies as a Penny Pilot Security pursuant to Exchange Rule 21.5, Interpretation and Policy .01 or is a non-penny options class.

[8] The term ''Professional'' is defined in Exchange Rule 16.1 to mean any person or entity that (A) is not a broker or dealer in securities, and (B) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).

[9] As defined on the Exchange's fee schedule, the terms ''Firm'' and ''Market Maker'' apply to any transaction identified by a member for clearing in the Firm or Market Maker range, respectively, at the Options Clearing Corporation (''OCC'').

[10] The NBBO Setter Program is a program that provides additional rebates for executions resulting from orders that add liquidity that set either the national best bid (''NBB'') or national best offer (''NBO'').

[11] As defined on the Exchange's fee schedule, TCV is total consolidated volume calculated as the volume reported by all exchanges to the consolidated transaction reporting plan for the month for which the fees apply.

[12] As defined on the Exchange's fee schedule, ADV is average daily volume calculated as the number of contracts added or removed, combined, per day on a monthly basis. The fee schedule also provides that routed contracts are not included in ADV calculation.

greater than 0.30% of TCV with a rebate of $0.42 per contract for Customer orders that add liquidity to the BATS Options order book in Penny Pilot Securities and a rebate of $0.44 per contract for Customer orders that add liquidity to the BATS Options order book in Penny Pilot Securities for Members with an ADV equal to or greater than 1% of average TCV. Finally, the Exchange currently offers its Grow with Us pricing program to Customer orders that add liquidity by providing a Member with enhanced rebates to the extent such Member shows a minimum of 5 basis points TCV improvement over the Member's previous High Water Mark. Under the current pricing structure, a Member that does not qualify for the lower tier applicable to Members with an ADV equal to or greater than 0.30% of average TCV but achieves at least a 5 basis point increase over its previous High Water Mark is provided a rebate of $0.38 per contract for Customer orders that add liquidity to the BATS Options order book in Penny Pilot Securities. A Member that qualifies for the lower tier applicable to Members with an ADV equal to or greater than 0.30% of average TCV but not the 1% of average TCV tier that achieves at least a 5 basis point increase over its previous High Water Mark is provided a rebate of $0.45 per contract for Customer orders that add liquidity to the BATS Options order book in Penny Pilot Securities. A Member that qualifies for the highest tier applicable to Members with an ADV equal to or greater than 1% of average TCV that achieves at least a 5 basis point increase over its previous High Water Mark is provided a rebate of $0.46 per contract for Customer orders that add liquidity to the BATS Options order book in Penny Pilot Securities.

The Exchange proposes to adjust the existing volume tiers, to add an additional volume tier, and to modify the rebates paid for Customer orders that add liquidity to the BATS Options order book in Penny Pilot Securities.

The Exchange proposes to decrease the lower volume tier level from an ADV equal to or greater than 0.30% of average TCV to an ADV equal to or greater than 0.25% of average TCV. The Exchange also proposes to lower the upper volume tier level from an ADV equal to or greater than 1% of average TCV to an ADV equal to or greater than 0.75% of average TCV. Lastly, the Exchange proposes to add an additional volume tier level at an ADV equal to or greater than 1.25% of average TCV. This proposal would result in three distinct discounted volume tiers for Customer orders that add liquidity to BATS Options in Penny Pilot Securities, as follows: greater than or equal to 0.25%, but less than 0.75%; greater than or equal to 0.75%, but less than 1.25%; and equal to or greater than 1.25%.

The Exchange proposes to increase its rebate for any Member that qualifies for the lower tier applicable to Members with an ADV equal to or greater than 0.25% of average TCV but not the 0.75% of average TCV tier from a rebate of $0.42 per contract to a rebate of $0.43 per contract for Customer orders that add liquidity to BATS Options in Penny Pilot Securities. The Exchange proposes to increase its rebate for any Member that qualifies for the middle tier applicable to Members with an ADV equal to or greater than 0.75% of average TCV but not the 1.25% of average TCV tier from a rebate of $0.44 per contract to a rebate of $0.46 per contract for Customer orders that add liquidity to BATS Options in Penny Pilot Securities. The Exchange proposes to add a rebate for Members that qualify for the proposed upper tier applicable to Members with an ADV equal to or greater than 1.25% of average TCV of $0.47 per contract for Customer orders that add liquidity to BATS Options in Penny Pilot Securities.

As part of the Grow with Us pricing program, the Exchange also proposes to reduce its rebate for any Member that does not qualify for the lower tier applicable to Members with an ADV equal to or greater than 0.25% of average TCV but achieves a 10 basis point increase over its previous High Water Mark from a rebate of $0.38 per contract to a rebate of $0.31 per contract for Customer orders that add liquidity to BATS Options in Penny Pilot Securities. The Exchange proposes to reduce the rebate for any Member that qualifies for the lower tier applicable to Members with an ADV equal to or greater than 0.25% of average TCV but not the 0.75% of average TCV tier that achieves at least a 10 basis point increase over its previous High Water Mark from a rebate of $0.45 per contract to a rebate of $0.44 per contract for Customer orders that add liquidity to BATS Options in Penny Pilot Securities. The Exchange proposes to increase its rebate for any Member that qualifies for the middle tier applicable to Members with an ADV equal to or greater than 0.75% of average TCV but not the 1.25% of average TCV tier that achieves at least a 10 basis point increase over its previous High Water Mark from a rebate of $0.46 per contract to a rebate of $0.47 per contract for Customer orders that add liquidity to BATS Options in Penny Pilot Securities.

(iii) Customer Fees for Removing Liquidity in Penny Pilot Securities

The Exchange currently charges fees for Customer orders that remove liquidity from the BATS Options order book in Penny Pilot Securities pursuant to a tiered pricing structure, as described below. The Exchange proposes to modify this tiered pricing structure and the fees associated therewith as well as modify the fees associated with the Grow with Us pricing program.

The Exchange currently charges Members with an ADV less than 0.30% of TCV with a fee of $0.44 per contract for Customer orders that remove liquidity from the BATS Options order book in Penny Pilot Securities. The Exchange currently charges Members with an ADV greater than 0.30% of TCV but less than 1.0% of TCV with a fee of $0.40 per contract for Customer orders that remove liquidity from the BATS Options order book in Penny Pilot Securities. The Exchange currently charges Members with an ADV greater than than 1.0% of TCV with a fee of $0.36 per contract for Customer orders that remove liquidity from the BATS Options order book in Penny Pilot Securities. Finally, the Exchange currently offers its Grow with Us pricing program to Customer orders that remove liquidity by reducing the fees charged to a Member to the extent such Member shows a minimum of 5 basis points TCV improvement over the Member's previous High Water Mark. Under the current pricing structure, any Member that does not qualify for the lower tier applicable to Members with an ADV equal to or greater than 0.30% of average TCV but achieves at least a 5 basis point increase over its previous High Water Mark is charged a fee of $0.42 per contract for Customer orders that remove liquidity from the BATS Options order book in Penny Pilot Securities. A Member that qualifies for the lower tier applicable to Members with an ADV equal to or greater than 0.30% of average TCV but not the 1% of average TCV tier that achieves at least a 5 basis point increase over its previous High Water Mark is charged a fee of $0.38 per contract for Customer orders that remove liquidity from the BATS Options order book in Penny Pilot Securities. A Member that qualifies for the highest tier applicable to Members with an ADV equal to or greater than 1% of average TCV that achieves at least a 5 basis point increase over its previous High Water Mark is charged a fee of $0.36 per contract for Customer orders that remove liquidity from the BATS Options order book in Penny Pilot Securities.

The Exchange proposes to adjust the existing volume tiers, to add an

additional volume tier, and to modify the fees charged for Customer orders that remove liquidity from the BATS Options order book in Penny Pilot Securities.

The Exchange proposes to decrease the lower volume tier level from an ADV equal to or greater than 0.30% of average TCV to an ADV equal to or greater than 0.25% of average TCV. The Exchange also proposes to lower the upper volume tier level from an ADV equal to or greater than 1% of average TCV to an ADV equal to or greater than 0.75% of average TCV. Lastly, the Exchange proposes to add an additional volume tier level at an ADV equal to or greater than 1.25% of average TCV. This proposal would result in three distinct discounted volume tiers for Customer orders that remove liquidity from BATS Options in Penny Pilot Securities, as follows: greater than or equal to 0.25%, but less than 0.75%; greater than or equal to 0.75%, but less than 1.25%; and equal to or greater than 1.25%.

The Exchange proposes to increase its fee for any Member that does not qualify for the lower tier applicable to Members with an ADV equal to or greater than 0.25% of average TCV from a fee of $0.44 per contract to $0.45 per contract for Customer orders that remove liquidity from BATS Options in Penny Pilot Securities. The Exchange proposes to increase its fee for any Member that qualifies for the lower tier applicable to Members with an ADV equal to or greater than 0.25% of average TCV but not the 0.75% of average TCV tier from a fee of $0.40 per contract to $0.44 per contract for Customer orders that remove liquidity from BATS Options in Penny Pilot Securities. The Exchange proposes to add a fee for any Member that qualifies for the middle tier applicable to Members with an ADV equal to or greater than 0.75% of average TCV but not the 1.25% of average TCV tier from a fee of $0.43 per contract for Customer orders that remove liquidity from BATS Options in Penny Pilot Securities. The Exchange proposes to increase the fee for any Member that qualifies for the proposed upper tier applicable to Members with an ADV equal to or greater than 1.25% of average TCV from $0.36 per contract to $0.42 for Customer orders that remove liquidity from BATS Options in Penny Pilot Securities.

As part of the Grow with Us pricing program, the Exchange also proposes to increase its fee for any Member that does not qualify for the lower tier applicable to Members with an ADV equal to or greater than 0.25% of average TCV but achieves a 10 basis point increase over its previous High Water Mark from a fee of $0.42 per contract to a fee of $0.44 per contract for Customer orders that remove liquidity from BATS Options in Penny Pilot Securities. The Exchange proposes to increase the fee for any Member that qualifies for the lower tier applicable to Members with an ADV equal to or greater than 0.25% of average TCV but not the 0.75% of average TCV tier that achieves at least a 10 basis point increase over its previous High Water Mark from a fee of $0.38 per contract to a rebate [sic] of $0.43 per contract for Customer orders that remove liquidity from BATS Options in Penny Pilot Securities. The Exchange proposes to add a fee for any Member that qualifies for the middle tier applicable to Members with an ADV equal to or greater than 0.75% of average TCV but not the 1.25% of average TCV tier that achieves at least a 10 basis point increase over its previous High Water Mark of $0.42 per contract for Customer orders that remove liquidity from BATS Options in Penny Pilot Securities.

(iv) Non-Customer Rebates for Adding Liquidity in Penny Pilot Securities

The Exchange currently provides a rebate of $0.22 per contract for Professional, Firm, and Market Maker orders that add liquidity to the BATS Options order book in Penny Pilot Securities and are removed by a Customer order. The Exchange currently provides a rebate of $0.32 per contract for Professional, Firm, and Market Maker orders that add liquidity to the BATS Options order book in Penny Pilot Securities and are removed by a Professional, Firm, or Market Maker order.

In order to further incentivize liquidity on BATS Options, the Exchange proposes to increase its rebate for Professional, Firm, and Market Maker orders that add liquidity to the BATS Options order book in Penny Pilot Securities and are removed by a Customer order from $0.22 per contract to $0.25 per contract. The Exchange also proposes to increase its rebate for Professional, Firm, and Market Maker orders that add liquidity to the BATS Options order book in Penny Pilot Securities and are removed by a Professional, Firm, or Market Maker order from $0.32 per contract to $0.35 per contract.

(v) Non-Customer Fees for Removing Liquidity in Penny Pilot Securities

The Exchange currently charges a fee of $0.45 per contract for Professional, Firm, and Market Maker orders that remove liquidity from BATS Options in Penny Pilot Securities, where the Member does not qualify for a lower charge based on TCV improvement. The Exchange currently charges a fee of $0.44 per contract for Professional, Firm, and Market Maker orders that remove liquidity from BATS Options in Penny Pilot Securities where the Member shows a minimum of 5 basis points of TCV improvement over their previous High Water Mark.

The Exchange proposes to increase its fees for Professional, Firm, and Market Maker orders that remove liquidity from BATS Options in Penny Pilot Securities where the Member does not qualify for a lower charge based on TCV improvement from $0.45 per contract to $0.47 per contract. The Exchange also proposes to increase its fees for Professional, Firm, and Market Maker orders that remove liquidity from BATS Options in Penny Pilot Securities where the Member shows a minimum of 10 basis points of TCV improvement, as proposed above, over their previous High Water Mark from $0.44 per contract to $0.46 per contract.

(vi) NBBO Setter Liquidity Rebates for Orders

The Exchange's NBBO Setter Program is a program intended to incentivize aggressive quoting on BATS Options by providing an additional rebate upon execution for all orders that add liquidity that set either the NBB or NBO (the ''NBBO Setter Rebate''),[13] subject to certain volume requirements. The Exchange currently provides an additional $0.06 per contract rebate for executions of Professional, Firm and Market Maker orders that qualify for the NBBO Setter Rebate by Members with an ADV equal to or greater than 0.30% of average TCV but less than 1% of average TCV and an additional $0.10 per contract for qualifying executions of Professional, Firm and Market Maker orders by Members with an ADV equal to or greater than 1% of TCV.

The Exchange also applies its Grow with Us pricing program to the NBBO Setter Rebate. Accordingly, any Member that does not qualify for NBBO Setter Rebates applicable to Members with an ADV equal to or greater than 0.30% of average TCV but achieves at least a 5 basis point increase over its previous High Water Mark receives NBBO Setter Rebates of $0.03 per contract for qualifying executions. Similarly, any Member that qualifies for the lower tier

[13] An order that is entered at the most aggressive price both on the BATS Options book and according to then current OPRA data will be determined to have set the NBB or NBO for purposes of the NBBO Setter Rebate without regard to whether a more aggressive order is entered prior to the original order being executed.

applicable to Members with an ADV equal to or greater than 0.30% of average TCV but not the 1% of average TCV tier that achieves at least a 5 basis point increase over its previous High Water Mark is provided a NBBO Setter Rebate of $0.08 per contract for qualifying executions.

The Exchange proposes to adjust the existing volume tiers, to add an additional volume tier, and to modify the rebates paid as part of the NBBO Setter Rebate program.

The Exchange proposes to decrease the lower volume tier level from an ADV equal to or greater than 0.30% of average TCV to an ADV equal to or greater than 0.25% of average TCV. The Exchange also proposes to lower the upper volume tier level from an ADV equal to or greater than 1% of average TCV to an ADV equal to or greater than 0.75% of average TCV. Lastly, the Exchange proposes to add an additional volume tier level at an ADV equal to or greater than 1.25% of average TCV. This proposal would result in three distinct discounted volume tiers for the NBBO Setter Rebate, as follows: greater than or equal to 0.25%, but less than 0.75%; greater than or equal to 0.75%, but less than 1.25%; and equal to or greater than 1.25%.

The Exchange proposes to decrease its NBBO Setter Rebate for executions of Professional, Firm, and Market Maker orders that qualify for the NBBO Setter Rebate by any Member that qualifies for the lower tier applicable to Members with an ADV equal to or greater than 0.25% of average TCV but not the 0.75% of average TCV from $0.06 per contract to $0.03 per contract. The Exchange also proposes to decrease its NBBO Setter Rebate for executions of Professional, Firm, and Market Maker orders that qualify for the NBBO Setter Rebate by any Member that qualifies for the lower tier applicable to Members with an ADV equal to or greater than 0.75% of average TCV but not the 1.25% of average TCV from $0.10 per contract to $0.06 per contract. The Exchange proposes to add an NBBO Setter Rebate for executions of Professional, Firm, and Market Maker orders that qualify for the NBBO Setter Rebate by any Member that qualifies for the highest tier applicable to Members with an ADV equal to or greater than 1.25% of average TCV of $0.10 per contract.

The Exchange proposes to eliminate its current NBBO Setter Rebate of $0.03 for a Member that does not qualify for the lower tier but does achieve an increase over its previous High Water Mark and under current pricing receives a Grow with Us benefit. The Exchange proposes to decrease its rebate for executions of Professional, Firm, and Market Maker orders that qualify for the NBBO Setter Rebate by a Member that qualifies for the lower tier applicable to Members with an ADV equal to or greater than 0.25% of average TCV but not the 0.75% of average TCV that also show a minimum of 10 basis points TCV improvement over their previous high water mark, as proposed above, from $0.08 per contract to $0.05 per contract. The Exchange also proposes to add a rebate for executions of Professional, Firm, and Market Maker orders that qualify for the NBBO Setter Rebate by a Member that qualifies for the middle tier applicable to Members with an ADV equal to or greater than 0.75% of average TCV but not the 1.25% of average TCV that also show a minimum of 10 basis points TCV improvement over their previous high water mark, as proposed above, of $0.08 per contract.

(vii) Non-Customer Fees for Removing Liquidity in non-Penny Pilot Securities

The Exchange currently charges a fee of $0.80 per contract for Professional, Firm, and Market Maker orders that remove liquidity from BATS Options in non-Penny Pilot Securities. The Exchange proposes to increase the fee for Professional, Firm, and Market Maker orders that remove liquidity from BATS Options in non-Penny Pilot Securities from $0.80 per contract to $0.84 per contract.

(viii) Rebates for Adding Liquidity in Non-Penny Pilot Securities

The Exchange currently provides a rebate of $0.75 per contract for Customer orders that add liquidity to BATS Options in non-Penny Pilot Securities. The Exchange also currently provides a rebate of $0.70 per contract for Professional, Firm, and Market Maker orders that remove liquidity from BATS Options in non-Penny Pilot Securities.

The Exchange proposes to increase the rebate for Customer orders that add liquidity to BATS Options in non-Penny Pilot Securities from $0.75 per contract to $0.80 per contract. The Exchange also proposes to decrease the rebate for Professional, Firm, and Market Maker orders that add liquidity to BATS Options in non-Penny Pilot Securities from $0.70 per contract to $0.60 per contract.

(ix) Eliminating the Enhanced NBBO Setter Rebate

In order to further incentivize aggressive liquidity by incenting displayed size of contracts, the Exchange implemented the Enhanced NBBO Setter Rebate on June 1, 2012. The Enhanced NBBO Setter Rebate provides twice the rebate for executions that qualify for an NBBO Setter Rebate and result from an order with a displayed size that equals or exceeds 25 contracts. Due to limited customer participation, however, the Exchange proposes to eliminate the Enhanced NBBO Setter Rebate altogether. Over the implementation period, participation has been low, and eliminating the Enhanced NBBO Setter Rebate will act to simplify the Exchange's fee schedule while eliminating an underutilized pricing program.

(x) Executions on Away Options Exchanges

The Exchange proposes to change pricing with respect to orders routed to away options exchanges. The Exchange currently charges certain flat rates for routing to other options exchanges that have been placed into groups based on the approximate cost of routing to such venues. The grouping of away options exchanges is based on the cost of transaction fees assessed by each venue as well as costs to the Exchange for routing (i.e., clearing fees, connectivity and other infrastructure costs, membership fees, etc.) (collectively, ''Routing Costs'').

The Exchange currently has two categories for the Nasdaq Options Market (''NOM'') under which it charges: (i) A fee of $0.50 per contract for Customer orders and $0.57 per contract for Professional, Firm, or Market Maker orders routed to and executed at NOM in all options other than Specified Symbols; [14] and (ii) a fee of $0.90 per contract for Customer orders and $0.95 per contract for Professional, Firm, or Market Maker orders routed to and executed at NOM in Specified Symbols.

Based on recent changes to NOM pricing,[15] including the elimination of the above described unique pricing for Specified Symbols, the Exchange proposes to eliminate the distinction between Specified Symbols and non-Specified Symbols in its fee schedule. In addition to this change, the Exchange is proposing to move NOM Penny Pilot Securities into the grouping with C2 Options Exchange, Inc. (''C2''), NYSE Arca, Inc. (''ARCA'') in Make/Take Issues, and NASDAQ OMX PHLX LLC (''PHLX'') in Make/Take Issues and to eliminate the grouping that currently

[14] As defined on the Exchange's fee schedule, the term ''Specified Symbols'' refers to FB, GOOG, and GRPN.

[15] Securities Exchange Act Release No. 68029 (October 10, 2012), 75 FR 63384 (October 16, 2012) (SR–NASDAQ–2012–114).

includes only NOM in Penny Pilot Securities.

As of November 1, ARCA is also adjusting its pricing structure to more closely resemble that of NOM in non-Penny Pilot Securities.[16] Specifically, ARCA is proposing to charge $0.79 for Customer orders that remove liquidity in non-Penny Pilot Securities and $0.85 for Professional, Firm, and Market Maker orders that remove liquidity in non-Penny Pilot Securities. As such, the Exchange proposes to move ARCA into a grouping with NOM in non-Penny Pilot Securities and to charge fees for Customer orders executed at ARCA in Classic Issues of $0.90 per contract and to charge fees for Professional, Firm, and Market Maker orders executed at ARCA in Classic Issues of $0.95 per contract. In order to more accurately describe ARCA's pricing structure, the Exchange also proposes to change references to ARCA (Classic Issues) to ARCA (non-Penny Pilot Securities) and references to ARCA (Make/Take Issues) to ARCA (Penny Pilot Securities).

The Exchange generally imposes routing fees that approximate the Exchange's Routing Costs, however, in order to maintain some level of consistency in its fee schedule, the Exchange does not always adjust its routing fees when an away options exchange adjusts its pricing. Because the Exchange doesn't always adjust its routing fees to be perfectly in line with away options exchanges, over time, the Exchange can end up charging less for executions at the away options exchanges than are required to cover its Routing Costs. Currently, this is the case for several of the away options exchange groupings. As such, the Exchange is proposing the following:

- To increase the fees for Customer orders executed at NYSE MKT LLC (''AMEX''), BOX Options Exchange LLC (''BOX''), Chicago Board Options Exchange, Inc. (''CBOE''), NASDAQ OMX BX, Inc. (''BX Options''), International Securities Exchange, LLC (''ISE'') (Classic issues), and PHLX (Classic issues) from $0.10 per contract to $0.11 per contract.
- To increase the fees for Professional, Firm, and Market Maker orders executed at AMEX, BOX, CBOE, BX Options, ISE (Classic issues), and PHLX (Classic issues) from $0.55 per contract to $0.57 per contract.
- To increase the fees for Professional, Firm, and Market Maker orders executed at ISE in Make/Take issues from $0.55 per contract to $0.57 per contract.
- To increase the fees for Customer orders executed at C2, ARCA in Make/Take issues, PHLX in Make/Take issues, and NOM in Penny Pilot Securities from $0.50 per contract to $0.52 per contract.
- To increase the fees for Professional, Firm, and Market Maker orders executed at C2, ARCA in Make/Take issues, PHLX in Make/Take issues, and NOM in Penny Pilot Securities from $0.55 per contract to $0.57 per contract.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[17] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[18] 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. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive.

The Exchange believes that continuing to provide additional financial incentives to Members that demonstrate an increase over their previous High Water Mark offers an additional, flexible way to achieve financial incentives from the Exchange and encourages Members to add increasing amounts of liquidity to BATS Options each month. The Grow with Us pricing program, therefore, is reasonable in that it rewards a Member's growth patterns. Such increased volume increases potential revenue to the Exchange, and will allow the Exchange to continue to provide and potentially expand the incentive programs operated by the Exchange. The increased liquidity also benefits all investors by deepening the BATS Options liquidity pool, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection. The Grow with Us program is also fair and equitable and not unreasonably discriminatory in that it is available to all Members, even for Members that do not meet the Exchange's volume based tiers. More specifically, the heightened requirement to achieve a 10 basis point, rather than 5 basis point, improvement over a Member's previous High Water Mark is reasonable because this higher level will incentivize growth by Members of BATS Options with a more meaningful threshold. The proposed increase to the basis point requirement is fair and equitable and not unreasonably discriminatory due to the fact that Grow with Us pricing is available to all Members. As noted above, the Exchange believes that this pricing structure is reasonable and not unreasonably discriminatory because the Exchange is incentivizing Members to increase their activity on BATS Options, to the benefit of other BATS Options participants.

Volume-based rebates and fees such as the ones maintained by BATS Options, and as amended by this proposal, have been widely adopted in the cash equities markets, and are equitable because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and introduction of higher volumes of orders into the price and volume discovery processes. Accordingly, the Exchange believes that the proposed changes to the tiered pricing structure are not unfairly discriminatory because they are consistent with the overall goals of enhancing market quality. Similarly, the Exchange believes that continuing to base its tiered fee structure based on overall TCV, rather than a static number of contracts irrespective of overall volume in the options industry, is a fair and equitable approach to pricing.

Specifically, the proposals to adjust the thresholds of existing volume tiers, add additional volume tiers, and to modify the rebates paid for Customer orders that add liquidity to the BATS Options order book in Penny Pilot Securities are reasonable in that they are consistent with the aforementioned goal of promoting market quality because they reward Members for contributing to the growth of and liquidity available on BATS Options, thereby furthering the price discovery process. The Exchange believes that the proposed adjustment to the tiered pricing structure is reasonable, fair and equitable because the threshold has been lowered to permit additional Members to qualify for the lowest tier. With respect to the proposed reduction of the rebate for Members that do not qualify for tiered pricing on Customer orders in Penny Pilot Securities, but that do qualify for Grow with Us pricing, the Exchange

[16] SR–NYSEArca–2012–121 (October 25, 2012).

[17] 15 U.S.C. 78f.

[18] 15 U.S.C. 78f(b)(4).

believes this adjustment is reasonable because the threshold to achieve the enhanced rebate at the lowest tier is relatively low and, as proposed, has become lower. Further, in order to incentivize Members to achieve the rebates applicable to the lowest tier, the Exchange has increased this rebate. In sum, the Exchange believes that the proposed changes to tiered Customer rebates in Penny Pilot Securities are reasonable, fair and equitable because, as a general matter, they are geared at improving incentives for Members that are truly enhancing the market quality of BATS Options. Further, the Exchange does not believe that the proposed changes are unreasonably discriminatory because tiered rebates for Customer orders are available to all Members on an equal basis.

The Exchange also believes that the proposed increase to rebates paid for Professional, Firm or Market Maker orders in Penny Pilot Securities is reasonable in that it will further incentivize Members to add liquidity to BATS Options and will help to offset proposed increases in fees. The Exchange further believes that the proposed increase to rebates for such orders is fair and equitable and not unreasonably discriminatory because such rebates are available to all Members that submit Professional, Firm or Market Maker orders to the Exchange.

Despite the increases in fees for all orders that remove liquidity (Customer, Professional, Firm and Market Maker orders) in Penny Pilot Securities, the Exchange believes that its proposed fee structure is reasonable as the Exchange's standard fees in Penny Pilot Securities remain generally equivalent to standard fees charged by other markets with similar fee structures, such as NYSE Arca and NOM. The increase in fees is also reasonable because the Exchange has also proposed to increase the majority of the rebates available for orders that qualify for volume-based tier or the Grow with Us program. Similarly, the Exchange believes that the increases are fair and equitable because the various programs offered by the Exchange to receive reduced fees and enhanced rebates provide all Members with several different ways to offset the increase in fees or receive a reduction in fees. As noted above, the Exchange believes that such volume-based tiers are fair and equitable and not unreasonably discriminatory because they are consistent with the overall goals of enhancing market quality. While Professional, Firm and Market Maker orders will be assessed comparably higher transaction fees than those assessed to other Customer orders, as proposed, the Exchange does not believe that this pricing is unreasonably discriminatory because the securities markets generally, and the Exchange in particular, have historically aimed to improve markets for investors and develop various features within the market structure for customer benefit. The Exchange also notes that Professional, Firm and Market Maker orders qualify for additional rebates under the Exchange's NBBO Setter Program, which is not applicable to Customer orders.

The Exchange's proposals to modify the NBBO Setter Program's rebates are necessary because such modifications align with the other modifications to the Exchange's tier structure (i.e., by creating a third tier). Although some rebates provided under the NBBO Setter Program, as amended, will be less than under the previous structure, this change is reasonable due to the increased rebate provided to all Professional, Firm and Market Maker orders. In particular, the elimination of the $0.03 rebate for orders eligible for the NBBO Setter Program submitted by Members that do not qualify for the lowest tier but that do qualify for Grow with Us pricing is reasonable because such members will receive an additional $0.03 rebate on all of their Professional, Firm and Market Maker orders. Despite the fact that Customer orders are not eligible for NBBO Setter Rebates, the proposed modifications to NBBO Setter Rebates are fair and equitable and not unreasonably discriminatory because in many cases, Customer orders that do not set the NBBO are eligible for even higher rebates than certain Professional, Firm, and Market Maker orders that did set the NBBO and receive a NBBO Setter Rebate.

As explained above, the Exchange believes that elimination of the Enhanced NBBO Setter Rebate is reasonable, fair and equitable and not unreasonably discriminatory because this enhanced rebate program has not been widely utilized and eliminating the Enhanced NBBO Setter Rebate will act to simplify the Exchange's fee schedule while also allowing the Exchange to allocate resources devoted to the program to other pricing programs.

The Exchange believes that its proposed modifications to fees and rebates for non-Penny Pilot Securities are reasonable in light of the benefits to Members to the extent the corresponding rebates, which are still significantly higher than typical rebates available for adding liquidity, incentivize aggressive quoting that will result in better execution prices, as described in further detail below. The Exchange also believes that providing financial incentives to achieve aggressive quoting and incentivize liquidity providers to narrow the spread while charging more to those who realize the economic benefit of that narrower spread is a fair and equitable approach to pricing. The Exchange's proposal to increase fees and to reduce rebates for Professional, Firm and Market Maker orders in non-Penny Pilot Securities is reasonable, fair and equitable for several reasons, including that the proposed fee is only a slight increase to existing fees and that the Exchange has proposed other changes to the fee schedule in which Professional, Firm, and Market Maker orders will receive additional rebates. The proposal to increase the rebate for Customer orders in non-Penny Pilot Securities, in turn, is reasonable because it is intended to encourage Members to submit Customer orders in non-Penny Pilot Securities to the Exchange. Finally, the Exchange notes that in non-Penny Pilot Securities it is continuing to charge more for, and rebating less to, non-Customer orders than Customer orders, and the proposed changes will increase the gap between such orders. The Exchange believes that this proposed pricing structure for non-Penny Pilot Securities is not unreasonably discriminatory because it accounts for the difference of assumed information and sophistication level between the different trading capacities. Since Professional, Firm and Market Maker capacity members are assumed to have more informed (and hence less desirable to counterparties) orders, those orders have a slightly higher transaction cost associated with them. The Exchange further notes that the charges and rebates to all non-Customer orders is equivalent regardless of capacity and therefore non-discriminatory.

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. Where contracts are quoted in $0.05 increments, 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 BATS, for securities quoted in penny increments are commonly in the $0.30 to $0.45 range. A $0.30 rebate in a penny quoted security is a rebate

equivalent to 30% of the value of the minimum tick. A $0.45 charge 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, 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 − $0.45 access fee = $0.55 better economics). This math is equally true for securities quoted in wider increments. Rebates and access fees near the $0.80 level equate to only 20% of the value of the minimum tick. An 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 $0.75, is receiving economic benefit of $4.25 ($0.05 improved tick = $5.00 in proceeds − $0.75 access fee = $4.25). The Exchange believes that encouraging liquidity providers to quote more aggressively and narrow the spread in non-Penny Pilot Securities will continue to benefit investors 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 non-Penny Pilot Securities are reasonable.

As explained above, the Exchange generally attempts to approximate the cost of routing to other options exchanges, including other applicable costs to the Exchange for routing. The Exchange believes that this pricing model, based on approximate Routing Costs is a reasonable, fair and equitable approach to pricing. As noted above, in order to maintain some level of consistency in its fee schedule, the Exchange does not always adjust its routing fees when an away options exchange adjusts its pricing, and thus, over time, the Exchange can end up charging less for executions at the away options exchanges than are required to cover its Routing Costs. The proposed increases to fees, therefore, are reasonable, fair and equitable because they will generally allow the Exchange to provide routing services at levels that allow the Exchange to cover applicable Routing Costs rather than subsidizing routing by Exchange Members. The Exchange believes that its routing fees are not unreasonably discriminatory because they apply equally to all Members and are intended to provide a service to Members that is generally at the same cost that the Exchange incurs for routing. Also, although routing options are available to all Members, Members are not required to use the Exchange's routing services, but instead, the Exchange's routing services are completely optional. Members can manage their own routing to different options exchanges or can utilize a myriad of other routing solutions that are available to market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Particularly with respect to routing fees, the proposed changes will assist the Exchange in recouping costs for routing orders to other options exchanges on behalf of its participants, and absent such change, the Exchange would be subsidizing routing to other options exchanges by Exchange participants. The Exchange also notes that Users may choose to mark their orders as ineligible for routing to avoid incurring routing fees.[19] With respect to the changes to fees and rebates for executions on the Exchange that are set forth in this proposal, the Exchange does not believe that any such changes burden competition, but instead, enhance competition, as they are intended to increase the competitiveness of, and draw additional volume to, the Exchange's platform. As stated above, the Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels set by the Exchange to be excessive.

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

Pursuant to Section 19(b)(3)(A)(ii) of the Act[20] and Rule 19b–4(f)(2) thereunder,[21] the Exchange has designated this proposal as establishing or changing 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–BATS–2012–043 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2012–043. 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 BATS. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You

[19] *See* BATS Rule 21.1(d)(8) (describing ''BATS Only'' orders for BATS Options) and BATS Rule 21.9(a)(1) (describing the BATS Options routing process, which requires orders to be designated as available for routing).

[20] 15 U.S.C. 78s(b)(3)(A)(ii).

[21] 17 CFR 240.19b–4(f)(2).

should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2012–043, and should be submitted on or before December 7, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27871 Filed 11–15–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68207; File No. SR–CME–2012–43]

Self-Regulatory Organizations; Chicago Mercantile Exchange Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change To Comply With CFTC Part 22 Regulations

November 9, 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, Chicago Mercantile Exchange Inc. (''CME'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I and II below, which Items have been prepared primarily by CME. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to approve the proposed rule change on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CME proposes to amend certain of its rules to comply with the Commodity Futures Trading Commission's Part 22 Regulations. The text of the proposed rule change is available at the CME's Web site at *http://www.cmegroup.com*, at the principal office of CME, 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, CME 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 III below. CME has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.[3]

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

CME is registered as a derivatives clearing organization (''DCO'') with the Commodity Futures Trading Commission (''CFTC'') and operates a substantial business clearing futures and swaps contracts subject to the jurisdiction of the CFTC. CME proposes to make changes to CME Rules 802 and 901; CME Rules 8G04, 8G802, 8H04 and 8H802 to comply with the CFTC's Part 22 Regulations. The compliance date for these Regulations is November 14, 2012.[4] CME will also make corresponding changes to CME's Clearing House Manuals of Operation for Interest Rate Swaps and CME's Clearing House Manuals of Operation for Credit Default Swaps to account for the proposed rule changes.

The proposed rule changes are intended, among other things, to implement CFTC requirements regarding the protection of cleared swaps customer contracts and collateral which became effective on April 9, 2012. DCOs like CME are required to comply with these requirements by November 14, 2012, as set forth in Part 22 of the CFTC Regulations.[5] The CFTC Part 22 Regulations implement the new CFTC customer protection model for cleared swaps customers—the legal segregation with operational commingling model (''LSOC Model'' or ''Complete Legal Segregation Model'').

The proposed rule changes also set forth new requirements for post-default cleared swaps customer account processing. Under the proposed process, upon the default of a clearing member, CME would cease netting of settlement variation within the operationally commingled account and calculate obligations to CME separately for each customer. As further set forth in the rule, each cleared swaps customer would then be required to pay directly to CME any obligations to CME associated with its cleared swaps positions. Where appropriate, similar rules have been adopted in the related sections of the default rules of each of CME's three financial safeguard packages: base products, interest rate swaps (''IRS'') and credit default swaps (''CDS'').

The proposed changes to CME Rules 802 and 901 can be summarized as follows:

- Rule 802.A harmonizes the definition of a clearing member default with those in Rules 8G802.A and 8H802.A.
- Rule 802.B clarifies the approach the Clearing House may take in liquidating any open contracts of a defaulted clearing member, including book entry that offsets open commodity contracts on the books of the defaulting clearing member; liquidation in the open market; and/or one or more private auctions amongst qualified market participants invited by the Clearing House to submit confidential bids.
- Rule 802.G sets forth new requirements for post-default cleared swaps customer account processing, with the Clearing House treating positions and collateral of a defaulting clearing member's cleared swaps customers in accordance with Part 22 of the Commission's regulations. The rule also requires the Clearing House to cease netting of settlement variation in the cleared swaps customer account class upon a clearing member default and discusses the processes that the Clearing House would use to manage such customer accounts.
- New Rule 901.P provides that each Clearing Member would be required to use systems and appropriate procedures to accurately track and provide to the Clearing House the positions and collateral of each of its cleared swaps customers.

The proposed changes to CME Rules 8G802 and 8G04 can be summarized as follows:

- Rule 8G802.A clarifies the rights of CME for the use of an IRS Clearing Member's and its customer's collateral in the event of a default of an IRS Clearing Member in conformity with the Part 22 regulations. Rule 8G802.A.1(i) would also harmonize the definition of a clearing member default with rules 802.A and 8H802.A.
- Rule 8G802.B sets forth amended procedures for establishing a close out

[22] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] The Commission has modified the text of the summaries prepared by CME.

[4] The original compliance date for CFTC's Part 22 Regulations was November 8, 2012. Subsequent to CME filing the proposed rule change with the Commission, due to the effects of Hurricane Sandy, the CFTC issued a no-action letter applicable for the period from November 8, 2012, to November 13, 2012, which in effect delayed the compliance date for the provisions of CFTC's Part 22 rules relevant to this proposed rule change to November 14, 2012. *See* Commodity Futures Trading Commission Letter No. 12–30, Staff No-Action Relief, Temporary Delay of Compliance Date for Part 22 Rules Due to Effects of Hurricane Sandy (October 31, 2012) (*http://cftc.gov/ucm/groups/public/@lrlettergeneral/documents/letter/12-30.pdf*).

[5] *See supra* note 4.

value for IRS contracts to be consistent with Part 22. Section B.3 of the rule would provide for revised netting and offset provisions for the final settlement cycle upon an IRS Termination Event.

• Rule 8G802.G is amended to remove the customer mutualization within the customer account class for IRS to conform to the Part 22 Regulations.

• Rule 8G802.I sets forth the new requirements for cleared swaps customer account processing with CME after the default of an IRS Clearing Member treating positions and collateral of a defaulting clearing member's cleared swaps customers in accordance with Part 22 of the Commission's regulations. The rule also requires CME to cease netting of settlement variation in the cleared swaps customer account class upon an IRS Clearing Member default and establishes processes for CME to use to manage such customer accounts.

• New Rule 8G04.5 provides that each IRS Clearing Member would be required to use systems and appropriate procedures to accurately track and provide to CME the IRS positions and collateral of each of its cleared swaps customers.

• The IRS Manual is also being revised to make conforming changes related to the Part 22 regulations.

The proposed changes to CME Rules 8H802 and 8H04.12 can be summarized as follows:

• Rule 8H802.A clarifies the rights of CME for the use of a CDS Clearing Member's and its customer's collateral in the event of a default of a CDS Clearing Member in conformity with the Part 22 Regulations.

• Rule 8H802.B sets forth amended procedures for establishing a close out value for CDS contracts to be consistent with Part 22. Section B.3 of the rule would provide for revised netting and offset provisions for the final settlement cycle upon a CDS Termination Event.

• Rule 8H802.G is amended to remove the customer mutualization of the customer account class for CDS to conform to the Part 22 regulations.

• Rule 8H802.I sets forth the new requirements for cleared swaps customer account processing with CME after the default of a CDS Clearing Member treating positions and collateral of a defaulting clearing member's cleared swaps customers in accordance with Part 22 of the Commission's regulations. The rule also requires CME to cease netting of settlement variation in the cleared swaps customer account class upon the default of a CDS Clearing Member and establishes processes for CME to use to manage such customer accounts.

• New Rule 8H04.12 provides that each CDS Clearing Member would be required to use systems and appropriate procedures to accurately track and provide to CME the CDS positions and collateral of each of its cleared swaps customers.

• The CDS Manual is also being revised to make conforming changes related to the Part 22 Regulations.

CME proposes to make these rule changes effective on November 14, 2012. CME also made a filing, CME Submission 12–347, with its primary regulator, the CFTC, with respect to the proposed rule changes.

CME believes the proposed changes are consistent with the requirements of the Exchange Act including Section 17A. The rule changes are being proposed to comply directly with the CFTC's Part 22 Regulations, which are designed to protect investors, or in CME's view, are critical in facilitating CME's compliance with Part 22 (e.g., the new provisions for post-default cleared swaps customer account processing that require the Clearing House to cease netting of settlement variation in the cleared swaps customer account class and require each cleared swaps customer to pay directly to CME any obligations to CME associated with its cleared swaps positions).[6] As such, the proposed changes are designed to promote the prompt and accurate clearance and settlement of securities transactions and derivatives agreements, contracts and transactions, to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency and, in general, help to protect investors and the public interest. CME, a derivatives clearing organization registered with the CFTC, further notes that it is required to implement the proposed changes to comply with applicable CFTC regulations. CME notes that the policies of the Commodity Exchange Act (''CEA'') with respect to clearing are comparable to a number of the policies underlying the Exchange Act, such as promoting market transparency for derivatives markets, promoting the prompt and accurate clearance of transactions and protecting investors and the public interest.

[6] Telephone conversation among Tim Elliot, Executive Director and Associate General Counsel, CME; Jason Silverstein, Executive Director and Associate General Counsel, CME; Gena Lai, Senior Special Counsel, SEC; Justin Byrne, Attorney-Advisor, SEC; November 9, 2012.

B. Self-Regulatory Organization's Statement on Burden on Competition

CME does not believe that the proposed rule change will have any impact, or impose any burden, on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

CME has not solicited, and does not intend to solicit, comments regarding this proposed rule change. CME has not received any unsolicited written comments from interested parties.

III. 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–CME–2012–43 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–CME–2012–43. 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 CME and on CME's Web site at *http://www.cmegroup.com/market-regulation/rule-filings.html.*

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–CME–2012–43 and should be submitted on or before December 7, 2012.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

Section 19(b) of the Act [7] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization. The Commission finds that the proposed rule change is consistent with the requirements of the Act, in particular the requirements of Section 17A of the Act, and the rules and regulations thereunder applicable to CME.[8] Specifically, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act, which requires, among other things, that the rules of a registered clearing agency be designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible and to protect investors and the public interest.[9]

In its filing, CME requested that the Commission approve this proposed rule change on an accelerated basis for good cause shown. CME cites as the reason for this request that the proposed changes are necessary to facilitate CME's compliance with new CFTC regulations that become effective on November 14, 2012.

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[10] for approving the proposed rule change prior to the 30th day after the date of publication of notice in the **Federal Register** because, as a registered derivatives clearing organization, CME must amend certain of its rules to comply with the CFTC's Part 22 Regulations that will become effective on November 14, 2012.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (SR–CME–2012–43) be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27873 Filed 11–15–12; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78s(b).

[8] 15 U.S.C. 78q–1. In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68201; File No. SR–Phlx–2012–131]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Cabinet Trading Pilot Program in Rule 1059

November 9, 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, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the Cabinet Trading Pilot program in Rule 1059. The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the pilot program in Commentary .02 of Exchange Rule 1059, Accommodation Transactions, which sets forth specific procedures for engaging in cabinet trades, to allow the Commission adequate time to consider permanently allowing transactions to take place on the Exchange in open outcry at a price of at least $0 but less than $1 per option contract.[3] Prior to the pilot program, Rule 1059 required that all orders placed in the cabinet were assigned priority based upon the sequence in which such orders were received by the specialist. All closing bids and offers would be submitted to the specialist in writing, and the specialist effected all closing cabinet transactions by matching such orders placed with him. Bids or offers on orders to open for the accounts of customer, firm, specialists and ROTs could be made at $1 per option contract, but such orders could not be placed in and must yield to all orders in the cabinet. Specialists effected all cabinet transactions by matching closing purchase or sale orders which were placed in the cabinet or, provided there was no matching closing purchase or sale order in the cabinet, by matching a closing purchase or sale order in the cabinet with an opening purchase or sale order.[4] All cabinet transactions were reported to the Exchange following

[3] Cabinet or accommodation trading of option contracts is intended to accommodate persons wishing to effect closing transactions in those series of options dealt in on the Exchange for which there is no auction market.

[4] Specialists and ROTs are not subject to the requirements of Rule 1014 in respect of orders placed pursuant to this Rule. Also, the provisions of Rule 1033(b) and (c), Rule 1034 and Rule 1038 do not apply to orders placed in the cabinet. Cabinet transactions are not reported on the ticker.

the close of each business day.[5] Any (i) member, (ii) member organization, or (iii) other person who was a non-member broker or dealer and who directly or indirectly controlled, was controlled by, or was under common control with, a member or member organization (any such other person being referred to as an affiliated person) could effect any transaction as principal in the over-the-counter market in any class of option contracts listed on the Exchange for a premium not in excess of $1.00 per contract.

On December 30, 2010, the Exchange filed an immediately effective proposal that established the pilot program being extended by this filing. The pilot program allowed transactions to take place in open outcry at a price of at least $0 but less than $1 per option contract until June 1, 2011.[6] These lower priced transactions are traded pursuant to the same procedures applicable to $1 cabinet trades, except that pursuant to the pilot program (i) bids and offers for opening transactions are only permitted to accommodate closing transactions in order to limit use of the procedure to liquidations of existing positions, and (ii) the procedures are also made available for trading in options participating in the Penny Pilot Program.[7] On May 31, 2011, the Exchange filed an immediately effective proposal that extended the pilot program until December 1, 2011 to consider whether to seek permanent approval of the temporary procedure.[8] On November 30, 2011, the Exchange filed an immediately effective proposal that extended the pilot program until June 1, 2012.[9] On May 29, 2012, the Exchange filed an immediately effective proposal that extended the pilot program until December 1, 2012.[10] The Exchange now proposes an extension of the pilot program to allow additional time to consider its effects while the pilot program continues uninterrupted.

The Exchange believes that allowing a price of at least $0 but less than $1 will better accommodate the closing of options positions in series that are worthless or not actively traded, particularly due to recent market conditions which have resulted in a significant number of series being out-of-the-money. For example, a market participant might have a long position in a call series with a strike price of $100 and the underlying stock might now be trading at $30. In such an instance, there might not otherwise be a market for that person to close-out its position even at the $1 cabinet price (*e.g.,* the series might be quoted no bid).

The Exchange hereby seeks to extend the pilot period for such $1 cabinet trading until June 1, 2013. The Exchange seeks this extension to allow the procedures to continue without interruption.

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)(5) of the Act,[12] in particular, in that the proposal 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Exchange believes that allowing for liquidations at a price less than $1 per option contract pursuant to the pilot program will better facilitate the closing of options positions that are worthless or not actively trading, especially in Penny Pilot issues where cabinet trades are not otherwise permitted. The Exchange believes the extension is of sufficient length to allow the Commission to assess the impact of the Exchange's authority to allow transactions to take place in open outcry at a price of at least $0 but less than $1 per option in accordance with its attendant obligations and conditions.

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

The proposed rule change is effective upon filing pursuant to Section 19(b)(3)(A) of the Act[13] and paragraph (f)(6) of Rule 19b-4 thereunder,[14] in that the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. 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:

[5] *See* Exchange Rule 1059.

[6] Phlx Rule 1059, Commentary .02; *See* Securities Exchange Act Release No. 63626 (December 30, 2010), 76 FR 812 (January 6, 2011) (SR–Phlx–2010–185).

[7] Prior to the pilot, the $1 cabinet trading procedures were limited to options classes traded in $0.05 or $0.10 standard increments. The $1 cabinet trading procedures were not available in Penny Pilot Program classes because in those classes, an option series could trade in a standard increment as low as $0.01 per share (or $1.00 per option contract with a 100 share multiplier). The pilot allows trading below $0.01 per share (or $1.00 per option contract with a 100 share multiplier) in all classes, including those classes participating in the Penny Pilot Program.

[8] *See* Securities Exchange Act Release No. 64571 (May 31, 2011), 76 FR 32385 (June 6, 2011) (SR–Phlx–2011–72).

[9] *See* Securities Exchange Act Release No. 65852 (November 30, 2011), 76 FR 76212 (December 6, 2011) (SR–Phlx–2011–156).

[10] *See* Securities Exchange Act Release No. 67106 (June 4, 2012), 77 FR 34108 (June 8, 2012) (SR–Phlx–2012–74).

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6).

[15] The Exchange has fulfilled this requirement.

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–2012–131 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–2012–131.* This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2012–131 and should be submitted on or before December 7, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27869 Filed 11–15–12; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68199; File No. SR–NASDAQ–2012–059]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Designation of Longer Period for Commission Action on Proceedings to Determine Whether to Approve or Disapprove Proposed Rule Change To Establish ''Benchmark Orders'' Under NASDAQ Rule 4751(f)

November 9, 2012.

On May 1, 2012, The NASDAQ Stock Market LLC (''NASDAQ'' 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 establish various ''Benchmark Orders'' under NASDAQ Rule 4751(f). The proposed rule change was published for comment in the **Federal Register** on May 17, 2012.[3] On June 26, 2012, the Commission extended to August 15, 2012, the time period in which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[4] On August 14, 2012, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change.[5] In response to the Order Instituting Proceedings, the Commission received two comment letters on the proposed rule change.[6]

Section 19(b)(2) of the Act[7] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of the filing. The Commission may, however, extend the period for issuing an order approving or disapproving the proposed rule change by up to 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. In this case, the proposed rule change was published for notice and comment in the **Federal Register** on May 17, 2012; November 13, 2012, is 180 days from that date, and January 12, 2013, is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposal and the issues that commenters have raised concerning the proposal.

Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[8] designates January 12, 2013, as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–NASDAQ–2012–059).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27868 Filed 11–15–12; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 66972 (May 11, 2012), 77 FR 29435 (May 17, 2012) (''Notice'').

[4] *See* Securities Exchange Act Release No. 67258 (June 26, 2012), 77 FR 39314 (July 2, 2012).

[5] *See* Securities Exchange Act Release No. 67655 (August 14, 2012), 77 FR 50191 (August 20, 2012) (''Order Instituting Proceedings.'').

[6] *See* Letters to the Commission from James J. Angel, dated August 16, 2012; and Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA, dated October 5, 2012.

[7] 15 U.S.C. 78s(b)(2).

[8] 15 U.S.C. 78s(b)(2).

[9] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68206; File No. SR–NSX–2012–18]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee and Rebate Schedule

November 9, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Exchange Act'' or ''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on October 31, 2012 National Stock Exchange, Inc. (''NSX'' 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. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend its Fee and Rebate Schedule (the ''Fee Schedule'') issued pursuant to Exchange

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

Rule 16.1(a) to (i) create a separate definition of average daily volume (''ADV'') as it is used for Automatic Execution Mode (''Auto-Ex Mode'') versus Order Delivery Mode to include shares executed in NMS stocks with quoted prices at less than a dollar in the ADV calculation for Auto-Ex Mode, (ii) provide a fixed per share rebate for Midpoint Peg Zero Display Reserve Orders, and (iii) correct typographical inconsistencies within the Fee Schedule. The text of the proposed rule change is available on the Exchange's Web site at *www.nsx.com*, at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to change its Fee Schedule to (i) create separate definitions of ADV for orders executed using Auto-Ex Mode versus Order Delivery Mode to include within the Auto-Ex Mode ADV calculation shares of NMS stocks with quoted prices less than one dollar, (ii) create a fixed per share rebate for Midpoint Peg Zero Display Reserve Orders,[3] and (iii) correct typographical inconsistencies within the Fee Schedule. The proposed changes provide ETP Holders with greater clarity with regard to the application of rebates and fees as well as to provide additional incentives for ETP Holders to direct order flow that may provide investors with greater liquidity and potential price improvement to the Exchange.

Auto-Ex Mode ADV Calculation

The Exchange uses the ADV[4] calculation to determine the level of monthly fees (rebates) an ETP Holder will pay (receive) when removing (adding) liquidity. The Exchange is proposing to create separate ADV definitions for Auto-Ex Mode and Order Delivery Mode to include within the Auto-Ex Mode ADV calculation shares of NMS stocks with quoted prices less than one dollar. This change means that the Auto-Ex ADV calculation will include all shares in NMS stocks executed by an ETP Holder using Auto-Ex Mode regardless of the price. The Exchange believes that the proposed change will provide ETP Holders with an incentive to direct additional order flow that may provide investors with price improvement to the Exchange. The Exchange will not change the current ADV calculation for orders executed in Order Delivery Mode because, unlike Auto-Ex mode, ETP Holders that execute orders in Order Delivery Mode are not charged execution fees; they simply receive rebates for their executions. In addition, Order Delivery Mode incurs the Exchange greater regulatory and operational costs than Auto-Ex Mode. The Exchange notes that from May 2009 to September 2012, it included executions in securities priced at less than one dollar in the calculation of volume thresholds used to determine rebates payable for orders executed at one dollar or above.[5]

In addition, the Exchange notes that both EDGX Exchange Inc. (''EDGX'') and BATS Exchange Inc. (''BATS'') have similar rebate structures and do not exclude securities priced below one dollar in the calculation of volume thresholds used to determine rebates payable for orders executed at one dollar or above.[6]

Midpoint Peg Zero Display Reserve Orders

The Exchange also proposes a fixed per share rebate of $0.0017 for Midpoint Peg Zero Display Reserve Orders[7] executed through both Order Delivery and Auto-Ex modes. The ADV calculations for both Auto-Ex Mode and Order Delivery Mode will include shares executed through the use of Midpoint Peg Zero Display Reserve Orders. The Exchange will use the ADV calculation to determine the tier applicable for fees ETP Holders will be charged for removing liquidity, and rebates for orders that add liquidity other than Midpoint Peg Zero Display Reserve Orders. Rebates for all other order types remain unchanged. By offering a fixed per share rebate for Midpoint Peg Zero Display Reserve Orders, the Exchange believes it will encourage the use of the order type, while maintaining consistency with the Exchange's overall pricing philosophy of encouraging displayed liquidity. In addition, the Exchange is setting the rebate at such level in order to incentivize liquidity by encouraging ETP Holders to use Midpoint Peg Zero Display Reserve Orders since this order type provides ETP Holders that enter them and other ETP Holders an additional way to offer/access liquidity inside the NBBO, respectively. Also, EDGX and BATS have similar rebate structures for non-displayed orders.[8]

Typographical Inconsistencies

Finally, the Exchange is correcting typographical inconsistencies within the Fee Schedule by correcting endnote references, renumbering endnotes, and updating the heading in Section I.

Operative Date and Notice

The Exchange intends to make the proposed modifications, which are effective upon filing, operative as of the commencement of trading on November 1, 2012. Pursuant to Exchange Rule 16.1(c), the Exchange will ''provide ETP Holders with notice of all relevant dues, fees, assessments and charges of the Exchange'' through the issuance of a Regulatory Circular of the changes to the Fee Schedule and will post a copy of the rule filing on the Exchange's Web site (*www.nsx.com*).

2. Statutory Basis

The Exchange believes that the proposed ADV definition changes are consistent with the provisions of Section 6(b) of the Act,[9] in general, and Section 6(b)(4) of the Act,[10] in particular in that each change is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using the facilities of the Exchange. Moreover, the proposed ADV

[3] NSX Rule 11.11(c)(2)(B).

[4] As set forth in the current Explanatory Endnotes of the Fee Schedule, ''ADV'' means, with respect to an ETP Holder, the average number of shares the ETP Holder has executed on the Exchange in all NMS stocks quoted at prices equal to or greater than a dollar when the Exchange is open for trading (excluding partial trading days) in Auto-Ex Mode or in Order Delivery Mode during the calendar month (or partial month, as applicable).

[5] *See* Securities and Exchange Act Release No. 59974 (May 26, 2009), 74 FR 26453 (June 2, 2009)(SR–NSX–2009–03) and Securities Exchange Act Release No. 67816 (September 10, 2012), 77 FR 56886 (September 17, 2012).

[6] *See* Note 1 to EDGX's Fee Schedule *available at http://www.directedge.com/Portals/0/docs/Fee%20Schedule/2012/EDGX/EDGX%20Fee%20Schedule%20-%20October.pdf* (October 1, 2012). *See also* BATS Fee Schedule *available at http://cdn.batstrading.com/resources/regulation/rule_book/BATS-Exchanges_Fee_Schedules.pdf* (October 1, 2012).

[7] NSX Rule 11.11(c)(2)(B).

[8] *See supra* note 4.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

definitions are not unfairly discriminatory in that all ETP Holders are eligible to submit (or not submit) liquidity adding trades and quotes, and may do so at their discretion in the daily volumes they choose during the course of the measurement period.[11] The volume adjustments are reasonable methods to incentivize the submission of such orders. All similarly situated ETP Holders are subject to the same fee structure, and access to the Exchange is offered on terms that are not unfairly-discriminatory.[12] Volume-based rebates and discounts have been widely adopted in the equities markets, and are equitable because they are open to all members on an equal basis and provide rebates that are reasonably related to the value of an exchange's market quality associated with the requirements for the favorable pricing tier.

In addition, the Exchange believes the fixed per share rebate for Midpoint Peg Zero Display Reserve Orders is consistent with Section 6(b)(5) of the Act in that it is equitably allocated and not unfairly discriminatory because all ETP Holders are eligible to submit (or not submit) these types of orders, and may do so at their discretion during the course of the month.[13] The fixed rebate is a reasonable method to incentivize the submission of such orders amongst all its ETP Holders regardless of which volume tier they are eligible for. The Exchange believes that by encouraging the use of the Midpoint Peg Zero Display Reserve Order, ETP Holders seeking to access liquidity inside the NBBO would be more motivated to direct their orders to NSX because they would have a heightened expectation of the availability of liquidity at the NBBO. The increased liquidity also benefits all investors by deepening NSX's liquidity pool, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, and improving investor protection. In addition, an ETP Holder whose order is executed against a Midpoint Peg Zero Display Reserve Order would be able to obtain an execution at the NBB or NBO while minimizing the risk that incremental latency associated with routing the order to an away destination may result in an inferior execution. Lastly, the Exchange believes that offering a fixed per share rebate for Midpoint Peg Zero Display Reserve Order is reasonable because the pricing is similar to analogous order types offered by other exchanges.[14]

Lastly, the Exchange believes correcting the typographical inconsistencies and updating the heading in Section I in the Fee Schedule are reasonable in that they provide clarity to ETP holders to how the Exchange's fee and rebate structure operates by clarifying important cross-references. The corrections are equitable and not unfairly discriminatory in that the Fee Schedule applies to all ETP Holders.[15]

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 rebates 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 has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has taken effect upon filing pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act [16] and subparagraph (f)(2) of Rule 19b–4 [17] thereunder, because, as provided in (f)(2), it changes ''a due, fee or other charge applicable only to a member'' (known on the Exchange as an ETP Holder). 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–NSX–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–NSX–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, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSX–2012–18 and should be submitted on or before December 7, 2012.

[11] 15 U.S.C. 78f(b)(5).

[12] The Exchange believes that not changing the current ADV calculation for orders executed in Order Delivery Mode is not unfairly discriminatory because, unlike Auto-Ex, ETP Holders that execute orders in Order Delivery Mode are not charged execution fees, they simply receive rebates for their executions. In addition, Order Delivery Mode incurs the Exchange greater regulatory and operational costs than Auto-Ex Mode.

[13] 15 U.S.C. 78f(b)(5).

[14] *See supra* note 4.

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

[17] 17 CFR 240.19b–4.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27872 Filed 11–15–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68201; File No. SR–Phlx–2012–131]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Cabinet Trading Pilot Program in Rule 1059

November 9, 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, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the Cabinet Trading Pilot program in Rule 1059. The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the pilot program in Commentary .02 of Exchange Rule 1059, Accommodation Transactions, which sets forth specific procedures for engaging in cabinet trades, to allow the Commission adequate time to consider permanently allowing transactions to take place on the Exchange in open outcry at a price of at least $0 but less than $1 per option contract.[3] Prior to the pilot program, Rule 1059 required that all orders placed in the cabinet were assigned priority based upon the sequence in which such orders were received by the specialist. All closing bids and offers would be submitted to the specialist in writing, and the specialist effected all closing cabinet transactions by matching such orders placed with him. Bids or offers on orders to open for the accounts of customer, firm, specialists and ROTs could be made at $1 per option contract, but such orders could not be placed in and must yield to all orders in the cabinet. Specialists effected all cabinet transactions by matching closing purchase or sale orders which were placed in the cabinet or, provided there was no matching closing purchase or sale order in the cabinet, by matching a closing purchase or sale order in the cabinet with an opening purchase or sale order.[4] All cabinet transactions were reported to the Exchange following the close of each business day.[5] Any (i) Member, (ii) member organization, or (iii) other person who was a non-member broker or dealer and who directly or indirectly controlled, was controlled by, or was under common control with, a member or member organization (any such other person being referred to as an affiliated person) could effect any transaction as principal in the over-the-counter market in any class of option contracts listed on the Exchange for a premium not in excess of $1.00 per contract.

On December 30, 2010, the Exchange filed an immediately effective proposal that established the pilot program being extended by this filing. The pilot program allowed transactions to take place in open outcry at a price of at least $0 but less than $1 per option contract until June 1, 2011.[6] These lower priced transactions are traded pursuant to the same procedures applicable to $1 cabinet trades, except that pursuant to the pilot program (i) bids and offers for opening transactions are only permitted to accommodate closing transactions in order to limit use of the procedure to liquidations of existing positions, and (ii) the procedures are also made available for trading in options participating in the Penny Pilot Program.[7] On May 31, 2011, the Exchange filed an immediately effective proposal that extended the pilot program until December 1, 2011 to consider whether to seek permanent approval of the temporary procedure.[8] On November 30, 2011, the Exchange filed an immediately effective proposal that extended the pilot program until June 1, 2012.[9] On May 29, 2012, the Exchange filed an immediately effective proposal that extended the pilot program until December 1, 2012.[10] The Exchange now proposes an extension of the pilot program to allow additional time to consider its effects while the pilot program continues uninterrupted.

The Exchange believes that allowing a price of at least $0 but less than $1 will better accommodate the closing of options positions in series that are worthless or not actively traded, particularly due to recent market conditions which have resulted in a significant number of series being out-of-the-money. For example, a market

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Cabinet or accommodation trading of option contracts is intended to accommodate persons wishing to effect closing transactions in those series of options dealt in on the Exchange for which there is no auction market.

[4] Specialists and ROTs are not subject to the requirements of Rule 1014 in respect of orders placed pursuant to this Rule. Also, the provisions of Rule 1033(b) and (c), Rule 1034 and Rule 1038 do not apply to orders placed in the cabinet. Cabinet transactions are not reported on the ticker.

[5] *See* Exchange Rule 1059.

[6] Phlx Rule 1059, Commentary .02; *See* Securities Exchange Act Release No. 63626 (December 30, 2010), 76 FR 812 (January 6, 2011) (SR–Phlx–2010–185).

[7] Prior to the pilot, the $1 cabinet trading procedures were limited to options classes traded in $0.05 or $0.10 standard increments. The $1 cabinet trading procedures were not available in Penny Pilot Program classes because in those classes, an option series could trade in a standard increment as low as $0.01 per share (or $1.00 per option contract with a 100 share multiplier). The pilot allows trading below $0.01 per share (or $1.00 per option contract with a 100 share multiplier) in all classes, including those classes participating in the Penny Pilot Program.

[8] *See* Securities Exchange Act Release No. 64571 (May 31, 2011), 76 FR 32385 (June 6, 2011) (SR–Phlx–2011–72).

[9] *See* Securities Exchange Act Release No. 65852 (November 30, 2011), 76 FR 76212 (December 6, 2011) (SR–Phlx–2011–156).

[10] *See* Securities Exchange Act Release No. 67106 (June 4, 2012), 77 FR 34108 (June 8, 2012) (SR–Phlx–2012–74).

participant might have a long position in a call series with a strike price of $100 and the underlying stock might now be trading at $30. In such an instance, there might not otherwise be a market for that person to close-out its position even at the $1 cabinet price (e.g., the series might be quoted no bid).

The Exchange hereby seeks to extend the pilot period for such $1 cabinet trading until June 1, 2013. The Exchange seeks this extension to allow the procedures to continue without interruption.

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)(5) of the Act,[12] in particular, in that the proposal 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Exchange believes that allowing for liquidations at a price less than $1 per option contract pursuant to the pilot program will better facilitate the closing of options positions that are worthless or not actively trading, especially in Penny Pilot issues where cabinet trades are not otherwise permitted. The Exchange believes the extension is of sufficient length to allow the Commission to assess the impact of the Exchange's authority to allow transactions to take place in open outcry at a price of at least $0 but less than $1 per option in accordance with its attendant obligations and conditions.

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.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is effective upon filing pursuant to Section 19(b)(3)(A) of the Act[13] and paragraph (f)(6) of Rule 19b-4 thereunder,[14] in that the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. 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–2012–131 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.

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6).

[15] The Exchange has fulfilled this requirement.

All submissions should refer to File Number SR–Phlx–2012–131. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml)*. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2012–131 and should be submitted on or before December 7, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27870 Filed 11–15–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68187; File No. SR–NASDAQ–2012–125]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Routing Fees

November 8, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4thereunder,[2] notice is hereby given that on October 31, 2012, The NASDAQ Stock Market

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASDAQ Stock Market LLC proposes to modify Chapter XV, Section 2, governing pricing for NASDAQ members using the NASDAQ Options Market (''NOM''), NASDAQ's facility for executing and routing standardized equity and index options. While changes pursuant to this proposal are effective upon filing, the Exchange has designated the proposed amendment to be operative on November 1, 2012.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to recoup costs that the Exchange incurs for routing and executing certain orders in equity options to the International Securities Exchange, LLC (''ISE'').

The Exchange's Pricing Schedule at Chapter XV, Section 2(4) currently includes the following fees for routing Customer, Firm, Market Maker and Professional orders to away markets:

Exchange	Customer	Firm	MM	Professional
BATS Penny	$0.55	$0.55	$0.55	$0.55
BATS non-Penny	0.86	0.91	0.91	0.91
BOX	0.11	0.55	0.55	0.11
BX Options	0.11	0.54	0.54	0.54
CBOE	0.11	0.55	0.55	0.31
CBOE orders greater than 99 contracts in NDX, MNX ETFs, ETNs & HOLDRs	0.29	0.55	0.55	0.31
C2	0.55	0.55	0.55	0.55
ISE	0.11	0.55	0.55	0.29
ISE Select Symbols *	0.31	0.55	0.55	0.39
NYSE Arca Penny Pilot	0.55	0.55	0.55	0.55
NYSE Arca Non Penny Pilot	0.11	0.55	0.55	0.11
NYSE AMEX	0.11	0.55	0.55	0.31
PHLX (for all options other than PHLX Select Symbols)	0.11	0.55	0.55	0.31
PHLX Select Symbols **	0.50	0.55	0.55	0.51

* These fees are applicable to orders routed to ISE that are subject to Rebates and Fees for Adding and Removing Liquidity in Select Symbols. See ISE's Schedule of Fees for the complete list of symbols that are subject to these fees.

** These fees are applicable to orders routed to PHLX that are subject to Rebates and Fees for Adding and Removing Liquidity in Select Symbols. See PHLX's Pricing Schedule for the complete list of symbols that are subject to these fees.

The Exchange is proposing to amend the ISE Select Symbol Customer Routing Fee from $0.31 to $0.35 per contract when routing Select Symbols to ISE. ISE amended its fee for removing liquidity for Priority Customer orders from $0.20 to $0.25 per contract.[3] The Exchange is seeking to amend the Customer Routing Fee for ISE Select Symbols to recoup the fee increase when routing to ISE.

Nasdaq Options Services LLC (''NOS''), a member of the Exchange, is the Exchange's exclusive order router.[4] NOS is the Routing Facility for NOM. Each time NOS routes to away markets NOS is charged a clearing fee[5] and, in the case of certain exchanges, a transaction fee is also charged in certain symbols, which fees are passed through to the Exchange. The Exchange currently recoups clearing and transaction charges incurred by the Exchange as well as certain other costs incurred by the Exchange when routing to away markets, such as administrative and technical costs associated with operating NOS, membership fees at away markets, and technical costs associated with routing.[6] The Exchange is proposing to assess a fixed fee of $0.10 per contract in addition to the actual transaction fee of $0.25 per contract which is assessed by ISE when routing a Customer order in a Select Symbol for a total of $0.35 per contract.

As with all fees, the Exchange may adjust these Routing Fees in response to competitive conditions by filing a new proposed rule change.

2. Statutory Basis

NASDAQ believes that its proposal to amend its rules is consistent with Section 6(b) of the Act[7] in general, and furthers the objectives of Section 6(b)(4) of the Act[8] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

The Exchange believes that the proposed Customer ISE Select Symbols Routing Fee is reasonable because the Exchange seeks to recoup costs incurred by the Exchange when routing Customer orders to ISE in Select Symbols on behalf of NOM Options Participants.

[3] *See* Securities Exchange Act Release No. 67628 (August 9. 2012), 77 FR 49049 (August 15, 2012) (SR–ISE–2012–71).

[4] *See* NASDAQ Rules at Chapter VI, Section 11(e) (Order Routing).

[5] The Options Clearing Corporation (''OCC'') recently amended its clearing fee to $0.01 per contract side. *See* Securities Exchange Act Release No. 68025 (October 10, 2012), 77 FR 63398 (October 16, 2012) (SR–OCC–2012–18).

[6] The Exchange incurs costly connectivity charges related to telecommunication lines and other related costs when routing orders. Also, in addition to membership fees and transaction fees, the Exchange also incurs an Options Regulatory Fee when routing to an away market that assesses that fee.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

Each destination market's transaction charge varies and there is a standard clearing charge for each transaction incurred by the Exchange along with other administrative and technical costs that are incurred by the Exchange. The Exchange believes that the proposed Customer Routing Fee would enable the Exchange to recover the remove fee assessed to NOM Options Participants by ISE in Select Symbols, plus clearing and other administrative and technical fees for the execution of certain Customer orders routed to ISE. The Exchange also believes that the proposed Customer Routing Fee is equitable and not unfairly discriminatory because the Exchange would assess the ISE Select Symbol Customer Routing Fee uniformly to all Customer orders that are routed to ISE.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In addition, a NOM Options Participant may designate an order as not available for routing to avoid routing fees.[9]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[10] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. 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–NASDAQ–2012–125 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2012–125. 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 filing also will be available for inspection and copying at NASDAQ's principal office and on its Internet Web site. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2012–125, and should be submitted on or before December 7, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27924 Filed 11–15–12; 8:45 am]

BILLING CODE 8011–01–P

[9] *See* NOM Rules at Chapter VI, Section 11.

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68188; File No. SR–BX–2012–071]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Routing 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 October 31, 2012, NASDAQ OMX BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Chapter XV, Section 2 entitled ''BX Options Market—Fees and Rebates.'' Specifically, the Exchange proposes to amend a Customer fee for routing options to the International Securities Exchange, LLC (''ISE''). While changes pursuant to this proposal are effective upon filing, the Exchange has designated the proposed amendment to be operative on November 1, 2012.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaqtrader.com/micro.aspx?id=BXRulefilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to recoup costs that the Exchange incurs for routing and executing certain orders in equity options to ISE. The Exchange's Pricing Schedule at Chapter XV, Section 2(4) currently includes the following fees for routing Customer, Firm, Market Maker, Broker-Dealer and Professional orders to away markets:

Exchange	Customer	Firm/market maker/ broker-dealer	Professional
BATS (Penny Pilot)	$0.55	$0.55	$0.55
BOX	0.11	0.55	0.11
CBOE	0.11	0.55	0.31
CBOE orders greater than 99 contracts in ETFs, ETNs and HOLDRS)	0.29	N/A	0.31
C2	0.55	0.55	0.55
ISE (Standard)	0.11	0.55	0.29
ISE (Select Symbols) *	0.31	0.55	0.39
NOM	0.55	0.55	0.55
NYSE Arca (Penny Pilot)	0.55	0.55	0.55
NYSE Amex	0.11	0.55	0.31
PHLX (for all options other than PHLX Select Symbols)	0.11	0.55	0.36
PHLX Select Symbols **	0.50	0.55	0.55

* These fees are applicable to orders routed to ISE that are subject to Rebates and Fees for Adding and Removing Liquidity in Select Symbols. See ISE's Schedule of Fees for the complete list of symbols that are subject to these fees.

** These fees are applicable to orders routed to PHLX that are subject to Rebates and Fees for Adding and Removing Liquidity in Select Symbols. See PHLX's Pricing Schedule for the complete list of symbols that are subject to these fees.

The Exchange is proposing to amend the ISE (Select Symbols) Customer Routing Fee from $0.31 to $0.35 per contract when routing Select Symbols to ISE. ISE amended its fee for removing liquidity for Priority Customer orders from $0.20 to $0.25 per contract.[3] The Exchange is seeking to amend the Customer Routing Fee for ISE Select Symbols to recoup the fee increase when routing to ISE.

Nasdaq Options Services LLC (''NOS''), a member of the Exchange, is the Exchange's exclusive order router.[4] NOS is the Routing Facility for BX Options. Each time NOS routes to away markets NOS is charged a clearing fee[5] and, in the case of certain exchanges, a transaction fee is also charged in certain symbols, which fees are passed through to the Exchange. The Exchange currently recoups clearing and transaction charges incurred by the Exchange as well as certain other costs incurred by the Exchange when routing to away markets, such as administrative and technical costs associated with operating NOS, membership fees at away markets, and technical costs associated with routing.[6] The Exchange is proposing to assess a fixed fee of $0.10 per contract in addition to the actual transaction fee of $0.25 per contract which is assessed by ISE when routing a Customer order in a Select Symbol for a total of $0.35 per contract.

As with all fees, the Exchange may adjust these Routing Fees in response to competitive conditions by filing a new proposed rule change.

2. Statutory Basis

BX believes that its proposal to amend its rules is consistent with Section 6(b) of the Act[7] in general, and furthers the objectives of Section 6(b)(4) of the Act[8] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

The Exchange believes that the proposed Customer ISE Select Symbols Routing Fee is reasonable because the Exchange seeks to recoup costs incurred by the Exchange when routing Customer orders to ISE in Select Symbols on behalf of BX Options Participants. Each destination market's transaction charge varies and there is a standard clearing charge for each transaction incurred by the Exchange along with other administrative and technical costs that are incurred by the Exchange. The Exchange believes that the proposed Customer Routing Fee would enable the Exchange to recover the remove fee assessed to BX Options Participants by ISE in Select Symbols, plus clearing and other administrative and technical fees for the execution of certain Customer orders routed to ISE. The Exchange also believes that the proposed Customer Routing Fee is equitable and not unfairly discriminatory because the Exchange would assess the ISE Select Symbol Customer Routing Fee uniformly to all Customer orders that are routed to ISE.

B. Self-Regulatory Organization's Statement on Burden on Competition

BX does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In addition, a BX Options Participant may designate an order as not available for routing to avoid routing fees.[9]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[3] *See* Securities Exchange Act Release No. 67628 (August 9. 2012), 77 FR 49049 (August 15, 2012) (SR–ISE–2012–71).

[4] *See* BX Options Rules at Chapter VI, Section 11(e) (Order Routing).

[5] The Options Clearing Corporation (''OCC'') recently amended its clearing fee to $0.01 per contract side. *See* Securities Exchange Act Release No. 68025 (October 10, 2012), 77 FR 63398 (October 16, 2012) (SR–OCC–2012–18).

[6] The Exchange incurs costly connectivity charges related to telecommunication lines and other related costs when routing orders. Also, in addition to membership fees and transaction fees, the Exchange also incurs an Options Regulatory Fee when routing to an away market that assesses that fee.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

[9] *See* BX Rules at Chapter VI, Section 11(e).

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.[10] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. 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–2012–071 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2012–071. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, 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 Exchange's principal office and on its Internet Web site. 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–2012–071, and should be submitted on or before December 7, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27925 Filed 11–15–12; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

DIAS Holding, Inc., EarthBlock Technologies, Inc., Ensurapet, Inc., FIIC Holdings, Inc., GeM Solutions, Inc., Gold Star Tutoring Services Inc., and GPS Industries, Inc.; Order of Suspension of Trading

November 14, 2012.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of DIAS Holding, Inc. because it has not filed any periodic reports since the period ended September 30, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of EarthBlock Technologies, Inc. because it has not filed any periodic reports since the period ended December 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Ensurapet, Inc. because it has not filed any periodic reports since the period ended December 31, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of FIIC Holdings, Inc. because it has not filed any periodic reports since the period ended September 30, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Gold Star Tutoring Services, Inc. because it has not filed any periodic reports since the period ended September 30, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of GeM Solutions, Inc. because it has not filed any periodic reports since the period ended March 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of GPS Industries, Inc. because it has not filed any periodic reports since the period ended March 31, 2009.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies. Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EST on November 14, 2012, through 11:59 p.m. EST on November 28, 2012.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2012–28017 Filed 11–14–12; 11:15 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of Reporting Requirements Submitted for OMB Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before December 17, 2012. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for

review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Curtis Rich, *Curtis.rich@sba.gov* Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *OMB Reviewer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030.

SUPPLEMENTARY INFORMATION:

Title: ''HUBZone Program Electronic Application, Re-certification and Program Examination.''

Frequency: On Occasion.

SBA Form Number: N/A.

Description of Respondents: HUBZone eligible applicants.

Responses: 6,377.

Annual Burden: 10,725.

Curtis Rich,

Management Analyst.

[FR Doc. 2012–27643 Filed 11–15–12; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13271 and #13272]

Louisiana Disaster Number LA–00048

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 11.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Louisiana (FEMA—4080—DR), dated 08/31/2012.

Incident: Hurricane Isaac.

Incident Period: 08/26/2012 through 09/10/2012.

Effective Date: 10/25/2012.

Physical Loan Application Deadline Date: 11/29/2012.

EIDL Loan Application Deadline Date: 05/29/2013.

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 President's major disaster declaration for the State of Louisiana, dated 08/31/2012 is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 11/29/2012.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Joseph P. Loddo,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2012–27837 Filed 11–15–12; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 8088]

The Designation of Qari Zakir, Also Known as Abdul Rauf, as a Specially Designated Global Terrorist pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Qari Zakir, also known as Abdul Rauf, committed, or poses 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.

Consistent with the determination in section 10 of Executive Order 13224 that ''prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously,'' I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: September 20, 2012.

Hillary Rodham Clinton,

Secretary of State.

[FR Doc. 2012–27943 Filed 11–15–12; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2012–48]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 6, 2012.

ADDRESSES: You may send comments identified by Docket Number FAA–2012–0954 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to

http://www.regulations.gov at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Theresa White, ANM–113, Standardization Branch, Federal Aviation Administration, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA 98057–3356; email *Theresa.j.White@FAA.gov;* (425) 227–2956; fax: 425–227–1320; Andrea Copeland, ARM–208, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; email *andrea.copeland@faa.gov;* (202) 267–8081.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 5, 2012.

Ida M. Klepper,

Acting Director, Office of Rulemaking.

Petition For Exemption

Docket No.: FAA–2012–0954.

Petitioner: L–3 Communications Integrated Systems, L.P.

Sections of 14 CFR Affected: 14 CFR 25.562 and 25.785(b).

Description of Relief Sought: The petitioner seeks exemption from 14 CFR 25.562 and 25.785(b) to permit use of single and multiple-place side-facing divans in its Boeing Model 747–8 airplanes operated in private use.

[FR Doc. 2012–27518 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2012–0067]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated July 25, 2012, the Peninsula Corridor Joint Powers Board (PCJPB or Caltrain) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 215. FRA assigned the petition Docket Number FRA–2012–0067.

Caltrain seeks a waiver of compliance from the Railroad Freight Car Safety Standards contained in 49 CFR 215.303–*Stenciling of restricted cars,* which requires stenciling on restricted freight cars with a clearly legible letter ''R'' followed by the basis of the restriction. This request is made for two flat-straight deck cars (Car Numbers JPBX 711 and JPBX 712). Caltrain also requested a Special Approval to continue in service the same cars in accordance with 49 CFR 215.203(c)–*Restricted cars.* The ages of these cars are more than 50 years from their original construction dates, and therefore, they are restricted per 49 CFR 215.203(a), unless Caltrain receives a Special Approval from FRA.

Caltrain states that the purpose of this petition is to allow Caltrain to operate the subject cars for transportation of decorations during the annual Holiday Trains, which is a successful community supported event. Caltrain stated that the principal business owner of these two cars is PCJPB and the operator and maintainer is TransitAmerica Services, Inc. Each car has been inspected and determined to be safe for continued operation. These two cars were built on August 1, 1953. The maximum speed is 50 mph. The territorial limits are Caltrain Main Track #1 and #2 between Milepost 0 and Milepost 52, as well as Caltrain yard tracks. These two cars will not be interchanged.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate Docket Number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by December 31, 2012 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or online at http://www.dot.gov/privacy.html.

Issued in Washington, DC, on November 8, 2012.

Brenda Moscoso,

Director, Office of Safety Analysis.

[FR Doc. 2012–27852 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2012–0074]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated August 14, 2012, the City of Oshkosh, WI (the City), has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR Part 222–Use of Locomotive Horns at Public Highway-Rail Grade Crossings. FRA assigned the petition Docket Number FRA–2012–0074.

The City is seeking a waiver from the provisions of 49 CFR Section 222.9–*Definitions* regarding the definition of a non-traversable curb. The City is seeking relief so that an existing safety measure at public crossing, County Highway Y (DOT #690219D), may be deemed an acceptable supplemental safety measure (SSM). County Highway Y is equipped with flashing lights, gates, and medians that comply with all of the requirements necessary to be a ''gates with medians or channelization

devices'' SSM with non-traversable curbs, except for the fact that the posted highway speed limit is 45 mph instead of 40 mph as required in the definition.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by December 31, 2012 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or online at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC, on November 8, 2012.

Brenda Moscoso,

Director, Office of Safety Analysis.

[FR Doc. 2012–27858 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2012–0060]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated June 18, 2012, the Port Authority Trans-Hudson Corporation (PATH) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations related to periodic brake equipment maintenance found in 49 CFR 238.309(b)(2), which requires brake equipment maintenance at the 1104-day interval.

PATH is asking for an extension of 6 months to complete these processes for all equipment overhauls. PATH states that the material and inventory necessary to complete the required maintenance will not be available from the vendor (WABTEC) in sufficient time for completion. FRA assigned the petition Docket Number FRA–2012–0060.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by December 31, 2012 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or online at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC, on November 8, 2012.

Brenda Moscoso,

Director, Office of Safety Analysis.

[FR Doc. 2012–27860 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2012–0079]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated September 24, 2012, Long Island Rail Road (LIRR) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain Federal hours of service requirements for train employees engaged in commuter or intercity rail passenger transportation contained at 49 CFR 228.405(a)(3). FRA assigned the petition Docket Number FRA–2012–0079.

In its petition, LIRR seeks a waiver allowing the series of at most 14 consecutive calendar days to reset after a general pick, or after a large timetable revision. A general pick, as described by LIRR, is a biannual event allowing train employees to bid on jobs with jobs being

awarded based on an employee's seniority. FRA's current policy only allows a maximum series of at most 14 consecutive calendar days to reset at the end of the 14th day, or when an employee does not initiate an on-duty period for any 2 calendar days within the 14 consecutive calendar-day series.

In support of the request, LIRR explained that after the first general pick, about 20 employees were required to take 1 or 2 workdays off to avoid violating Federal requirements. As a result, employees suffered financially, and employee availability was reduced, disrupting LIRR's ability to provide timely and efficient service for its customers. LIRR argues that allowing the 14 consecutive calendar-day series to reset after a general pick, or a large timetable revision, will prevent any future employee financial losses and disruptions in LIRR's ability to provide optimum service to its customers.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate Docket Number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by December 31, 2012 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or online at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC, on November 8, 2012.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2012–27863 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2010–0164]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated October 9, 2012, the Albany Port Railroad (APRR) and the United Transportation Union (UTU) have jointly petitioned the Federal Railroad Administration (FRA) for an extension of their waiver of compliance from certain provisions of the Federal hours of service laws contained at 49 U.S.C. 21103(a)(4). FRA assigned the petition Docket Number FRA–2012–0068.

In the petition, APRR and UTU seek relief from 49 U.S.C. 21103(a)(4), which in part requires a train employee to receive 48 hours off duty after initiating an on-duty period for 6 consecutive days. Specifically, APRR and UTU seek an extension of the waiver to allow a train employee to initiate an on-duty period for 6 consecutive days followed by 24 hours off duty. In support of the request, APRR explained they have four train employees of which three work a single regular assignment Monday through Friday, beginning at 6 a.m. and usually ending at 1 p.m. The remaining employee holds a relief position and works for the other three employees when they require a day off. Finally, APRR states that the work is always performed within the confines of the Albany Port, which consists of yard tracks with a speed of 5 mph.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by December 31, 2012 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or online at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC, on November 8, 2012.

Ron Hynes,

Director, Office of Safety Assurance and Compliance.

[FR Doc. 2012–27865 Filed 11–15–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35665]

Aiken Railway Company, LLC—Lease and Operation Exemption—Lines of Norfolk Southern Railway Company in Aiken County, SC

On October 31, 2012, Aiken Railway Company, LLC (AIKR), a noncarrier, filed a verified notice of exemption under 49 CFR 1150.31 to lease from Norfolk Southern Railway Company (NSR), and to operate, two segments of rail line referred to as the SA Line and the AB Line. The SA Line extends 12.45 miles between milepost SA 63.45 at or near Warrenville, SC, and milepost SA 51.0 at or near Oakwood, SC. The AB Line extends 6.45 miles between milepost AB 23.75 at or near Aiken, SC, and milepost AB 17.3 at or near Seclay, SC. This transaction is related to a notice of exemption filed on November 5, 2012, in which Western Carolina Railway Service Corporation (WCRS), and Steven C. Hawkins and Cheryl R. Hawkins (collectively, the Hawkins) seek Board approval to continue in control of AIKR upon AIKR's becoming a Class III rail carrier. *W. Carolina Ry. Serv. Corp.—Continuance in Control Exemption—Aiken Ry.,* Docket No. FD 35691.

As a result of this transaction, and pursuant to a lease agreement between AIKR and NSR, AIKR will provide freight rail service over the lines. As consideration for the lease, AIKR has agreed to bring the lines (except for a sub-segment between mileposts SA 51.0 and SA 55.0) up to the Federal Railroad Administration's Class 1 standards. AIKR states that the lines connect only with NSR and that it will interchange with NSR in Aiken, SC. AIKR states that the transaction does not, however, impose any interchange commitments.

The effective date of this exemption is November 30, 2012. AIKR states that it expects to commence operations on December 1, 2012, more than 30 days after the notice of exemption was filed. The effective date of the related continuance in control exemption in Docket No. FD 35691, however, is December 5, 2012. WCRS and the Hawkins are reminded that they are not authorized to control AIKR until the continuance in control exemption becomes effective on December 5, 2012.

AIKR certifies that its projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class III rail carrier. AIKR further certifies that its projected annual revenues as a result of this transaction will not exceed $5 million.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed by November 23, 2012 (at least seven days prior to the date the exemption becomes effective).

An original and ten copies of all pleadings, referring to Docket No. FD 35665 must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on J. Marshall Lawson, 4840 Forest Drive, Suite 6B, PMB–295, Columbia, SC 29206–4810.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: November 13, 2012.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2012–27941 Filed 11–15–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Office of the Secretary

List of Countries Requiring Cooperation With an International Boycott

In accordance with section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries which require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the basis of the best information currently available to the Department of the Treasury, the following countries require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

Iraq
Kuwait
Lebanon
Libya
Qatar
Saudi Arabia
Syria
United Arab Emirates
Yemen

Dated: November 6, 2012.

Danielle Rolfes,

International Tax Counsel, (Tax Policy).

[FR Doc. 2012–27737 Filed 11–15–12; 8:45 am]

BILLING CODE 4810–25–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Rate for Use in Federal Debt Collection and Discount and Rebate Evaluation

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice of rate for use in Federal debt collection and discount and rebate evaluation.

SUMMARY: Pursuant to Section 11 of the Debt Collection Act of 1982, as amended, (31 U.S.C. 3717), the Secretary of the Treasury is responsible for computing and publishing the percentage rate to be used in assessing interest charges for outstanding debts owed to the Government. Treasury's Cash Management Requirements (TFM Volume I, Part 6, Chapter 8000) prescribe use of this rate by agencies as a comparison point in evaluating the cost-effectiveness of a cash discount. In addition, 5 CFR 1315.8 of the Prompt Payment rule on ''Rebates'' requires that this rate be used in determining when agencies should pay purchase card invoices when the card issuer offers a rebate. Notice is hereby given that the applicable rate is 1.00 percent for calendar year 2013.

DATES: The rate will be in effect for the period beginning on January 1, 2013, and ending on December 31, 2013.

FOR FURTHER INFORMATION CONTACT: Inquiries should be directed to the E-Commerce Division, Financial Management Service, Department of the Treasury, 401 14th Street SW., Washington, DC 20227 (Telephone: 202–874–9428).

SUPPLEMENTARY INFORMATION: The rate reflects the current value of funds to the Treasury for use in connection with Federal Cash Management systems and is based on investment rates set for purposes of Public Law 95–147, 91 Stat. 1227. Computed each year by averaging Treasury Tax and Loan (TT&L) investment rates for the 12-month period ending every September 30, rounded to the nearest whole percentage, for applicability effective each January 1, the rate is subject to quarterly revisions if the annual average, on a moving basis, changes by 2 percentage points. The rate in effect for the calendar year 2013 reflects the average investment rates for the 12-

month period that ended September 30, 2012.

Dated: November 4, 2012.

Sheryl R. Morrow,

Assistant Commissioner, Payment Management.

[FR Doc. 2012–27766 Filed 11–15–12; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 2063

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 2063, U.S. Departing Alien Income Tax Statement.

DATES: Written comments should be received on or before January 15, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3869, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: U.S. Departing Alien Income Tax Statement.

OMB Number: 1545–0138.

Form Number: 2063.

Abstract: Form 2063 is used by a departing resident alien against whom a termination assessment has not been made, or a departing nonresident alien who has no taxable income from United States sources, to certify that they have satisfied all U.S. income tax obligations. The data is used by the IRS to certify that departing aliens have complied with U.S. income tax laws.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Responses: 20,540.

Estimated Time per Response: 50 minutes.

Estimated Total Annual Burden Hours: 17,049.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 6, 2012.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2012–27825 Filed 11–15–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Nonaccrual-Experience Method of Accounting Under Section 448(d)(5).

DATES: Written comments should be received on or before January 15, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Martha R. Brinson at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3869, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Nonaccrual-Experience Method of Accounting Under Section 448(d)(5).

OMB Number: 1545–1855.

Regulation Project Number: TD 9285.

Abstract: This document contains final regulations relating to the use of a nonaccrual-experience method of accounting by taxpayers using an accrual method of accounting and performing services. The final regulations reflect amendments under the Job Creation and Worker Assistance Act of 2002. The final regulations affect qualifying taxpayers that want to adopt, change to, or change a nonaccrual-experience method of accounting under section 448(d)(5) of the Internal Revenue Code (Code).

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 8,000.

Estimated Time per Respondent: 3 hours.

Estimated Total Annual Burden Hours: 24,000.

The following paragraph applies to all of the collections of information covered by this notice:

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

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

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 7, 2012.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2012–27826 Filed 11–15–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the Extended Carryback of Losses to or From a Consolidated Group.

DATES: Written comments should be received on or before January 15, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Martha R. Brinson at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3869, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Extended Carryback of Losses to or From a Consolidated Group.

OMB Number: 1545–2171.

Regulation Project Number: TD 9490.

Abstract: This document contains final and temporary regulations under section 1502 that affect corporations filing consolidated returns. The regulations contain rules regarding the implementation of section 172(b)(1)(H) within a consolidated group. These regulations also permit certain acquiring consolidated groups to elect to waive all or a portion of the pre-acquisition carryback period pursuant to section 172(b)(1)(H) for specific losses attributable to certain acquired members.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 4,000.

Estimated Time per Respondent: 0.25 hours.

Estimated Total Annual Burden Hours: 1,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 7, 2012.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2012–27827 Filed 11–15–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Corporations; Consolidated Returns-Special Rules Relating To Dispositions and Deconsolidations of Subsidiary Stock (§§ 1.337(d)–2 and 1.1502–20).

DATES: Written comments should be received on or before January 15, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Martha R. Brinson at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3869, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Corporations; Consolidated Returns—Special Rules Relating To Dispositions and Deconsolidations of Subsidiary Stock.

OMB Number: 1545–1160.

Regulation Project Number: CO–93–90.

Abstract: This regulation prevents elimination of corporate-level tax because of the operation of the consolidated returns investment adjustment rules. Statements are required for dispositions of a subsidiary's stock for which losses are claimed, for basis reductions within 2 years of the stock's deconsolidation, and for elections by the common parent to retain the net operating losses of a disposed subsidiary.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 3,000.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 6,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 6, 2012.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2012–27828 Filed 11–15–12; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 77 Friday,

No. 222 November 16, 2012

Book 2 of 2 Books

Pages 68891–69380

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415, 421, 423, 425, 486, and 495

[CMS–1590–FC]

RIN 0938–AR11

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This major final rule with comment period addresses changes to the physician fee schedule, payments for Part B drugs, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It also implements provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items. In addition, it implements statutory changes regarding the termination of non-random prepayment review. This final rule with comment period also includes a discussion in the Supplementary Information regarding various programs . (See the Table of Contents for a listing of the specific issues addressed in this final rule with comment period.)

DATES: *Effective date:* The provisions of this final rule with comment period are effective on January 1, 2013 with the exception of provisions in § 410.38 which are effective on July 1, 2013. The incorporation by reference of certain publications listed in the rule was approved by the Director of the Federal Register on May 16, 2012.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2012. (See the **SUPPLEMENTARY INFORMATION** section of this final rule with comment period for a list of the provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS–1590–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *www.regulations.gov.* Follow the instructions for ''submitting a comment.''

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1590–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1590–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 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 FURTHER INFORMATION CONTACT:

Elliott Isaac, (410) 786–4735, for any physician payment issue not identified below.

Ryan Howe, (410) 786–3355, for issues related to practice expense methodology and direct practice expense inputs, telehealth services, and issues related to primary care and care coordination.

Sara Vitolo, (410) 786–5714, for issues related to potentially misvalued services, malpractice RVUs, molecular pathology, and payment for new preventive service HCPCS G-codes, and the sustainable growth rate.

Carol Schwartz, (410) 786- 0576, for issues related to colonoscopy and preventive services.

Ken Marsalek, (410) 786–4502, for issues related to the multiple procedure payment reduction and payment for the technical component of pathology services.

Craig Dobyski, (410) 786–4584, for issues related to geographic practice cost indices.

Pam West, (410) 786–2302, for issues related to therapy services.

Chava Sheffield, (410) 786–2298, for issues related to certified registered nurse anesthetists scope of benefit.

Roberta Epps, (410) 786–4503, for issues related to portable x-ray.

Anne Tayloe-Hauswald, (410) 786–4546, for issues related to ambulance fee schedule and Part B drug payment.

Amanda Burd, (410) 786–2074, for issues related to the DME provisions.

Debbie Skinner, (410) 786–7480, for issues related to non-random prepayment complex medical review.

Latesha Walker, (410) 786–1101, for issues related to ambulance coverage—physician certification statement.

Alexandra Mugge, (410) 786–4457, for issues related to physician compare.

Christine Estella, (410) 786–0485, for issues related to the physician quality reporting system, incentives for e-prescribing, and Medicare shared savings program.

Pauline Lapin, (410) 786–6883, for issues related to the chiropractic services demonstration budget neutrality issue.

Gift Tee, (410) 786–9316, for issues related to the physician feedback reporting program and value-based payment modifier.

Jamie Hermansen, (410) 786–2064, for issues related to Medicare coverage for hepatitis B vaccine.

Andrew Morgan, (410) 786–2543, for issues related to e-prescribing under Medicare Part D.

SUPPLEMENTARY INFORMATION:

Provisions open for comment: We will consider comments that are submitted as indicated above in the ''Dates'' and ''Addresses'' sections on the following subject areas discussed in this final rule with comment period:

- Interim final work, practice expense, and malpractice RVUs (including physician time, direct practice expense (PE) inputs, and the equipment utilization rate assumption) for new, revised, potentially misvalued, and certain other CY 2013 HCPCS codes as indicated in the sections that follow and listed in Addendum C to this final rule with comment period; and
- The appropriate direct PE inputs for establishing nonfacility PE RVUs for CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural).

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: *www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1 (800) 743–3951.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a table of contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR). Information on the regulations impact appears throughout the preamble and, therefore, is not discussed exclusively in section VIII. of this final rule with comment period.

I. Executive Summary and Background
II. Provisions of the Final Rule With Comment Period
  A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)
  B. Potentially Misvalued Codes Under the Physician Fee Schedule
  C. Malpractice RVUs
  D. Geographic Practice Cost Indices (GPCIs)
  E. Medicare Telehealth Services for the Physician Fee Schedule
  F. Extension of Payment for Technical Component of Certain Physician Pathology Services
  G. Therapy Services
  H. Primary Care and Care Coordination
  I. Payment for Molecular Pathology Services
  J. Payment for New Preventive Services HCPCS G Codes
  K. Certified Registered Nurse Anesthetists Scope of Benefit
  L. Ordering of Portable X-Ray Services
  M. Addressing Interim Final Relative Value Units (RVUs) From CY 2012 and Establish Interim Final Rule RVU's for CY 2013
  N. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate
III. Other Provisions of the Final Rule With Comment Period
  A. Ambulance Fee Schedule
  B. Part B Drug Payment: Average Sales Price (ASP) Issues
  C. Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery
  D. Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review
  E. Ambulance Coverage-Physician Certification Statement
  F. Physician Compare Web Site
  G. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System
  H1. Electronic Prescribing (eRx) Incentive Program
  H2. The PQRS-Medicare EHR Incentive Pilot
  I. Medicare Shared Savings Program
  J. Discussion of Budget Neutrality for the Chiropractic Services Demonstration
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IV. Additional Provisions
  A. Waiver of Deductible for Surgical Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test and Colorectal Cancer Screening Test Definition—Technical Correction
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VIII. Regulatory Impact Analysis

Acronyms

Because of the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below:

AHRQ [HHS] Agency for Healthcare Research and Quality
AMA American Medical Association
AMA RUC AMA [/Specialty Society] Relative [Value] Update Committee
ARRA American Recovery and Reinvestment Act (Pub. L. 111–5)
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA [Medicare, Medicaid, and SCHIP] Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
BLS Bureau of Labor Statistics
BN Budget neutrality
CAH Critical access hospital
CBSA Core-Based Statistical Area
CF Conversion factor
CfC Conditions for Coverage
CFR Code of Federal Regulations
CNS Clinical nurse specialist
CoPs Conditions of Participation
CORF Comprehensive Outpatient Rehabilitation Facility
CPI Consumer Price Index
CPT [Physicians] Current Procedural Terminology *(CPT codes, descriptions and other data only are copyright 2012 American Medical Association. All rights reserved.)*
CRNA Certified registered nurse anesthetist
CY Calendar year
DHS Designated health services
DME Durable medical equipment
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DOTPA Development of Outpatient Therapy Payment Alternatives
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
E/M Evaluation and management
EHR Electronic health record
eRx Electronic prescribing
FFS Fee-for-service
FR **Federal Register**
GAF Geographic adjustment factor
GAO [U.S.] Government Accountability Office
GPRO Group Practice Reporting Option
GPCI Geographic practice cost index
HAC Hospital-acquired conditions
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HIT Health information technology
HITECH Health Information Technology for Economic and Clinical Health Act (Title IV of Division B of the Recovery Act, together with Title XIII of Division A of the Recovery Act)
HPSA Health Professional Shortage Area
ICD International Classification of Diseases
IMRT Intensity Modulated Radiation Therapy
IOM Internet-only Manual
IPCI Indirect practice cost index
IPPS Inpatient prospective payment system
IWPUT Intra-service work per unit of time
MAC Medicare Administrative Contractor
MCTRJCA Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96)
MEDCAC Medicare Evidence Development and Coverage Advisory Committee

(formerly the Medicare Coverage Advisory Committee)
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MIEA–TRHCA Medicare Improvements and Extension Act of 2006 (that is, Division B of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109–432)
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MMEA Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309)
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173)
MPPR Multiple procedure payment reduction
MQSA Mammography Quality Standards Act of 1992 (Pub. L. 102–539)
NP Nurse practitioner
NPP Nonphysician practitioner
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act (Pub. L. 101–239)
OIG [HHS] Office of Inspector General
PA Physician assistant
PC Professional component
PE Practice expense
PE/HR Practice expense per hour
PERC Practice Expense Review Committee
PFS Physician Fee Schedule
PGP [Medicare] Physician Group Practice
PLI Professional liability insurance
PPS Prospective payment system
PQRS Physician Quality Reporting System
PRA Paperwork Reduction Act
PPTRA Physician Payment and Therapy Relief Act of 2010 (Pub. L. 111–286)
PVBP Physician and Other Health Professional Value-Based Purchasing Workgroup
RAC [Medicare] Recovery Audit Contractor
RFA Regulatory Flexibility Act
RIA Regulatory impact analysis
RVU Relative value unit
SBRT Stereotactic body radiation therapy
SGR Sustainable growth rate
TC Technical component
TIN Tax identification number
TPTCCA Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78)
TRHCA Tax Relief and Health Care Act of 2006 (Pub. L. 109–432)
VBP Value-based purchasing

Addenda Available Only Through the Internet on the CMS Web Site

In the past, the Addenda referred to throughout the preamble of our annual PFS proposed and final rules with comment period were included in the printed **Federal Register**. However, effective with the CY 2012 PFS final rule with comment period, the PFS Addenda no longer appear in the **Federal Register**. Instead these Addenda to the annual proposed and final rules with comment period will be available only through the Internet. The PFS Addenda along with other supporting documents and tables referenced in this final rule with comment period are available through the Internet on the CMS Web site at *www.cms.gov/PhysicianFeeSched/*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2013 PFS final rule with comment period, refer to item CMS–1590–FC. Readers who experience any problems accessing any of the Addenda or other documents referenced in this final rule with comment period and posted on the CMS Web site identified above should contact Elliott Isaac at (410) 786–4735.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2012 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major final rule with comment period revises payment policies under the Medicare Physician Fee Schedule (PFS) and makes other policy changes related to Medicare Part B payment. These changes are applicable to services furnished in CY 2013. It also implements provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items. In addition, it implements statutory changes regarding the termination of non-random prepayment review.

2. Summary of the Major Provisions

The Social Security Act (Act) requires us to establish payments under the PFS based on national uniform relative value units (RVUs) and the relative resources used in furnishing a service. The Act requires that national RVUs be established for physician work, practice expense (PE), and malpractice expense. In this major final rule with comment period, we establish payment rates for CY 2013 for the PFS, payments for Part B drugs, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and in the relative value of services. It also implements provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items, and by removing certain regulations regarding the termination of non-random prepayment review. It also establishes new claims-based data reporting requirements for therapy services to implement a provision in the Middle Class Tax Relief and Jobs Creation Act (MCTRCA). In addition, this rule:

- Identifies Potentially Misvalued Codes to be Evaluated.
- Establishes Additional Multiple Procedure Payment Reductions (MPPR).
- Expands Medicare Telehealth Services.
- Implements Regulatory Changes Regarding Payment for Technical Component of Certain Physician Pathology Services to Conform to Statute.
- Requires the Inclusion of Specific Information on Claims for Therapy Services.
- Establishes New Transitional Care Management Services.
- Clarifies Services Included in the Certified Registered Nurse Anesthetists Scope of Benefit.
- Modifies Ordering Requirements for Portable X-ray Services.
- Updates the Ambulance Fee Schedule.
- Sets Part B Drug Payment Rates for 2013.
- Addresses Ambulance Coverage—Physician Certification Statement.
- Updates policies regarding the—
  - ++ Physician Compare Web site.
  - ++ Physician Quality Reporting System.
  - ++ Electronic Prescribing (eRx) Incentive Program.
  - ++ Electronic Health Record (EHR) Incentive Program.
  - ++ Medicare Shared Savings Program.
- Discusses Budget Neutrality for the Chiropractic Demonstration.
- Addresses Implementation of the Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program.
- Establishes Medicare Coverage of Hepatitis B Vaccine.
- Updates Existing Standards for e-prescribing under Medicare Part D and Lifting the LTC Exemption.

3. Summary of Costs and Benefits

The statute requires that we establish by regulation each year payment amounts for all physicians' service. These payment amounts are required to be adjusted to reflect the variations in

the costs of providing services in different geographic areas. The statute also requires that annual adjustments to the RVUs not cause annual estimated expenditures to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs would cause expenditures to change by more than $20 million, we must make adjustments to preserve budget neutrality.

Several changes affect the specialty distribution of Medicare expenditures. This final rule with comment period reflects the Administration's priority to improve payment for primary care services. As described in Section II.N, in the absence of Congressional action, an overall reduction of 26.5 percent will be imposed in the conversion factor used to calculate payment for physicians' services on or after January 1, 2013 due to the Sustainable Growth Rate (SGR). To isolate the impact of changes that we are proposing in this final rule with comment period, we analyze and discuss the policies' impact with a constant conversion factor. In the absence of a change in the conversion factor, payments to primary care specialties will increase and payments to select other specialties will decrease due to several changes in how we calculate payments for CY 2013.

The largest payment increase for primary care specialties overall will result from a new payment for managing a beneficiary's care when the beneficiary is discharged from an inpatient hospital, a SNF, an outpatient hospital observation, partial hospitalization services, or a community mental health center. Payments to primary care specialties also will increase due to redistributions from changes in payments for services furnished by other specialties. Because of the budget-neutral nature of this system, decreases in payments for one service result in increases in payments in others.

Payments to primary care specialties are also impacted by the completion of the 4-year transition to new PE RVUs using the new Physician Practice Information Survey (PPIS) data that was adopted in the CY 2010 PFS final rule with comment period. The projected impacts of using the new PPIS data are generally consistent with the impacts discussed in the CY 2012 final rule with comment period (76 FR 72452).

Several types of providers are projected to see decreases in Medicare PFS payments, mainly as a result of the potentially misvalued codes initiative. We have received numerous new codes with new values and revised codes with new values for CY 2013 as a result of our ongoing misvalued codes initiative, an effort to improve payment accuracy. Many of the new and revised codes that we valued on an interim basis for CY 2013 originated with the potentially misvalued codes initiative. Reductions for pathology, neurology, and independent laboratories are a result of the misvalued code initiative. In the case of independent laboratories, we note that independent laboratories receive the majority of the Medicare revenue from the Clinical Lab Fee Schedule, which is unaffected by the misvalued code initiative. Radiation therapy centers will see an overall decrease of 9 percent primarily as a result of the PPIS transition discussed above and a change in the interest rate assumption used to calculate PE. Radiation oncology sees a 7 percent decrease for the same reasons as radiation therapy centers.

B. Background

We note that throughout this final rule with comment period, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, psychologists, or clinical social workers) who are permitted to bill Medicare under the PFS for their services. Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, ''Payment for Physicians' Services.'' The Act requires that CMS make payments under the PFS using national uniform relative value units (RVUs) based on the relative resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, PE, and malpractice expense. Before the establishment of the resource-based relative value system, Medicare payment for physicians' services was based on reasonable charges.

1. Development of the Relative Value System

a. Work RVUs

The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (Pub. L. 101–239), and OBRA 1990, (Pub. L. 101–508). The final rule published on November 25, 1991 (56 FR 59502) set forth the fee schedule for payment for physicians' services beginning January 1, 1992.

The physician work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original physician work RVUs for most codes in a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes for the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

Section 1848(b)(2)(B) of the Act specifies that the RVUs for anesthesia services are based on RVUs from a uniform relative value guide, with appropriate adjustment of the conversion factor (CF), in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. We established a separate CF for anesthesia services, and we continue to utilize time units as a factor in determining payment for these services. As a result, there is a separate payment methodology for anesthesia services.

We establish physician work RVUs for new and revised codes based, in part, on our review of recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (AMA RUC).

b. Practice Expense Relative Value Units (PE RVUs)

Initially, only the physician work RVUs were resource-based, and the PE and malpractice RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432), and Section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service. We were to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs.

We established the resource-based PE RVUs for each physicians' service in a final rule, published November 2, 1998 (63 FR 58814), effective for services furnished in 1999. Separate PE RVUs are established for procedures that can be furnished in both a nonfacility setting, such as a physician's office, and a facility setting, such as a hospital outpatient department (HOPD). The difference between the facility and nonfacility RVUs reflects the fact that a facility typically receives separate payment from Medicare for its costs of furnishing the service, apart from payment under the PFS. The nonfacility

RVUs reflect all of the direct and indirect PEs of furnishing a particular service. Based on the BBA requirement to transition to a resource-based system for PE over a 4-year period, resource-based PE RVUs did not become fully effective until 2002.

This resource-based system was based on two significant sources of actual PE data. Panels of physicians, practice administrators, and nonphysician health professionals (for example, registered nurses (RNs)), who were nominated by physician specialty societies and other groups identified the direct inputs required for each physicians' service. (We have since refined and revised these inputs based on recommendations from the AMA RUC.) Aggregate specialty-specific information on hours worked and PEs was obtained from the AMA's Socioeconomic Monitoring System (SMS).

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) directed us to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed in CY 2010. Direct PE RVUs were calculated for CY 2013 using this methodology, unless otherwise noted.

In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). For this update, we used the Physician Practice Information Survey (PPIS) conducted by the AMA. The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) using a survey instrument and methods highly consistent with those used prior to CY 2010. We note that in CY 2010, for oncology, clinical laboratories, and independent diagnostic testing facilities (IDTFs), we continued to use the supplemental survey data to determine PE/HR values (74 FR 61752). Beginning in CY 2010, we provided for a 4-year transition for the new PE RVUs using the updated PE/HR data. In CY 2013, the final year of the transition, PE RVUs are calculated based on the new data.

c. Resource-Based Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based malpractice RVUs for services furnished on or after CY 2000. The resource-based malpractice RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The malpractice RVUs were based on malpractice insurance premium data collected from commercial and physician-owned insurers.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review all RVUs no less often than every 5 years. Prior to CY 2013, we conducted separate periodic reviews of work RVUs and PE RVUs. The First Five-Year Review of Work RVUs was published on November 22, 1996 (61 FR 59489) and was effective in 1997. The Second Five-Year Review of Work RVUs was published in the CY 2002 PFS final rule with comment period (66 FR 55246) and was effective in 2002. The Third Five-Year Review of Work RVUs was published in the CY 2007 PFS final rule with comment period (71 FR 69624) and was effective on January 1, 2007. The Fourth Five-Year Review of Work RVUs was published in the CY 2012 PFS final rule with comment period (76 FR 73026).

Initially refinements to the direct PE inputs relied on input from the AMA RUC-established the Practice Expense Advisory Committee (PEAC). Through March 2004, the PEAC provided recommendations to CMS for more than 7,600 codes (all but a few hundred of the codes included in the AMAs Current Procedural Terminology (CPT) codes). As part of the CY 2007 PFS final rule with comment period (71 FR 69624), we implemented a new bottom-up methodology for determining resource-based PE RVUs and transitioned the new methodology over a 4-year period. A comprehensive review of PE was undertaken prior to the 4-year transition period for the new PE methodology from the top-down to the bottom-up methodology, and this transition was completed in CY 2010. In CY 2010, we also incorporated the new PPIS data to update the specialty-specific PE/HR data used to develop PE RVUs, adopting a 4-year transition to PE RVUs developed using the PPIS data.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In the CY 2005 PFS final rule with comment period (69 FR 66236), we implemented the first Five-Year Review of the malpractice RVUs (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). The second Five-Year Review and update of resource-based malpractice RVUs was published in the CY 2010 PFS final rule with comment period (74 FR 61758) and was effective in CY 2010.

In addition to the Five-Year Reviews, beginning for CY 2009, CMS and the AMA RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to Section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, which requires the agency to periodically identify, review and adjust values for potentially misvalued codes with an emphasis on the following categories: (1) Codes and families of codes for which there has been the fastest growth; (2) codes or families of codes that have experienced substantial changes in PEs; (3) codes that are recently established for new technologies or services; (4) multiple codes that are frequently billed in conjunction with furnishing a single service; (5) codes with low relative values, particularly those that are often billed multiple times for a single treatment; (6) codes which have not been subject to review since the implementation of the fee schedule (the so-called 'Harvard valued codes'); and (7) other codes determined to be appropriate by the Secretary.

e. Application of Budget Neutrality to Adjustments of RVUs

Budget neutrality (BN) typically requires that expenditures not increase or decrease as a result of changes or revisions to policy. However, section 1848(c)(2)(B)(ii)(II) of the Act requires

adjustment only if the change in expenditures resulting from the annual revisions to the PFS exceeds a threshold amount. Specifically, adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have been if the adjustments were not made. In accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs would cause expenditures to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Components of the Fee Schedule Payment Amounts

To calculate the payment for each physicians' service, the components of the fee schedule (work, PE, and malpractice RVUs) are adjusted by geographic practice cost indices (GPCIs). The GPCIs reflect the relative costs of physician work, PE, and malpractice in an area compared to the national average costs for each component.

RVUs are converted to dollar amounts through the application of a CF, which is calculated by CMS' Office of the Actuary (OACT).

The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work × GPCI work) + (RVU PE × GPCI PE) + (RVU malpractice × GPCI malpractice)] × CF.

3. Most Recent Changes to the Fee Schedule

The CY 2012 PFS final rule with comment period (76 FR 73026) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2011 interim RVUs and implemented interim RVUs for new and revised codes for CY 2012 to ensure that our payment systems are updated to reflect changes in medical practice and the relative values of services. In the CY 2012 PFS final rule with comment period, we announced the following for CY 2012: the total PFS update of −27.4 percent; the initial estimate for the sustainable growth rate (SGR) of −16.9 percent; and the conversion factor (CF) of $24.6712. These figures were calculated based on the statutory provisions in effect on November 1, 2011, when the CY 2012 PFS final rule with comment period was issued.

A correction notice was issued (77 FR 227) to correct several technical and typographical errors that occurred in the CY 2012 PFS final rule with comment period.

On December 23, 2011, the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) (Pub. L. 112–78) was signed into law. Section 301 of the TPTCCA specified a zero percent update to the PFS from January 1, 2012 through February 29, 2012. As a result, the CY 2012 PFS conversion factor was revised to $34.0376 for claims with dates of service on or after January 1, 2012 through February 29, 2012. In addition, the TPTCCA extended several provisions affecting Medicare services furnished on or after January 1, 2012 through February 29, 2012, including:

- Section 303—the 1.0 floor on the physician work geographic practice cost index;
- Section 304—the exceptions process for outpatient therapy caps;
- Section 305—the payment to independent laboratories for the technical component (TC) of physician pathology services furnished to certain hospital patients, and
- Section 307—the 5 percent increase in payments for mental health services.

On February 22, 2012, the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96) (MCTRJCA) was signed into law. Section 3003 of the MCTRJCA extended the zero percent PFS update to the remainder of CY 2012. As a result of the MCTRJCA, the CY 2012 PFS CF was maintained as $34.0376 for claims with dates of service on or after March 1, 2012 through December 31, 2012. In addition:

- Section 3004 of MCTRJCA extended the 1.0 floor on the physician work geographic practice cost index through December 31, 2012;
- Section 3006 continued payment to independent laboratories for the TC of physician pathology services furnished to certain hospital patients through June 30, 2012; and
- Section 3005 extended the exceptions process for outpatient therapy caps through CY 2012 and made several other changes related to therapy claims and caps.

II. Provisions of the Final Rule for the Physician Fee Schedule

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing the service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. Section 121 of the Social Security Amendments of 1994 (Pub. L. 103–432), enacted on October 31, 1994, amended section 1848(c)(2)(C)(ii) of the Act to require us to develop a methodology for a resource-based system for determining PE RVUs for each physician's service. We develop PE RVUs by looking at the direct and indirect physician practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. In addition, we note that section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have otherwise been if the adjustments were not made. Therefore, if revisions to the RVUs cause expenditures to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We use a ''bottom-up'' approach to determine the direct PE by adding the costs of the resources (that is, the clinical staff, equipment, and supplies) typically involved with furnishing each service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are based on our review of recommendations received from the AMA RUC. For a detailed explanation of the bottom-up direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units Under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the

AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS), which was expanded (relative to the SMS) to include nonphysician practitioners (NPPs) paid under the PFS.

The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs using a consistent survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and healthcare professional groups. We believe the PPIS is the most comprehensive source of PE survey information available to date. Therefore, we used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data beginning in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we finalized a 4-year transition (75 percent old/25 percent new for CY 2010, 50 percent old/50 percent new for CY 2011, 25 percent old/75 percent new for CY 2012, and 100 percent new for CY 2013) from the previous PE RVUs to the PE RVUs developed using the new PPIS data.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

We do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend these data with Medicare-recognized specialty data. Similarly, we do not use the PPIS data for sleep medicine since there is not a full year of Medicare utilization data for that specialty given when the specialty code was created.

Supplemental survey data on independent labs, from the College of American Pathologists, were implemented for payments in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for medical oncology, independent laboratories, and IDTFs were updated to CY 2006 using the MEI to put them on a comparable basis with the PPIS data.

Previously, we have established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead use the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other for physician time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the ''All Physicians'' PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183).

There were five specialties whose utilization data were newly incorporated into ratesetting for CY 2012. In accordance with the final policies adopted in the CY 2012 final rule with comment period (76 FR 73036), we use proxy PE/HR values for these specialties by crosswalking values from other, similar specialties as follows: Speech Language Pathology from Physical Therapy; Hospice and Palliative Care from All Physicians; Geriatric Psychiatry from Psychiatry; Intensive Cardiac Rehabilitation from Cardiology, and Certified Nurse Midwife from Obstetrics/gynecology.

For CY 2013, there are two specialties whose utilization data will be newly incorporated into ratesetting. We proposed to use proxy PE/HR values for these specialties by crosswalking values from other specialties that furnish similar services as follows: Cardiac Electrophysiology from Cardiology; and Sports Medicine from Family Practice. These proposed changes are reflected in the ''PE HR'' file available on the CMS Web site under the supporting data files for the CY 2013 PFS final rule with comment period at *www.cms.gov/PhysicianFeeSched/*.

We did not receive any comments regarding our proposal to use these proxy PE/HR values for these specialties, and we continue to believe that the values crosswalked from other specialties that furnish similar services are appropriate. Therefore, we are finalizing our CY 2013 proposals to update the PE/HR data as reflected in the ''PE HR'' file available on the CMS Web site under the supporting data files for the CY 2013 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*.

As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), CY 2013 is the final year of the 4-year transition to the PE RVUs calculated using the PPIS data. Therefore, the CY 2013 PE RVUs are developed based entirely on the PPIS data, except as noted in this section.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, equipment, and supplies) typically involved with furnishing the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.A.2.b. of this final rule with comment period describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the physician work RVUs. We also incorporated the

survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is described as follows:

• For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. For example, if the direct portion of the PE RVUs for a given service was 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that furnished the service, the initial indirect allocator would be 6.00 since 2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00.

• Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 6.00 plus 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

• Next, we next incorporate the specialty-specific indirect PE/HR data into the calculation. As a relatively extreme example for the sake of simplicity, assume in our previous example that, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00. In this case, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

d. Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a hospital or facility setting, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. Because Medicare makes a separate payment to the facility for its costs of furnishing a service, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

e. Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components: a professional component (PC) and a technical component (TC), each of which may be furnished independently or by different providers, or they may be furnished together as a ''global'' service. When services have PC and TC components that can be billed separately, the payment for the global component equals the sum of the payment for the TC and PC. This is a result of using a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global components, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global components, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global under the bottom-up methodology.)

f. PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746).

(1) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data from the surveys.

(2) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service. Apply a scaling adjustment to the direct inputs.

Step 2: Calculate the current aggregate pool of direct PE costs. This is the product of the current aggregate PE (aggregate direct and indirect) RVUs, the CF, and the average direct PE percentage from the survey data.

Step 3: Calculate the aggregate pool of direct costs. This is the sum of the product of the direct costs for each service from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3 calculate a direct PE scaling adjustment so that the aggregate direct cost pool does not exceed the current aggregate direct cost pool and apply it to the direct costs from Step 1 for each service.

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors offset one another.

(3) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global components.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs, the clinical PE RVUs, and the work RVUs. For most services the indirect allocator is: indirect percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

• If the service is a global service (that is, a service with global, professional, and technical components), then the indirect allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs + work RVUs.

• If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs.

(**Note:** For global services, the indirect allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes in the examples in Table 1, the formulas were divided into two parts for each service.

• The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).

• The second part is either the work RVUs, clinical PE RVUs, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the current aggregate pool of PE RVUs by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global components, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global component.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(4) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment.

The final PE BN adjustment is calculated by comparing the results of Step 18 to the current pool of PE RVUs. This final BN adjustment is required in order to redistribute RVUs from step 18 to all PE RVUs in the PFS and because certain specialties are excluded from the PE RVU calculation for ratesetting purposes, but all specialties are included for purposes of calculating the final BN adjustment. (See ''Specialties excluded from ratesetting calculation'' later in this section.)

(5) Setup File Information

• *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain nonphysician practitioners paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthestist.
57	Individual certified prosthetist-orthotist.
58	Individuals not included in 55, 56, or 57.
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (e.g., drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
95	Competitive Acquisition Program (CAP) Vendor.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
1	Supplier of oxygen and/or oxygen related equipment.
2	Pedorthic personnel.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION—Continued

Specialty code	Specialty description
3	Medical supply company with pedorthic personnel.

In the CY 2013 PFS proposed rule, we proposed to calculate the specialty mix for low volume services (fewer than 100 billed services in the previous year) using the same methodology we used for non-low volume services. We currently use the survey data from the dominant specialty for these low volume services. We proposed to calculate a specialty mix for these services rather than use the dominant specialty in order to smooth year-to-year fluctuations in PE RVUs due to changes in the dominant specialty. However, the PE RVUs for the affected HCPCS codes were inadvertently displayed in Addendum B for the CY 2013 PFS proposed rule using our previously established methodology of using the dominant specialty for these services. While we received comments on our proposal, including some suggesting alternative methods for handling low volume services, we do not believe that it would be appropriate to make changes to the current methodology since the correct impact of the proposed calculation was not reflected in the displayed PE RVUs. We appreciate the commenters' perspective on the proposal, and will take those comments into account as we consider the best methodology for calculating the specialty mix for low volume services in future rulemaking.

• *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services, but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the physician time file is used; where it is not present, the intraoperative percentage from the payment files used by Medicare contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80, 81, 82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of physician time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPR) including the final ophthalmology and cardiovascular diagnostic services MPPR discussed in section II.B.4. of this final rule with comment period. We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the budget-neutrality calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since the average allowed charge is used when simulating RVUs and therefore includes all discounts. A time adjustment of 33 percent is made only for medical direction of two to four cases since that it is the only occasion where time units are duplicative.

Comment: One commenter expressed concern regarding the accuracy of the 33 percent time adjustment made for these services.

Response: We note that we did not make any proposals regarding the 33 percent time adjustment for medical direction in the CY 2013 PFS proposed rule. As such, we do not believe it would be appropriate to modify that

figure in this final rule. However, we would welcome any independently verifiable data that could inform the accuracy of our assumption regarding duplicative time units. The 33 percent time adjustment effectively assumes medical direction of three cases. We would consider any such data for future rulemaking.

• *Work RVUs:* The setup file contains the work RVUs from this final rule with comment period.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

*(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate)^ life of equipment)))) + maintenance)*

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.

usage = 0.5 is the standard equipment utilization assumption; 0.75 for certain expensive diagnostic imaging equipment (see 74 FR 61753 through 61755 and section II.A.3. of the CY 2011 PFS final rule with comment period).

price = price of the particular piece of equipment.

interest rate = sliding scale (see proposal below)

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

The interest rate we have previously used was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164). In the CY 2012 proposed rule (76 FR 42783), we solicited comment regarding reliable data on current prevailing loan rates for small businesses. In response to that request, the AMA RUC recommended that rather than applying the same interest rate across all equipment, CMS should consider a ''sliding scale'' approach which varies the interest rate based on the equipment cost, useful life, and SBA (Small Business Administration) maximum interest rates for different categories of loan size and maturity. The maximum interest rates for SBA loans are as follows:

• Fixed rate loans of $50,000 or more must not exceed Prime plus 2.25 percent if the maturity is less than 7 years, and Prime plus 2.75 percent if the maturity is 7 years or more.

• For loans between $25,000 and $50,000, maximum rates must not exceed Prime plus 3.25 percent if the maturity is less than 7 years, and Prime plus 3.75 percent if the maturity is 7 years or more.

• For loans of $25,000 or less, the maximum interest rate must not exceed Prime plus 4.25 percent if the maturity is less than 7 years, and Prime plus 4.75 percent, if the maturity is 7 years or more.

The current Prime rate is 3.25 percent.

Based on that recommendation, for CY 2013, we proposed to use a ''sliding scale'' approach based on the current SBA maximum interest rates for different categories of loan size (price of the equipment) and maturity (useful life of the equipment). Additionally, we proposed to update this assumption through annual PFS rulemaking to account for fluctuations in the Prime rate and/or changes to the SBA's formula to determine maximum allowed interest rates.

Comment: Both MedPAC and the AMA RUC supported the proposal. MedPAC stated:

We support CMS's proposal to use more accurate interest rate information because this will improve the accuracy of practice expense payment rates and redistribute dollars from overvalued codes to undervalued codes.

The AMA RUC commented:

The RUC appreciates that CMS intends to adopt the RUC recommendation of implementing a ''sliding scale'' for the interest rate utilized in computing equipment costs.

Other commenters, also supported the proposal. However, while physician organizations that represent specialties that provide medical equipment intensive services and medical equipment manufacturers generally acknowledged that the interest rate used in the calculation had not been updated in over 12 years, they did not support the specific proposed update approach. These commenters assertions included: The proposal is ''overly complicated'' to administer since the interest rates vary by loan size and maturity, and interest rates can fluctuate; the SBA loan program is designed to encourage loans to small businesses so the SBA rates are below market rates unrelated to the cost of capital for physician practices; the proposed methodology may be inconsistent with the statute since it does not reflect relative resources; CMS should factor in the opportunity cost for practices that pay cash for the equipment (a weighted average cost of capital (WACC) approach) using WACC measures available in the private sector; CMS should transition this policy given the investments in equipment that have already been made; CMS should use a multiyear average of the Prime rate rather than the most recent Prime rate in the calculation; and, CMS should only update the interest rate every few years to help ensure more stable practice expenses.

Response: We agree with MedPAC, the AMA RUC, and the commenters who supported our proposed approach for the interest rate calculation. Our proposed approach recognizes that the goal of the practice expense methodology is to calculate, as accurately as possible given the available data sources, the relative resources required to furnish services that are paid under the physician fee schedule. To continue to use an 11 percent interest rate assumption in the calculation of the equipment portion of the practice expense RVUs when this rate does not reflect a market rate would unnecessarily distort this relativity. We are unaware of, nor did commenters suggest, a readily available and transparent data source that specifically provides nationally representative data on the typical interest rates charged to physicians when obtaining financing for medical equipment. We believe that the use of the SBA maximum loan rates leads to a more reasonable estimate of relative resource used across the fee schedule and, consistent with the MedPAC comment, that the continued use of an 11 percent interest rate would inappropriately skew physician fee schedule relativity towards equipment intensive services.

Additionally, we disagree that the maximum SBA loan rates are not sufficient as an assumption for the rate at which a typical physician practice would obtain financing, nor did the commenters offer nationally representative data indicating that this is the case.

We agree with commenters that, in an ideal world, the interest rate assumption used in the equipment calculation would explicitly factor in the opportunity costs for practices that pay cash for the equipment (a WACC approach) and not just the cost of financing. However, as with the interest rates typically charged to physicians for medical equipment financing, we are unaware of any nationally representative data source that would provide the opportunity cost for physician practices deciding on purchasing medical equipment. Some commenters suggested we use proprietary WACC measures designed for industry and company stock valuations. We do not believe it would be appropriate to use proprietary measures in this calculation, nor do we believe that measures developed to value the stock prices of individual medical equipment companies or the medical device industry are necessarily applicable to the opportunity costs of

typical medical practices. Also, we do not agree that the opportunity cost of a physician practice purchase of medical equipment, if known or estimable, would exceed the SBA maximum loan rates.

We also do not believe that our proposal is overly complicated to administer. The Prime rate is readily available, as are the SBA loan maximums. As such, we believe our proposal is a very transparent approach. We stated that we would update the rate through our annual PFS rulemaking process. In response to comments on this aspect of our proposal, we are clarifying that we generally intend to update the interest rate calculation through future rulemaking when we broadly update one or more of the other direct practice expense inputs, such as pricing or labor wage rates, to maintain relatively between the practice expense components. Given that we do not anticipate updating the interest rate assumption every year, we do not believe it is necessary to use a rolling average in the calculation. Periodic updates using the most recent Prime rate will balance commenters' desire for stability in the PE RVUs with the need to maintain appropriate relativity under the PFS. We also do not believe a transition is appropriate in this situation. We believe it is important to update the interest rate assumptions to appropriately adjust the relativity of equipment in relation to other PE inputs and the relation of equipment intensive services to other services on the PFS.

In summary, we are finalizing without modification our proposal to use a ''sliding scale'' approach based on the current SBA maximum interest rates for different categories of loan size (price of the equipment) and maturity (useful life of the equipment). We will update the interest rate assumption through PFS rulemaking to account for fluctuations in the Prime rate and/or changes to the SBA's formula to determine maximum allowed interest rates. We are clarifying that we generally intend to update the interest rate calculation through future rulemaking only in years when we broadly update one or more of the other direct practice expense inputs. Accordingly, we anticipate updating the interest rate calculation less frequently than annually.

The effects of this policy on direct equipment inputs are reflected in the CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*. Additionally, we note that the PE RVUs included in Addendum B reflect this policy.

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TABLE 3: CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

	Step	Source	Formula	99213 Office visit, est Nonfacility	33533 CABG, arterial, single Facility	71020 Chest x-ray Nonfacility	71020-TC Chest x-ray Nonfacility	71020-26 Chest x-ray Nonfacility	93000 ECG, complete Nonfacility	93005 ECG, tracing Nonfacility	93010 ECG, report Nonfacility
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0.00	6.12	6.12	0.00
(2) Supply cost (Sup)	Step 1	AMA		2.98	0.00	3.39	3.39	0.00	1.19	1.19	0.00
(3) Equipment cost (Eqp)	Step 1	AMA		0.17	0.58	7.24	7.24	0.00	0.11	0.11	0.00
(4) Direct cost (Dir)	Step 1		'=(1)+(2)+(3)	16.48	78.1	16.38	16.38	0.00	7.42	7.42	0.00
(5) Direct adjustment (Dir. Adj.)	Steps 2-4	See footnote*		0.5989	0.5989	0.5989	0.5989	0.5989	0.5989	0.5989	0.5989
(6) Adjusted Labor	Steps 2-4	=Labor * Dir Adj	=(1)*(5)	7.98	46.43	3.44	3.44	0.00	3.67	3.67	0
(7) Adjusted Supplies	Steps 2-4	=Eqp * Dir Adj	=(2)*(5)	1.79	0.00	2.03	2.03	0.00	0.72	0.72	0
(8) Adjusted Equipment	Steps 2-4	=Sup * Dir Adj	=(3)*(5)	0.1	0.35	4.34	4.34	0.00	0.06	0.06	0
(9) Adjusted Direct	Steps 2-4		=(6)+(7)+(8)	9.87	46.78	9.81	9.81	0.00	4.44	4.44	0
(10) Conversion Factor (CF)	Step 5	PFS		34.0376	34.0376	34.0376	34.0376	34.0376	34.0376	34.0376	34.0376
(11) Adj. labor cost converted	Step 5	=(Lab * Dir Adj)/CF	=(6)/(10)	0.23	1.36	0.1	0.1	0.00	0.11	0.11	0.00
(12) Adj. supply cost converted	Step 5	=(Sup * Dir Adj)/CF	=(7)/(10)	0.05	0	0.06	0.06	0.00	0.02	0.02	0.00

	Step	Source	Formula	99213 Office visit, est Nonfacility	33533 CABG, arterial, single Facility	71020 Chest x-ray Nonfacility	71020-TC Chest x-ray Nonfacility	71020-26 Chest x-ray Nonfacility	93000 ECG, complete Nonfacility	93005 ECG, tracing Nonfacility	93010 ECG, report Nonfacility
(13) Adj. equipment cost converted	**Step 5**	**=(Eqp * Dir Adj)/CF**	**=(8)/(10)**	0.00	0.01	0.13	0.13	0.00	0.00	0.00	0.00
(14) Adj. direct cost converted	**Step 5**		**=(11)+(12)+(13)**	0.29	1.37	0.29	0.29	0.00	0.13	0.13	0.00
(15) Work RVU	**Setup File**	**PFS**		0.97	33.75	0.22	0.00	0.22	0.17	0.00	0.17
(16) Dir_pct	**Steps 6,7**	**Surveys**		0.31	0.18	0.31	0.31	0.31	0.31	0.31	0.31
(17) Ind_pct	**Steps 6,7**	**Surveys**		0.69	0.82	0.69	0.69	0.69	0.69	0.69	0.69
(18) Ind. Alloc. Formula (1st part)	**Step 8**	**See Step 8**		((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)
(19) Ind. Alloc.(1st part)	**Step 8**		**See 18**	0.87	6.43	0.71	0.71	0.00	0.32	0.32	0.00
(20) Ind. Alloc. Formula (2nd part)	**Step 8**	**See Step 8**		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)
(21) Ind. Alloc.(2nd part)	**Step 8**		**See 20**	0.97	33.75	0.32	0.10	0.22	0.28	0.11	0.17
(22) Indirect Allocator (1st + 2nd)	**Step 8**		**=(19)+(21)**	1.84	40.18	1.03	0.81	0.22	0.60	0.43	0.17

	Step	Source	Formula	99213 Office visit, est Nonfacility	33533 CABG, arterial, single Facility	71020 Chest x-ray Nonfacility	71020-TC Chest x-ray Nonfacility	71020-26 Chest x-ray Nonfacility	93000 ECG, complete Nonfacility	93005 ECG, tracing Nonfacility	93010 ECG, report Nonfacility
(23) Indirect Adjustment (Ind. Adj.)	**Steps 9-11**	**See Footnote****		0.4037	0.4037	0.4037	0.4037	0.4037	0.4037	0.4037	0.4037
(24) Adjusted Indirect Allocator	**Steps 9-11**	**=Ind Alloc * Ind Adj**		0.74	16.22	0.42	0.33	0.09	0.24	0.17	0.07
(25) Ind. Practice Cost Index (IPCI)	**Steps 12-16**			1.08	0.79	0.93	0.93	0.93	0.92	0.92	0.92
(26) Adjusted Indirect	**Step 17**	**= Adj.Ind Alloc * PCI**	**=(24)*(25)**	0.81	12.76	0.39	0.3	0.08	0.22	0.16	0.06
(27) PE RVU	**Step 18**	**=(Adj Dir + Adj Ind) * budn**	**=((14)+(26)) * budn**	1.09	14.12	0.67	0.59	0.08	0.35	0.29	0.06

Note: PE RVUs in table 2, row 28, may not match Addendum B due to rounding. * The direct adj = [current pe rvus * CF * avg dir pct]/[sum direct inputs] = [Step 2]/[Step 3]** The indirect adj = [current pe rvus * avg ind pct]/[sum of ind allocators] = [Step 9]/[Step 10]

Note: The use of any particular conversion factor (CF) in Table 3 to illustrate the PE calculation has no effect on the resulting RVUs.

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3. Changes to Direct PE Inputs for Specific Services

In this section, we discuss other specific CY 2013 proposals and changes related to direct PE inputs for specific services. The changes we proposed and are finalizing are included in the final rule CY 2012 direct PE database, which is available on the CMS Web site under the supporting data files for the CY 2012 PFS final rule with comment period at *www.cms.gov/PhysicianFeeSched/*. We note that we address comments on the interim direct PE inputs established in the CY 2012 PFS final rule with comment period in section II.M. of this final rule with comment period.

a. Equipment Minutes for Interrogation Device Evaluation Services

It has come to our attention that the pacemaker follow-up system (EQ138) associated with two interrogation device management service codes does not have minutes allocated in the direct PE input database. Based on our analysis of these services, we believed that 10 minutes should be allocated to the equipment for each of the following CPT codes: 93294 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system with interim physician analysis, review(s) and report(s)), and 93295 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable cardioverter-defibrillator system with interim physician analysis, review(s) and report(s)). Therefore, the direct PE input database was modified to allocate 10 minutes to the pacemaker follow-up system for CPT codes 93294 and 93295.

Comment: One commenter expressed support for this modification.

Response: We appreciate the support for the modification and will maintain the allocated equipment minutes in the final direct PE input database.

b. Clinical Labor for Pulmonary Rehabilitation Services (HCPCS Code G0424)

It has come to our attention that the direct PE input database includes 15 minutes of clinical labor time in the nonfacility setting allocated for a CORF social worker/psychologist (L045C) associated with HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day). Based on our analysis of this service, we believed that these 15 minutes should be added to the 15 minutes currently allocated to the Respiratory Therapist (L042B) associated with this service. Therefore, we proposed to modify the direct PE input database to allocate 15 additional minutes to the Respiratory Therapist (L042B) (for a total of 30 minutes) and to delete the CORF social worker/psychologist (L045C) associated with HCPCS code G0424.

Comment: One commenter supported the modification as accurate and fair. Another commenter suggested that the appropriate clinical staff time for the code should be 60 minutes since the code describes an hour long session. Furthermore, the same commenter expressed opposition to reassigning the 15 minutes to the Respiratory Therapist because the rate per minute of the Respiratory Therapist is lower than the rate per minute of the CORF social worker/psychologist and the change, however modest, may potentially reduce the PE RVUs for the service.

Response: We appreciate the support for the modification and understand the commenter's concerns. We recognize that for many services with code descriptors that include procedure time assumptions, the number of clinical labor minutes allocated during the service period corresponds to the time as described by the code. However, as we explained in the CY 2011 PFS final rule with comment period (75 FR 73299), because pulmonary rehabilitation services reported under HCPCS code G0424 can be furnished either individually or in groups, we believe that 30 minutes of respiratory therapist time would be more appropriate for valuing the typical pulmonary rehabilitation service. We also recognize that reclassifying the direct PE input labor category from CORF social worker/psychologist to Respiratory Therapist for 15 minutes will reduce the direct labor costs used in calculating PE RVUs for the service. However, we continue to believe that the Respiratory Therapist is the most appropriate labor category to include as a direct PE input for this service.

After consideration of the comments we received, we are finalizing the modification of the direct PE labor inputs for this service to allocate 15 additional minutes to the Respiratory Therapist (L042B) (for a total of 30 minutes) and to delete the CORF social worker/psychologist (L045C) associated with HCPCS code G0424.

c. Transcranial Magnetic Stimulation Services

For CY 2011, the CPT Editorial Panel converted Category III CPT codes 0160T and 0161T to Category I status (CPT codes 90867 (Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management), and 90868 (Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session)), which were contractor priced on the PFS. For CY 2012, the CPT Editorial Panel modified CPT codes 90867 and 90868, and created CPT code 90869 ((Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management.) In the CY 2012 PFS final rule with comment period, we established interim final values based on refinement of RUC-recommended work RVUs, direct PE inputs, and malpractice risk factor crosswalks for these services (76 FR 73201).

Subsequent to the development of interim final PE RVUs, it came to our attention that the application of our usual PE methodology resulted in anomalous PE values for these services. As we explain in section II.A.2.c.2 of this final rule with comment period, for a given service, we use the direct costs associated with a service (clinical staff, equipment, and supplies) and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator.

For services almost exclusively furnished by one specialty, the average percentage of indirect costs relative to direct costs would ordinarily be used to determine the initial indirect allocator. For specialties that typically incur significant direct costs relative to indirect costs, the initial indirect allocator for their services is generally lower than for the specialties that typically incur lower direct costs relative to indirect costs. Relative to direct costs, the methodology generally allocates a greater proportion of indirect PE to services furnished by psychiatrists, for example, than to services furnished by specialties that typically incur significant direct costs, such as radiation oncologists. In the case of TMS, however, the direct costs incurred by psychiatrists reporting the codes far exceed the direct costs typical to any other service predominantly furnished by psychiatrists. This drastic difference in the direct costs of TMS relative to most other services furnished by psychiatrists, results in anomalous PE values since code-level indirect PE allocation relies on typical resource costs for the specialties that furnish the service. In other words, the amount of indirect PE allocated to TMS services is

based on the proportion of indirect expense to direct expense that is typical of other psychiatric services, and is not on par with other services that require similar investments in capital equipment and high-cost, disposable supplies.

Historically, we have contractor-priced (meaning our claims processing contractors develop payment rates) for services with resource costs that cannot be appropriately valued within the generally applicable PE methodology used to price services across the PFS. Because there is no mechanism to develop appropriate payment rates for these services within our current methodology, we proposed to contractor price these codes for CY 2013.

Comment: One commenter objected to the proposal to contractor price these codes for CY 2013 and suggested that CMS should establish PE RVUs using the generally applicable PE methodology and must endeavor in ensuing rulemaking to revise the methodology to refine any values the agency views as ''anomalous.'' The commenter also questioned CMS's assumption that the direct costs for psychiatrists who furnish these services ''far exceed'' the direct costs for psychiatrists who do not furnish these services. The commenter stated that CMS made this assessment without any empirical support and that CMS needs to conduct a survey or obtain other data from psychiatrists before drawing any conclusions regarding the appropriateness of Medicare payment rates on this basis.

Response: We understand the commenter's objections, but as we explained in the proposal, we do not believe that there is a mechanism within the current methodology that allows us to develop appropriate payment rates for these services. We agree with the commenter that it may be appropriate to consider potential changes to the practice expense methodology to accommodate changing circumstances of medical practice. We do not agree with the commenter, however, that we have no means to pay appropriately for services when we recognize areas where the practice expense methodology is inadequate and that we must establish national RVUs based on that methodology, even when it does not accommodate the unique circumstances of particular services. Instead, we believe that in outlier cases, contractor pricing allows Medicare to pay more appropriately for particular services furnished to beneficiaries.

In our proposal, we pointed out that the direct costs incurred by psychiatrists reporting the codes far exceed the direct costs typical to any other service predominantly furnished by psychiatrists. The commenter objected to this assertion and claimed it was made without any empirical support. We made that assertion based on comparing the direct practice expense input costs for transcranial magnetic stimulation services and the current direct practice expense input costs in the direct PE database for services predominantly furnished by the specialty based on Medicare claims data. In our examination of 20 frequently billed psychiatry services (where greater than half of the Medicare allowed services were reported by psychiatrists), the total direct costs (clinical labor, disposable medical supplies, or medical equipment) in the direct PE input database summed to under $10 for all but 3 of these 20 services. Examples of these services include CPT codes 90807 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services), 90862 (Pharmacologic management, including prescription, use, and review of medication with no more than minimal medical psychotherapy), and 90845 (Psychoanalysis). For the three where the direct PE input costs summed to greater than $10, HCPCS code M0064 (Brief office visit for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental psychoneurotic and personality disorders), and CPT codes 90865 (Narcosynthesis for psychiatric diagnostic and therapeutic purposes (eg, sodium amobarbital (Amytal) interview)), and 90870 (Electroconvulsive therapy (includes necessary monitoring)), the service with the highest direct cost sum was $32.24. In contrast, the transcranial magnetic stimulation services treatment delivery (CPT code 90867) included direct PE inputs that summed to direct costs of $145.19. The disparity between the TMS direct costs and the direct costs in other frequent psychiatry codes was the basis for our assertion that the direct costs for this service far exceeded the direct costs typical to any other service predominantly furnished by psychiatrists. Thus, we continue to believe our decision to contractor price these codes is the proper one.

Comment: Another commenter requested that CMS use the existing methodology to price the codes or contractor price the codes. This commenter also urged CMS to consider alternate sources of data for resource costs as they become available, or to make appropriate future refinements to the practice expense methodology.

Response: We appreciate the commenter's support for our proposal as a suitable means of pricing the services. We will consider appropriate means to develop national prices for these services in the context of potential changes to the practice expense methodology and the availability of new data sources.

After consideration of these public comments, we are finalizing our proposal to contractor price CPT codes 90867, 90868, and 90869 for CY 2013.

d. Spinal Cord Stimulation Trial Procedures in the Nonfacility Setting

Stakeholders have recently brought to our attention that CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural) is frequently furnished in the physician office setting but is not priced in that setting. We note that the valuation of a service under the PFS in particular settings does not address whether those services are medically reasonable and necessary in the case of individual patients, including being furnished in a setting appropriate to the patient's medical needs and condition. However, because these services are being furnished in the nonfacility setting, we believed that CPT code 63650 should be reviewed to establish appropriate nonfacility inputs. We proposed to review CPT code 63650 and requested recommendations from the AMA RUC and other public commenters on the appropriate physician work RVUs (as measured by time and intensity), and facility and nonfacility direct PE inputs for this service. We understand that disposable leads comprise a significant resource cost for this service and are currently separately reportable to Medicare for payment purposes when the service is furnished in the physician office setting. Disposable medical supplies are not considered prosthetic devices paid under the Durable Medical Equipment, Prosthetic/Orthotic, and Supplies (DMEPOS) fee schedule and generally are incorporated as nonfacility direct PE inputs to PE RVUs. We sought comment on establishing nonfacililty PE RVUs for CPT code 63650.

Comment: Several commenters expressed concerns regarding the possibility of establishing nonfacility PE RVUs for this service based on the assumption that the nonfacility PFS payment rate would be lower than the rate paid by the Medicare hospital outpatient prospective payment system

(OPPS). These commenters stated that the supply, personnel, and administration costs are higher in the non-facility setting than in the facility setting and that current Medicare payment for L8680 under the DMEPOS fee schedule offsets the difference in costs between the facility and nonfacility setting. Many of these commenters also stated that it is more cost effective for the Medicare program for these services to be furnished in the nonfacility setting. These commenters also stated that it is more convenient for patients to receive this service in the nonfacility setting, so that Medicare should not implement nonfacility payment rates because doing so might discourage practitioners from furnishing the service in the nonfacility setting.

Response: We understand the commenters' interest in ensuring that Medicare beneficiaries retain access to the service in the nonfacility setting. We do not agree with the commenters' underlying assumption that developing accurate payment rates for the service in the nonfacility setting will necessarily deter practitioners from furnishing the service to Medicare beneficiaries outside the facility setting. Additionally, we do not know how to reconcile the contradictory contentions of many individual commenters that the costs of furnishing the services in the nonfacility setting are greater so that payment rates should be higher, but furnishing services there would still be more cost effective for Medicare.

Comment: One commenter supported the proposal to create nonfacility RVUs for this service since it would reduce overutilization of the service and lower the likelihood of fraud.

Response: We appreciate the support for the proposal, and we generally agree that developing accurate payment rates encourages appropriate utilization.

Comment: One commenter stated that CMS should continue to provide payment for HCPCS code L8680 until non-facility PE inputs for CPT code 63650 including the leads have been developed.

Response: We appreciate the commenter's concerns. We would continue a mechanism to provide payment for the disposable leads used in furnishing the service while we develop non-facility PE inputs. We also agree that once a practice expense payment reflects these disposable leads, that a separate payment mechanism would no longer be necessary.

Comment: The AMA RUC agreed that the direct practice expense inputs for the service should be reviewed to establish appropriate inputs in both the facility and nonfacility setting.

After consideration of the comments we received regarding our proposal to establish nonfacility PE RVUs for CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural), we continue to believe that it would be appropriate to do so since these services are being furnished in the nonfacility setting. The AMA RUC expects to review the direct PE inputs for this service during CY 2013. We anticipate receiving recommendations from the AMA RUC for the CY 2014 PFS, and we request comments from other stakeholders regarding the appropriate direct PE inputs for this service

B. Potentially Misvalued Codes Under the Physician Fee Schedule

1. Valuing Services Under the PFS

To value services under the PFS, section 1848(c) of the Act requires the Secretary to determine relative values for physicians' services based on three components: work; practice expense (PE); and malpractice. Section 1848(c)(1)(A) of the Act defines the work component to include ''the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service.'' In addition, section 1848(c)(2)(C)(i) of the Act specifies that ''the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service.''

As discussed in detail in sections II.B.1.b. and II.B.1.c. of this final rule with comment period, the statute also defines the PE and malpractice components and provides specific guidance in the calculation of the RVUs for each of these components. Section 1848(c)(1)(B) of the Act defines the PE component as ''the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.'' Section 1848(c)(1)(C) of the Act defines the malpractice component as ''the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service.'' Clause (ii) and clause (iii) of section 1848 (c)(2)(C) of the Act specify that PE and malpractice expense RVUs shall be determined based on the relative PE/malpractice expense resources involved in furnishing the service.

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. On March 23, 2010, the Affordable Care Act was enacted, further requiring the Secretary to periodically identify and review potentially misvalued codes and make appropriate adjustments to the relative values of those services identified as being potentially misvalued. Section 1848(c)(2)(K) to the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, identified using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section I.B.1.a. of this final rule with comment period, each year we develop and propose appropriate adjustments to the RVUs, taking into account the recommendations provided by the American Medical Association Specialty Society Relative Value Scale Update Committee (AMA RUC), the Medicare Payment Advisory Commission (MedPAC), and others. For many years, the AMA RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with the recommendations of other public commenters, and with analyses of data sources, such as claims data, to inform the decision-making process as authorized by the law. We may also consider analyses of physician time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting Initiative (PQRI) databases. In addition to considering the most recently available data, we also assess the results of physician surveys and specialty recommendations submitted to us by the AMA RUC. We conduct a clinical review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available, in addition to taking into account the

results of consultations with organizations representing physicians. In accordance with section 1848(c) of the Act, we determine appropriate adjustments to the RVUs, explain the basis of these adjustments, and respond to public comments in the PFS proposed and final rules.

2. Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Services on the PFS

a. Background

In its March 2006 Report to the Congress, MedPAC noted that ''misvalued services can distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services.'' In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time for a number of reasons: For example, MedPAC stated, ''when a new service is added to the PFS, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' That is, the amount of physician work needed to furnish an existing service may decrease as physicians build experience furnishing that service. Services can also become overvalued when PEs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PEs rise. In the ensuing years since MedPAC's 2006 report, additional groups of potentially misvalued services have been identified by the Congress, CMS, MedPAC, the AMA RUC, and other stakeholders.

In recent years, CMS and the AMA RUC have taken increasingly significant steps to address potentially misvalued codes. As MedPAC noted in its March 2009 Report to Congress, in the intervening years since MedPAC made the initial recommendations, ''CMS and the AMA RUC have taken several steps to improve the review process.'' Most recently, section 1848(c)(2)(K)(ii) of the Act directed the Secretary to specifically examine, as determined appropriate, potentially misvalued services in seven categories as follows:

- Codes and families of codes for which there has been the fastest growth;
- Codes and families of codes that have experienced substantial changes in PEs;
- Codes that are recently established for new technologies or services;
- Multiple codes that are frequently billed in conjunction with furnishing a single service;
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment;
- Codes which have not been subject to review since the implementation of the PFS (the so-called 'Harvard-valued codes'); and
- Other codes determined to be appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Finally, section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) which may include consolidation of individual services into bundled codes for payment under the PFS.

In addition to these requirements, section 3003(b)(1) of the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA) (Pub. L. 112–96), requires that the Secretary conduct a study that examines options for bundled or episode-based payment to cover physicians' services currently paid under the PFS under section 1848 of the Act for one or more prevalent chronic conditions or episodes of care for one or more major procedures. In conducting the study, the Secretary shall consult with medical professional societies and other relevant stakeholders. Additionally, the study shall include an examination of related private payer payment initiatives. This section also requires that not later than January 1, 2013, the Secretary submit to certain committees of the Congress a report on the study. The report shall include recommendations on suitable alternative payment options for services paid under the PFS and on associated implementation requirements.

Bundling is one method for aligning incentives for hospitals, post-acute care providers, physicians, and other practitioners to partner closely across all specialties and settings that a patient may encounter to improve the patient's experience of care. The typical goals of developing an effective bundled payment system are to improve quality, reduce costs, and promote efficiency. Current work on bundling services paid under the PFS to date has been limited to targeting specific codes and sets of codes and repackaging those codes into ''bundles.'' As detailed above, through the potentially misvalued codes initiative we are currently identifying for review codes that are frequently billed together and codes with low relative values billed in multiples. Many of the codes identified through these screens have been referred to the CPT Editorial Panel for the development of a comprehensive or bundled code, and several bundled codes have already been created and valued. However, we believe that we now need to move beyond this ''repackaging'' of codes and examine the potential of a larger bundled payment within the PFS. In response to section 3003(b)(1) of the MCTRJCA, we have consulted with medical professional societies, private payers, healthcare system administrators, and other stakeholders; met with other CMS staff involved in other bundling initiatives; and performed an extensive literature review. Additionally, we have had representatives of specialty groups such as radiation oncologists volunteer to work with us to create a bundled payment for their services. If we were to engage in a bundling project for radiation therapy, we would want to do more than provide a single episode payment for the normal course of radiation therapy that aggregates the sum of the individual treatments. Radiation therapy has many common side effects that can vary based on the type of cancer the patient has and how it is being treated. Common side effects associated with radiation therapy include fatigue, skin problems, eating problems, blood count changes, emotional issues such as depression, etc* * * If we were to engage in a bundling project that includes radiation therapy, we would be interested in exploring whether it could also include treating and managing the side effects

that result from radiation therapy in addition to the radiation therapy itself. Such an episode-based payment would allow Medicare to pay for the full course of the typical radiation therapy as well as the many medical services the patient may be receiving to treat side effects.

We will continue to examine options for bundled or episode-based payments and will include our recommendations and implementation options in our report to the Congress. Following completion of this report, we will look forward with interest to the view of stakeholders that are interested in testing some of these concepts within the PFS.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

In accordance with our statutory mandate, we have identified and reviewed numerous potentially misvalued codes in all seven of the categories specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes in these areas over the upcoming years. In the current process, we identify potentially misvalued codes for review, and request recommendations from the AMA RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The AMA RUC, through its own processes, identifies potentially misvalued codes for review, and through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review processes, we have reviewed over 1,000 potentially misvalued codes to refine work RVUs and direct PE inputs. We have adopted appropriate work RVUs and direct PE inputs for these services as a result of these reviews.

Our prior reviews of codes under the potentially misvalued codes initiative have included codes in all seven categories specified in section 1848(c)(2)(K)(ii) of the Act, listed above. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055).

In the CY 2012 final rule with comment period, under the potentially misvalued codes category of ''Other codes determined to be appropriate by the Secretary,'' we finalized our proposal to review a list of the highest PFS expenditure services, by specialty, that had not been recently reviewed (76 FR 73059 through 73068). In the CY 2012 final rule with comment period we also finalized policy to consolidate the periodic reviews of physician work and PE at the same time (76 FR 73055 through 73958), and established a process for the annual public nomination of potentially misvalued services to replace the Five-Year review process (76 FR 73058 through 73059). Below we discuss the CY 2013 PFS proposals that support our continuing efforts to appropriately identify, review, and adjust values for potentially misvalued codes.

c. Validating RVUs of Potentially Misvalued Codes

In addition to identifying and reviewing potentially misvalued codes, section 1848(c)(2)(L) of the Act specifies that the Secretary shall establish a formal process to validate RVUs under the PFS. The validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may also include validation of the pre-, post-, and intra-service time components of work. The Secretary is directed, as part of the validation, to validate a sampling of the work RVUs of codes identified through any of the seven categories of potentially misvalued codes specified by section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. A summary of the comments along with our responses are included in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (77 FR 73054 through 73055). In September 2012 we entered into two contracts to assist us in validating RVUs of potentially misvalued codes; the implementation details for these contracts are currently under development. Contractors will explore models for the validation of physician work under the PFS, both for new and existing services. We plan to discuss these models further in future rulemaking.

d. Improving the Valuation of the Global Surgical Package

(1) Background

We applied the concept of payment for a global surgical package under the PFS at its inception on January 1, 1992 (56 FR 59502). For each global surgical procedure, we establish a single payment, which includes payment for a package of all related services typically furnished by the surgeon furnishing the procedure during the global period. Each global surgery is paid on the PFS as a single global surgical package. Each global surgical package payment rate is based on the work necessary for the typical surgery and related pre- and post-operative work. The global period may include 0, 10, or 90 days of post-operative care, depending on the procedure. For major procedures, those with a 90-day global period, the global surgical package payment also includes services typically furnished the day prior to the day of surgery.

Some global surgical packages have been valued by adding the RVU of the surgical procedure and all pre- and post-operative evaluation and management (E/M) services included in the global period. Others have been valued using magnitude estimation, in which case the overall RVU for the surgical package was determined without factoring in the specific RVUs associated with the E/M services in the global period. The number and level of E/M services identified with a global surgery payment are based on the typical case. Even though a surgical package may have been developed with several E/M services included, a physician is not required to furnish each pre- or post-operative visit to bill for the global surgical package.

Similar to other bundled services on the PFS, when a global surgery code is billed, the bundled pre- and post-operative care is not separately payable; surgeons or other physicians billing a surgical procedure, cannot separately bill for the E/M services that are included in the global surgical package.

(2) Measuring Post-Operative Work

The use of different methodologies for valuing global surgical packages since 1992 has created payment rates that reflect a wide range of E/M services within the post-operative period. This is especially true among those with 90-day global periods. More recently reviewed codes tend to have fewer E/M services in the global period, and the work RVUs of those E/M services are often

accounted for in the value for the global surgical package. The values of global surgical packages reviewed less recently frequently do not appear to include the full work RVUs of each E/M service in the global surgical package, and the numbers of E/M services included in the post-operative period can be inconsistent within a family of procedures.

In 2005, the HHS Office of Inspector General (OIG) examined whether global surgical packages are appropriately valued. In its report on eye and ocular surgeries, ''National Review of Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005'' (A–05–07–00077), the OIG reviewed a sample of 300 eye and ocular surgeries, and counted the actual number of face-to-face services in the surgeons' medical records to establish whether the surgeon furnished post-operative E/M services. The OIG findings show that surgeons typically furnished fewer E/M services in the post-operative period than were identified with the global surgical package payment for each procedure. A smaller percentage of surgeons furnished more E/M services than were identified with the global surgical package payment. The OIG could only review the number of face-to-face services and was not able to review the level of the E/M services that the surgeons furnished due to a lack of documentation in surgeons' medical records. The OIG concluded that the RVUs for the global surgical package are too high because they include the work of E/M services that are not typically furnished within the global period for the reviewed procedures.

Following the 2005 report, the OIG continued to investigate E/M services furnished during the global surgical period. In May 2012, the OIG published a report titled ''Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided'' (A–05–09–00053). For this investigation, the OIG sampled 300 musculoskeletal global surgeries and again found that, for the majority of sampled surgeries, physicians furnished fewer E/M services than were identified as part of the global period for that service. Once again, a smaller percentage of surgeons furnished more E/M services than were identified with the global surgical package payment. The OIG concluded that the RVUs for the global surgical package are too high because they include the work of E/M services that are not typically furnished within the global period for the reviewed procedures.

In both reports, the OIG recommended that we adjust the number of E/M services identified with the global surgical payments to reflect the number of E/M services that are actually being furnished. Under the PFS, we do not ask surgeons to detail the component bundled services on their claim when billing for the global surgical package as we do providers furnishing bundled services under other Medicare payment systems. Since it is not necessary for a surgeon to identify the level or CPT code of the E/M services actually furnished during the global period, there is very limited documentation on the frequency or level of post-operative services. Without sufficient documentation, a review of the medical record cannot accurately determine the number or level of E/M services furnished in the post-operative period. This is an area of concern, and is discussed in more detail later in this section.

As noted above, section 1848(c)(2)(K) of the Act, which codified and expanded the potentially misvalued codes initiative that CMS had begun, requires that the Secretary identify and review potentially misvalued services with an emphasis on several categories, and recognizes the Secretary's discretion to identify additional potentially misvalued codes. Several of the categories of potentially misvalued codes support better valuation of global surgical package codes. We have made efforts to prioritize the review of RVUs for services on the PFS that have not been reviewed recently or for services where there is a potential for misuse. One of the priority categories for review of potentially misvalued codes is services that have not been subject to review since the implementation of the PFS (the so-called ''Harvard-valued codes''). In the CY 2009 PFS proposed rule, we requested that the AMA RUC engage in an ongoing effort to review the remaining Harvard-valued codes, focusing first on the high-volume codes (73 FR 38589). For the Fourth Five-Year Review (76 FR 32410), we requested that the AMA RUC review services that have not been reviewed since the original implementation of the PFS with utilization greater than 30,000 (Harvard-valued—Utilization > 30,000). In the CY 2013 PFS proposed rule, we proposed to review Harvard-valued services with annual allowed charges that totaled at least $10,000,000 (Harvard-valued—Allowed charges ≥$10,000,000), and requested recommendations from the AMA RUC and other public commenters on appropriate values for these services (77 FR 44741).

Of the more than 1,000 identified potentially misvalued codes, just over 650 are surgical services with a global period of 0, 10, or 90 days. We have completed our review of 450 of these potentially misvalued surgical codes. As we stated in the CY 2013 PFS proposed rule, these efforts are important, but we believe the usual review process does not go far enough to assess whether the valuation of global surgical packages reflects the number and level of post-operative services that are typically furnished. To support our statutory obligation to identify and review potentially misvalued services and to respond to the OIG's concern that global surgical package payments are misvalued, we believe that we should gather more information on the E/M services that are typically furnished with surgical procedures. Information regarding the typical work involved in surgical procedures with a global period is necessary to evaluate whether certain surgical procedures are appropriately valued. While the AMA RUC reviews and recommends RVUs for services on the PFS, we complete our own assessment of those recommendations, and may adopt different RVUs. However, for procedures with a global period, the lack of detail in claims data and documentation restrict our ability to review and assess the appropriateness of their RVUs.

In the CY 2013 proposed rule, we requested comments on methods of obtaining accurate and current data on E/M services furnished as part of a global surgical package. We stated that we were especially interested in and invited comments on a claims-based data collection approach that would include reporting E/M services furnished as part of a global surgical package, as well as other valid, reliable, generalizable, and robust data to help us identify the number and level of E/M services typically furnished in the global surgical period for specific procedures.

The following is summary of the comments we received regarding the methods of obtaining accurate and current data on E/M services furnished as part of a global surgical package proposal.

Comment: Several commenters stated that the global payment methodology has restricted CMS' ability to audit the accuracy of the current value of services as well as the accuracy of the AMA RUC recommendations for services with a global period. Many commenters offered recommendations on how CMS could validate the current global surgical packages or obtain accurate and current data on E/M services furnished as a part

of the global surgical package. Some commenters recommended that CMS establish auditable documentation requirements for inpatient and outpatient post-operative visits, and many believed that these auditable post-operative visit notes should follow E/M documentation guidelines. Other commenters suggested that CMS adjust all surgical services to a 0-day global period, require surgeons to bill post-operative E/M services separately for payment purposes, and subject those billings to the same coding and documentation standards and audits to which other practitioners are already subject. Several commenters noted that CMS could validate the global surgical packages with the hospital Diagnosis-Related Group (DRG) length of stay data, and that CMS could explore the use of surgical specialties' registries to collect data on services furnished within the global period. Commenters also suggested that CMS could draw upon the OIG's approach and review the medical record for a statistically valid sample of claims and then extrapolate those results to clinically similar families of codes. One commenter suggested that CMS could establish G-codes through which a large sample of surgeons might report the number and intensity of post-operative visits.

In response to our request for comments on methods of obtaining accurate and current data on E/M services furnished as part of a global surgical package, some commenters stated that they believe post-operative work is appropriately surveyed, vetted and valued by the AMA RUC during its ongoing reviews of surgical procedures, and therefore, claims-based reporting is unnecessary in order to verify that the number of visits assigned to global surgical procedures is accurate. Some commenters stated that if CMS has concerns with a specific code, or group of codes, regarding the number of E/M visits valued within the physician work RVU, CMS should work with the AMA RUC to review these services. One commenter noted that there are 4,258 CPT codes on the PFS with a global period, but that only 271 of these CPT codes are billed more than 10,000 times annually, and most of the 271 CPT codes have been reviewed by CMS and the AMA RUC since 2005.

Response: We thank the commenters for their recommendations on this important issue. We will carefully weigh all comments received as we consider how best to measure the number and level of visits that occur during the global period.

In addition to the broader comments on measuring post-operative work, we also received a comment from the AMA RUC noting that the hospital and discharge management services included in the global period for many surgical procedures may have been inadvertently removed from the time file in 2007. With its comment letter, the AMA RUC sent us a revised time file with updated post-operative visits for the services that may be incorrectly displayed with zero visits. We are reviewing this file, and if appropriate, we intend to propose modifications to the physician time file in the CY 2014 PFS proposed rule. We note that should time have been removed from the physician time file inadvertently, it would not have affected the physician work RVUs or direct practice expense inputs for these services. It would have a small impact on the indirect allocation of practice expense at the specialty level, which we will review when we explore this potential time file change.

3. CY 2013 Identification and Review of Potentially Misvalued Services

a. Public Nomination of Potentially Misvalued Codes

In the CY 2012 PFS final rule, we finalized a public nomination process for potentially misvalued codes (76 FR 73058). Under the previous Five-Year Reviews for PE and work, we invited the public to nominate potentially misvalued codes for review. To allow for public input and to preserve the public's ability to identify and nominate potentially misvalued codes for review under our annual potentially misvalued codes initiative, we established a process by which the public can submit codes, along with documentation supporting the need for review, on an annual basis. Stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation during the 60-day public comment period following the release of the annual PFS final rule with comment period. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in the peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: technique; knowledge and technology; patient population; site-of-service; length of hospital stay; and physician time.
- Evidence of an anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work, that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of physician time, work RVU, or direct PE inputs using other data sources (for example, Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting System (PQRS) databases).
- National surveys of physician time and intensity from professional and management societies and organizations, such as hospital associations.

Under this newly established process, after we receive the nominated codes during the 60-day comment period following the release of the annual PFS final rule with comment period, we evaluate the supporting documentation and assess whether the submitted codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes, and propose -which nominated codes will be reviewed as potentially misvalued. We encourage the public to submit nominations for potentially misvalued codes in the 60-day comment period following the publication of this CY 2013 PFS final rule with comment period.

TABLE 4—CPT CODES NOMINATED AS POTENTIALLY MISVALUED FOR CY 2013 RULEMAKING

CPT Code	Short descriptor	CMS Action
33282	Implant pat-active ht record	Establish nonfacility inputs, and review the work, facility and nonfacility inputs together. Not considered a potentially misvalued code.
33284	Remove pat-active ht record	Establish nonfacility inputs, and review the work, facility and nonfacility inputs together. Not considered a potentially misvalued code.
36819	Av fuse uppr arm basilic	Review as a potentially misvalued code.
36825	Artery-vein autograft	Review as a potentially misvalued code.
53445	Insert uro/ves nck sphincter	Interim Final in CY 2012, Final for CY 2013. Comments addressed in section II.M.2.a. of this CY 2013 PFS final rule with comment period.
77336	Radiation physics consult	Review as a potentially misvalued code.
94762	Measure blood oxygen level	Adopt direct PE revisions discussed below on an interim final basis for CY 2013.
28820	Amputation of toe	Last reviewed for CY 2012. No further review required at this time.
28825	Partial amputation of toe	Last reviewed for CY 2012. No further review required at this time.
35188	Repair blood vessel lesion	Last reviewed for CY 2012. No further review required at this time.
35612	Artery bypass graft	Last reviewed for CY 2012. No further review required at this time.
35800	Explore neck vessels	Last reviewed for CY 2012. No further review required at this time.
35840	Explore abdominal vessels	Last reviewed for CY 2012. No further review required at this time.
35860	Explore limb vessels	Last reviewed for CY 2012. No further review required at this time.
43283	Lap esoph lengthening	Last reviewed for CY 2012. No further review required at this time.
43327	Esoph fundoplasty lap	Last reviewed for CY 2012. No further review required at this time.
43328	Esoph fundoplasty thor	Last reviewed for CY 2012. No further review required at this time.
43332	Transab esoph hiat hern rpr	Last reviewed for CY 2012. No further review required at this time.
43333	Transab esoph hiat hern rpr	Last reviewed for CY 2012. No further review required at this time.
43334	Transthor diaphrag hern rpr	Last reviewed for CY 2012. No further review required at this time.
43335	Transthor diaphrag hern rpr	Last reviewed for CY 2012. No further review required at this time.
43336	Thorabd diaphr hern repair	Last reviewed for CY 2012. No further review required at this time.
43337	Thorabd diaphr hern repair	Last reviewed for CY 2012. No further review required at this time.
43338	Esoph lengthening	Last reviewed for CY 2012. No further review required at this time.
47563	Laparo cholecystectomy/graph	Last reviewed for CY 2012. No further review required at this time.
49507	Prp i/hern init block >5 yr	Last reviewed for CY 2012. No further review required at this time.
49521	Rerepair ing hernia blocked	Last reviewed for CY 2012. No further review required at this time.
49587	Rpr umbil hern block > 5 yr	Last reviewed for CY 2012. No further review required at this time.
49652	Lap vent/abd hernia repair	Last reviewed for CY 2012. No further review required at this time.
49653	Lap vent/abd hern proc comp	Last reviewed for CY 2012. No further review required at this time.
49654	Lap inc hernia repair	Last reviewed for CY 2012. No further review required at this time.
49655	Lap inc hern repair comp	Last reviewed for CY 2012. No further review required at this time.
60220	Partial removal of thyroid	Last reviewed for CY 2012. No further review required at this time.
60240	Removal of thyroid	Last reviewed for CY 2012. No further review required at this time.
60500	Explore parathyroid glands	Last reviewed for CY 2012. No further review required at this time.
95800	Slp stdy unattended	Last reviewed for CY 2012. No further review required at this time.

In the 60 days following the release of the CY 2012 PFS final rule with comment period, we received nominations and supporting documentation for review of the codes listed above in Table 4. A total of 36 CPT codes were nominated. The majority of the nominated codes were codes for which we finalized RVUs in the CY 2012 PFS final rule. That is, the RVUs were interim in CY 2011 and finalized for CY 2012, or proposed in either the Fourth Five-Year Review of Work or the CY 2012 PFS proposed rule and finalized for CY 2012. In the CY 2013 proposed rule, we noted that under this annual public nomination process it would be highly unlikely that we would determine that a nominated code is appropriate for review under the potentially misvalued codes initiative if it had been reviewed in the years immediately preceding its nomination since we believe that the best information on the level of physician work and PE inputs already would have been available through that recent review. We stated that, nonetheless, we would evaluate the supporting documentation for each nominated code to ascertain whether the submitted information demonstrated that the code is potentially misvalued.

CPT codes 33282 (Implantation of patient-activated cardiac event recorder) and 33284 (Removal of an implantable, patient-activated cardiac event recorder) were nominated for review as potentially misvalued codes. The requestor stated that CPT codes 33282 and 33284 are misvalued in the nonfacility setting because these CPT codes currently are only priced in the facility setting even though physicians furnish these services in the office setting. The requestor asked that we establish appropriate payment for the services when furnished in a physician's office. Specifically, the requestor asked that CMS establish nonfacility PE RVUs for these services. In the CY 2013 proposed rule, we stated that we do not consider the lack of pricing in a particular setting as an indicator of a potentially misvalued code. However, given that these services are now furnished in the nonfacility setting, we believe that CPT codes 33282 and 33284 should be reviewed to establish appropriate nonfacility inputs. We noted, as did the requestor, that the valuation of a service under the PFS in a particular setting does not address whether those services and the setting in which they are furnished are medically reasonable and necessary for a patient's medical needs and condition. We proposed to review CPT codes 33282 and 33284 and requested recommendations from the AMA RUC and other public commenters on the appropriate physician work RVUs (as measured by time and intensity), and facility and nonfacility direct PE inputs for these services.

Like CPT codes 33282 and 33284, stakeholders requested that we establish appropriate payment for CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural) when furnished in an office

setting. In the CY 2013 proposed rule, we noted that this request was not submitted as a potentially misvalued code nomination. However, given that these services are now furnished in the nonfacility setting, we stated that we believed CPT code 63650 should be reviewed to establish appropriate nonfacility inputs. Please see section III.A.3 (Changes to Direct Inputs for Specific Services) for a discussion of spinal code stimulation trial procedures in the nonfacility setting.

The following is a summary of the comments we received in response to our proposal to review the physician work, facility, and nonfacility direct PE inputs for CPT codes 33282 and 33284.

Comment: Several commenters did not support our proposal to review CPT codes 33282 and 33284. Commenters stated that the very low utilization in the nonfacility setting does not justify a review of the codes for nonfacility PE inputs. One commenter noted that physicians are not interested in furnishing these services in the nonfacility setting due to concerns for patient safety. Commenters recommended that we not consider establishing nonfacility PE RVUs for these CPT codes until additional studies indicate a clinical need to furnish these services in the nonfacility setting. Additionally, commenters stated that they do not believe it is necessary to review physician work and PE in the facility setting, as that was not the concern that the stakeholder brought forward. The AMA RUC stated that it continues to support the current work RVUs and facility PE inputs for these services.

Another commenter recommended that CMS finalize the proposal to revalue CPT codes 33282 and 33284 in order to establish nonfacility PE RVUs. The commenter stated that the lack of nonfacility PE RVUs prevents physicians from furnishing these services in the office for select patients for whom this setting of care is safe and appropriate. This commenter recommended that CMS maintain the existing work RVUs, and focus the revaluation on the nonfacility PE inputs. The commenter requested that CMS remain flexible in its approach to nominated codes and allow for more expeditious review of codes by not requiring full provider surveys.

Response: After reviewing the comments received, we are finalizing our proposal to review the physician work, and facility and nonfacility direct PE inputs for CPT codes 33282 and 33284. We acknowledge that we received very few Medicare claims for these services in the nonfacility setting in CY 2011; nonetheless, we believe it is appropriate to consider the relative resources involved in furnishing this service in the nonfacility setting. We reiterate that the valuation of a service under the PFS in a particular setting does not address whether those services and the setting in which they are furnished are medically reasonable and necessary for a patient's medical needs and condition.

We acknowledge that commenters support the current work and facility RVUs, however, it is our policy generally to review the physician work, facility, and nonfacility direct PE inputs for each service together to ensure consistency in the inputs used to value the service. Based on information provided by the requestor and the 2011 nonfacility utilization for this code, we believe it is appropriate to review this service for nonfacility PE inputs. As explained above, we intend to review the work and facility inputs as well. Additionally, we note that the physician work and facility PE inputs for these two services have not been reviewed in over a decade, so we believe it is reasonable to assess whether the inputs on which the current payment rates are based accurately reflect the resources involved in furnishing these services today. Accordingly, we are finalizing our proposal to review the physician work, and facility and nonfacility direct practice expense inputs for CPT codes 33282 and 33284, and request comments on the appropriate physician work, and facility and nonfacility direct practice expense inputs for these services.

Traditionally, we have received recommendations from the AMA RUC on the appropriate physician work, PE, and malpractice inputs for services CMS plans to review and revalue. However, we understand that the AMA RUC may not issue recommendations for all codes under review by CMS. In addition to requesting recommendations from the AMA RUC on services we intend to review, we request and encourage recommendations on these services from other public commenters as well. We acknowledge the requestor's comment that CMS remain flexible in its approach to nominated codes and not require full practitioner surveys for CPT codes 33282 and 33284. We understand that practitioner surveys regarding work, malpractice, and PE are not always available, practical, or reliable. We encourage commenters to submit the best data available on the appropriate valuation and inputs for the services under review, including the information listed above under supporting documentation for the nomination of potentially misvalued codes.

In the CY 2013 proposed rule, we stated that we did not consider CPT codes 36819 (Arteriovenous anastomosis, open; by upper arm basilic vein transposition) and 36825 (Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); autogenous graft) to be potentially misvalued because these codes were last reviewed and valued for CY 2012 and the supporting documentation did not provide sufficient evidence to demonstrate that the codes should be reviewed as potentially misvalued for CY 2013 or CY 2014. The following is a summary of the comments we received in response to our proposal not to review CPT codes 36819 and 36825 as potentially misvalued codes.

Comment: One commenter reiterated its belief that CPT codes 36819 and 36825 are potentially misvalued because the work RVUs finalized by CMS in CY 2012 place these services out of rank order with services that involve similar resources. To support this position, the commenter provided a list showing these services relative to all services with a similar global period, intra-service time, and work RVU. The commenter also restated the rationale previously submitted to CMS when it nominated these services as potentially misvalued. The commenter requested that CMS reconsider the work RVUs of these two services.

Response: After reviewing the comments received and conducting a clinical review of CPT codes 36819 and 36825 alongside similar services, we agree with the commenter that these services may be out of rank order and are potentially misvalued. Therefore, we are modifying our proposal to not review CPT codes 36819 and 36825 as potentially misvalued codes. We will review CPT codes 36819 and 36825 along with their code families, which include CPT codes 36818 through 36821 and CPT codes 36825 through 36830, as potentially misvalued. We thank commenters for the additional supporting documentation provided, and request additional comments on the appropriate physician work and direct PE inputs for these services.

CPT code 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff) was nominated for review as a potentially misvalued code. CPT code 53445 was identified through the site-of-service anomaly potentially misvalued code screen for CY 2008. We completed our review and established RVUs for this

code on an interim basis for CY 2012 subject to public comment. In the CY 2013 proposed rule, we stated that we would consider the supporting documentation submitted under the potentially misvalued code nomination process for CPT code 53445 as comments on the CY 2012 interim final value, and would address the comments in the CY 2013 PFS final rule with comment period when we address the final value of the CPT code. A summary of the comments received on CPT code 53445 and our response to those comments is included in section II.M.2 of this final rule with comment period.

CPT code 77336 (Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy) was nominated for review as a potentially misvalued code. The requestor stated that CPT code 77336 is misvalued because changes in the technique for furnishing continuing medical physics consultations have resulted in changes to the knowledge required, time, and effort expended, and complexity of technology associated with the tasks performed by the physicist and other staff. Additionally the requestor stated that the direct PE inputs no longer accurately reflect the resources used to deliver this service and may be undervalued. CPT code 77336 was last reviewed for CY 2003. In the CY 2013 proposed rule, we stated that after evaluating the detailed supporting information that the commenter provided, we believed there may have been changes in technology and other PE inputs since we last reviewed the service, and that further review is warranted. As such, we proposed to review CPT code 77336 as potentially misvalued and requested recommendations from the AMA RUC and other public commenters on the direct PE inputs for this service and for the other services within this family of CPT codes.

The following is a summary of the comments we received in response to our proposal to review CPT code 77336 as potentially misvalued.

Comment: Commenters supported the CMS proposal to review CPT code 77336 and urged CMS to finalize it. The AMA RUC stated that it would review this service and provide recommendations to CMS on its valuation. Several commenters reiterated their rationale for why they believe CPT code 77336 is potentially misvalued and provided supporting documentation. Additionally, commenters indicated that the American Society for Physicists in Medicine (AAPM) would submit information on practice expense inputs and other data to support the revaluation of this CPT code, and expressed appreciation that CMS is willing to consider data and input from professional medical societies that do not participate in the AMA RUC process.

Response: After reviewing the comments received, we continue to believe that changes in technology may have altered the direct practice expense inputs associated with CPT code 77336 and are finalizing our proposal to review this service as potentially misvalued. We thank commenters for the supporting documentation provided, and request additional comments on the appropriate direct PE inputs for this service, as well as any other services that may be within this family of CPT codes.

CPT code 94762 (Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)) was nominated for review as a potentially misvalued code. Requestors stated that CPT code 94762 is misvalued because the time currently allocated to the various direct PE inputs does not accurately reflect current practice. Requestors also stated that independent diagnostic testing facilities are not appropriately accounted for in the current indirect PE methodology. In the CY 2013 proposed rule, we stated that, in response to these stakeholder concerns, we reviewed the PE inputs for CPT code 94762, which was last reviewed for CY 2010. We believed that CPT code 94762 is misvalued, and we proposed changes to the PE inputs for CY 2013. We stated that, following clinical review, we believed that the current time allocated to clinical labor and supplies appropriately reflects current practice. However, we believed that 480 minutes (8 hours) of equipment time for the pulse oximetry recording slot and pulse oximeter with printer are more appropriate for this overnight monitoring procedure code. As such, we proposed this refinement to the direct PE inputs for CPT code 94762 for CY 2013. These proposed adjustments were reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*.

The following is a summary of the comments received regarding the proposed direct PE adjustments to CPT code 94762.

Comment: Many commenters agreed with CMS' proposal to refine the equipment minutes for this service to 480 minutes. One commenter suggested that CMS should increase the proposed allocation of minutes to account for the time that the equipment is unavailable for use because the patient has yet to return it to the office.

Response: We appreciate the support for the proposal. We believe that the appropriate allocation of minutes for the equipment is the sum of the times within the intra-service period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. However, we also note that the equipment cost per minute calculation incorporates a utilization rate assumption that appropriately accounts for the time the equipment cannot be used because it is being transported to and from the office or between patients. Therefore, we are not revising our proposed adjustment to the equipment time.

Comment: Several commenters supported the proposed allocation of minutes to the equipment and also submitted invoices and other evidence for updating the direct PE inputs for the service. The AMA RUC and others submitted information to update the pulse oximeter and the recording software used in the service. The information submitted by the AMA RUC reflects a pulse oximeter priced at $1,418 and recording software priced at $990. Other commenters submitted various disposable supplies that might be used to furnish the service, including varying types of batteries, oximeter cables, and wristbands that might be used when furnishing this service.

Response: We appreciate the updated information furnished to us by stakeholders and other commenters. While we generally urge stakeholders to submit such price update requests through the process for updating supply and equipment prices we established for CY 2011, because we made a proposal specifically related to the equipment minutes allocated for this procedure, we believe it would be appropriate to consider the supplies and equipment price inputs associated with the service in conjunction with the proposal to change the equipment minutes. Based on the invoice information we received from commenters, we will update the price of the 'pulse oximetry recording software (prolonged monitoring)' (EQ212) and include a new equipment item ''Pulse Oximeter 920 M Plus'' priced at $1,418 as equipment inputs for

the code. In reviewing the requested supply items to include, we believe that it would be appropriate to include 6 AA batteries (SK095) as a disposable supply for the service as well as incorporate a new item, a disposable oximeter cable, priced at $11.08.

Based on these comments and our clinical review, we are adopting these direct PE inputs, including our adjusted allocation of equipment minutes, on an interim basis for CY 2013. These values are reflected in the CY 2013 PFS direct PE input database available under downloads for the CY 2013 PFS final rule with comment period on the CMS Web site at: *http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage*. We also note that the PE RVUs included in Addenda B and C reflect these interim direct PE inputs.

In the CY 2013 proposed rule, we stated that we did not consider the nominated codes that were last reviewed and valued for CY 2012 to be potentially misvalued because the supporting documentation did not provide sufficient evidence to demonstrate that the codes should be reviewed as potentially misvalued for CY 2013 or CY 2014. The supporting documentation for these services generally mirrored the public comments previously submitted, to which CMS has already responded. Below is a summary of the comments we received in response to our proposal to not review the CPT codes listed above in Table 4 not discussed above.

Comment: We received a few limited comments on the nominated codes not previously discussed above, however, like the code nominations, the comments and supporting documentation for these services mirrored the public comments previously submitted, to which CMS has already responded.

Response: Having received no new information on the CPT codes listed in Table 4 not previously discussed, we are finalizing our proposal not to review those services as potentially misvalued.

b. Potentially Misvalued Code Lists

As mentioned above, in the last several annual PFS proposed rules we have identified lists of potentially misvalued codes for review. We believe it is imperative that we continue to identify new lists of potentially misvalued codes for review to appropriately identify, review, and adjust values for potentially misvalued codes for CY 2013.

(1) Review of Harvard-Valued Services With Medicare Allowed Charges of $10,000,000 or More

For many years, we have been reviewing 'Harvard-valued' CPT codes through the potentially misvalued code initiative. The RVUs for Harvard-valued CPT codes have not been reviewed since they were originally valued in the early 1990s at the beginning of the PFS. While the principles underlying the relative value scale have not changed, over time the methodologies we use for valuing services on the PFS have changed, potentially disrupting the relativity between the remaining Harvard-valued codes and other codes on the PFS. At this time, nearly all CPT codes that were Harvard-valued and had Medicare utilization of over 30,000 allowed services per year have been reviewed. In the CY 2013 PFS proposed rule, we proposed to review Harvard-valued services with annual Medicare allowed charges of $10 million or greater. The CPT codes meeting these criteria have relatively low Medicare utilization (as we have reviewed the services with utilization over 30,000), but account for significant Medicare spending annually and have never been reviewed. In the CY 2013 proposed rule, we noted that several of the CPT codes meeting these criteria have already been identified as potentially misvalued through other screens and were scheduled for review for CY 2013. We also recognized that other codes meeting these criteria had been referred by the AMA RUC to the CPT Editorial Panel. We stated that, in these cases, we were not proposing re-review of these already identified services, but for the sake of completeness, we included those codes as a part of this category of potentially misvalued services. In our proposal, we recognized that the relatively low Medicare utilization for these services may make gathering information on the appropriate physician work and direct PE inputs difficult. We requested recommendations from the AMA RUC and other public commenters, and stated that we appreciate efforts expended to provide RVU and input recommendations to CMS for these lower volume services. Because survey sample sizes could be small for these lower volume services, we encouraged the use of valid and reliable alternative data sources and methodologies when developing recommended values. In sum, we proposed to review Harvard-valued CPT codes with annual allowed charges of $10 million or more as a part of the potentially misvalued codes initiative. In the CY 2013 proposed rule, we stated that the following codes met the criteria for this screen and proposed to review these CPT codes as potentially misvalued services.

TABLE 5—PROPOSED HARVARD-VALUED CPT CODES WITH ANNUAL ALLOWED CHARGES ≥$10,000,000

CPT Code	Short descriptor
13152 *	Repair of wound or lesion.
27446	Revision of knee joint.
29823	Shoulder arthroscopy/surgery.
36215 **	Place catheter in artery.
36245 **	Ins cath abd/l-ext art 1st.
43264 **	Endo cholangiopancreatograph.
50360	Transplantation of kidney.
52353 *	Cystouretero w/lithotripsy.
64450 *	N block other peripheral.
64590	Insrt/redo pn/gastr stimul.
66180	Implant eye shunt.
67036	Removal of inner eye fluid.
67917	Repair eyelid defect.
92286 **	Internal eye photography.
92982 *	Coronary artery dilation.
95860 *	Muscle test one limb.

* Scheduled for CY 2012 AMA RUC Review.
** Referred by the AMA RUC to the CPT Editorial Panel.

The following is summary of the comments we received in response to our proposal to review Harvard-valued CPT codes with annual allowed charges of $10 million or more as a part of the potentially misvalued codes initiative.

Comment: Comments on this proposal were specific to the CPT codes we proposed to review under this potentially misvalued code screen. A few commenters noted that CPT code 64590 (Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling) does not have annual allowed charges that meet the threshold of $10 million and stated that the code should be removed from the list. These commenters requested that CMS reexamine this list to ensure all codes meet the specified criteria. Other commenters pointed out that certain codes on the list are already scheduled for review by the medical specialty societies and the AMA RUC, and that some codes are scheduled for deletion by the CPT Editorial Panel. The AMA RUC stated that it would discuss the list of codes that meet the criteria for this screen and would determine the next steps in the AMA RUC's review of these services.

Response: After reviewing the comments received, and reexamining the Medicare claims data, we agree with commenters that CPT code 64590 does not have annual Medicare allowed charges of $10 million or greater, nor do CPT codes 29823 (Arthroscopy,

shoulder, surgical; debridement, extensive) and 95860 (Needle electromyography; 1 extremity with or without related paraspinal areas). In compiling the list, we inadvertently included allowed charges incurred in the ambulatory surgical center setting. We thank commenters for bringing this to our attention. Therefore, we have removed these three services from the proposed list of CPT codes that are Harvard-value with annual allowed charges of $10 million or greater.

In the CY 2013 proposed rule, we noted that several codes that met the criteria for this potentially misvalued code screen were currently under review for CY 2013 and others were scheduled for review by the CPT Editorial Panel. CPT codes 13152 (Repair, complex, eyelids, nose, ears and/or lips; 2.6 cm to 7.5 cm), 52353 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)), 64450 (Injection, anesthetic agent; other peripheral nerve or branch), 92286 (Special anterior segment photography with interpretation and report; with specular endothelial microscopy and cell count), and 95860 (Needle electromyography; 1 extremity with or without related paraspinal areas) were reviewed for CY 2013. A discussion of the interim final values for those services is in section III.M.3. of this final rule with comment period. CPT code 92982 (Percutaneous transluminal coronary balloon angioplasty; single vessel) has been deleted by the CPT Editorial Panel for CY 2013. We have updated the list of CPT codes meeting this potentially misvalued code screen to show the review status of the codes, and to remove the three CPT codes mentioned above that do not meet the parameters of the screen. We are finalizing the list of Harvard-valued CPT codes with annual allowed charges of $10 million or more in Table 6, and for CY 2014, we will review the services not already reviewed. We request public comments on the appropriate work RVUs and direct practice expense inputs for these services.

TABLE 6—HARVARD-VALUED CPT CODES WITH ANNUAL ALLOWED CHARGES ≥$10,000,000

CPT code	Short descriptor	Review status
13152	Repair of wound or lesion	Interim Final for CY 2013.
27446	Revision of knee joint	Review for CY 2014.
36215	Place catheter in artery	Review for CY 2014.
36245	Ins cath abd/l-ext art 1st	Review for CY 2014.
43264	Endo cholangiopancreatograph	Review for CY 2014.
50360	Transplantation of kidney	Review for CY 2014.
52353	Cystouretero w/lithotripsy	Interim Final for CY 2013.
64450	N block other peripheral	Interim Final for CY 2013.
66180	Implant eye shunt	Review for CY 2014.
67036	Removal of inner eye fluid	Review for CY 2014.
67917	Repair eyelid defect	Review for CY 2014.
92286	Internal eye photography	Interim Final for CY 2013.
92982	Coronary artery dilation	Deleted for CY 2013.

(2) Review of Services With Stand Alone PE Procedure Time

Improving the accuracy of procedure time assumptions used in PFS ratesetting continues to be a high priority of the potentially misvalued codes initiative. Procedure time is a critical measure of the resources typically used in furnishing particular services to Medicare beneficiaries, and procedure time assumptions are an important component in the development of work and PE RVUs. Discussions in the academic community have indicated that certain procedure times used for PFS ratesetting are overstated (McCall, N., J. Cromwell, et al. (2006). ''Validation of physician survey estimates of surgical time using operating room logs.'' *Med Care Res Rev* 63(6): 764–777. Cromwell, J., S. Hoover, et al. (2006). ''Validating CPT typical times for Medicare office evaluation and management (E/M) services.'' *Med Care Res Rev* 63(2): 236–255. Cromwell, J., N. McCall, et al. (2010). ''Missing productivity gains in the Medicare physician fee schedule: where are they?'' *Med Care Res Rev* 67(6): 236–255.) MedPAC and others have emphasized the importance of using the best available procedure time information in establishing accurate PFS payment rates. (MedPAC, Report to the Congress: Aligning Incentives in Medicare, June 2010, p. 230)

In recent years, CMS and the AMA RUC have taken steps to consider the accuracy of available data regarding procedure times used in the valuation of the physician work component of PFS payment. Generally, the AMA RUC derives estimates of physician work time from survey responses, and the AMA RUC reviews and analyzes those responses as part of its process for developing a recommendation for physician work. These procedure time assumptions are also used in determining the appropriate direct PE input values used in developing nonfacility PE RVUs. Specifically, physician intra-service time serves as the basis for allocating the appropriate number of minutes within the service period to account for the time used in furnishing the service to the patient. The number of intra-service minutes, or occasionally a particular proportion thereof, is allocated to both the clinical staff that assists the physician in furnishing the service and to the equipment used by either the physician or the staff in furnishing the service. This allocation reflects only the time the beneficiary receives treatment and does not include resources used immediately prior to or following the service. Additional minutes are often allocated to both clinical labor and equipment resources in order to account for the time used for necessary preparatory tasks immediately preceding the procedure or tasks typically performed immediately following it. For codes without physician work, the procedure times assigned to the direct PE inputs for such codes assume that the clinical labor performs the procedure. For these codes, the number of intra-service minutes assigned to clinical staff is independent and not based on any physician intra-service time assumptions. Consequently, the procedure time assumptions for these kinds of services have not been subject to all of the same mechanisms recently used by the AMA RUC and physician community in providing recommendations to CMS, and by CMS in the valuation of the physician work component of PFS payment. These

independent clinical labor time assumptions largely determine the RVUs for the procedure. To ensure that procedure time assumptions are as accurate as possible across the Medicare PFS, we believe that codes without physician work should be examined with the same degree of scrutiny as services with physician work.

For CY 2012, a series of radiation treatment services were reviewed as part of the potentially misvalued code initiative. Among these were intensity modulated radiation therapy (IMRT) delivery services and stereotactic body radiation therapy (SBRT) delivery services reported with CPT codes 77418 (Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session) 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), respectively. CPT code 77418 (IMRT treatment delivery) had been identified as potentially misvalued based on Medicare utilization data that indicated both fast growth in utilization and frequent billing with other codes. We identified this code as potentially misvalued in the CY 2009 PFS proposed rule (73 FR 38586). CPT code 77373 (SBRT treatment delivery) had been identified as potentially misvalued by the RUC as a recently established code describing services that use new technologies. There is no physician work associated with either of these codes since other codes are used to bill for planning, dosimetry, and radiation guidance. Both codes are billed per treatment session. Because the physician work associated with these treatments is reported using codes distinct from the treatment delivery, the primary determinant of PE RVUs for these codes is the number of minutes allocated for the procedure time to both the clinical labor (radiation therapist) and the resource-intensive capital equipment included as direct PE inputs.

In the CY 2012 PFS final rule with comment period, we received and accepted without refinement PE recommendations from the AMA RUC for these two codes. (We received the recommendation for CPT code 77418 (IMRT treatment delivery) too late in 2010 to be evaluated for CY 2011 and it was therefore included in the CY 2012 rulemaking cycle.) The AMA RUC recommended minor revisions to the direct PE inputs for the code to eliminate duplicative clinical labor, supplies, and equipment to account for the frequency with which the code was billed with other codes. For CPT code 77373 (SBRT treatment delivery), the RUC recommended no significant changes to the direct PE inputs.

Subsequent to the publication of the final rule, the AMA RUC and other stakeholders informed CMS that the direct PE input recommendation forwarded to CMS for IMRT treatment delivery (CPT code 77418) inadvertently omitted seven equipment items typically used in furnishing the service. These items had been used as direct PE inputs for the code prior to CY 2012. There is broad agreement among stakeholders that these seven equipment items are typically used in furnishing the services described by CPT code 77418. We were unable to reincorporate the items for CY 2012. These omitted items are listed in Table 7. In consideration of the comments from the AMA RUC and other stakeholders, we proposed to include the seven equipment items omitted from the RUC recommendation for CPT code 77418. These proposed adjustments were reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*. We note that the proposed PE RVUs included in Addendum B reflected the proposed updates.

TABLE 7—EQUIPMENT INPUTS OMITTED FROM RUC RECOMMENDATION FOR CPT CODE 77418 (IMRT TREATMENT DELIVERY)

Equipment code	Equipment description
ED011	computer system, record and verify.
ED035	video camera.
ED036	video printer, color (Sony medical grade).
EQ139	intercom (incl. master, pt substation, power, wiring).
ER006	IMRT physics tools.
ER038	isocentric beam alignment device.
ER040	laser, diode, for patient positioning (Probe).

It has come to our attention that there are discrepancies between the procedure time assumptions used in establishing nonfacility PE RVUs for these services and the procedure times made widely available to Medicare beneficiaries and the general public. Specifically, the direct PE inputs for IMRT treatment delivery (CPT code 77418) reflect a procedure time assumption of 60 minutes. These procedure minutes were first assigned to the code for CY 2002 based on a recommendation from the AMA RUC indicating that the typical treatment time for the IMRT patient was 40 to 70 minutes. The most recent RUC recommendation that CMS received for CY 2012 rulemaking supported the procedure time assumption of 60 minutes.

Information available to Medicare beneficiaries and the general public indicates that IMRT sessions typically last between 10 and 30 minutes. For example, the American Society for Radiation Oncology (ASTRO) publishes a patient fact sheet that explains that for all external beam radiation therapy, including IMRT, ''treatment is delivered in a series of daily sessions, each about 15 minutes long.'' [''Radiation Therapy for Prostate Cancer: Facts to Help Patients Make an Informed Decision'' available for purchase at *www.astro.org/MyASTRO/Products/Product.aspx?AstroID=6901*.] This fact sheet is intended for patients with prostate cancer, the typical diagnosis for Medicare beneficiaries receiving IMRT. Similarly, the American College of Radiology (ACR) and the Radiological Society of North America (RSNA) co-sponsor a Web site for patients called *http://radiologyinfo.org* that states that IMRT ''treatment sessions usually take between 10 and 30 minutes.''

The direct PE inputs for SBRT treatment delivery (CPT code 77373) reflect a procedure time assumption of 90 minutes. These procedure minutes were first assigned to the code for CY 2007 based on a recommendation from the AMA RUC. The most recent RUC recommendation that CMS received for CY 2012 rulemaking supported continuing that procedure time assumption.

In 2012, information available to Medicare beneficiaries and the general public states that SBRT treatment typically lasts no longer than 60 minutes. For example, the American College of Radiology (ACR) and the Radiological Society of North America (RSNA) Web site, *http://radiologyinfo.org*, states that SBRT ''treatment can take up to one hour.''

Given the importance of the procedure time assumption in the development of RVUs for these services, using the best available information is critical to ensuring that these services are valued appropriately. We believe medical societies and practitioners strive to offer their cancer patients accurate information regarding the IMRT or SBRT treatment experience. Therefore, we believe that the typical procedure time for IMRT delivery is between 10 and 30 minutes and that the

typical procedure time for SBRT delivery is under 60 minutes. The services are currently valued using procedure time assumptions of 60 and 90 minutes, respectively. We believe these procedure time assumptions, distinct from necessary preparatory or follow-up tasks by the clinical labor, are outdated and need to be updated using the best information available.

While we generally have not used publicly available resources to establish procedure time assumptions, we believe that the procedure time assumptions used in setting payment rates for the Medicare PFS should be derived from the most accurate information available. In the case of these services, we believe that the need to reconcile the discrepancies between our existing assumptions and more accurate information outweighs the potential value in maintaining relativity offered by only considering data from one source. We proposed to adjust the procedure time assumption for IMRT delivery (CPT code 77418) to 30 minutes. We proposed to adjust the procedure time assumption for SBRT delivery (CPT code 77373) to 60 minutes. These procedure time assumptions reflect the maximum number of minutes reported as typical in publicly available information. We note that in the case of CPT code 77418, the 'accelerator, 6–18 MV' (ER010) and the 'collimator, multileaf system w-autocrane' (ER017) are used throughout the procedure and currently have no minutes allocated for preparing the equipment, positioning the patient, or cleaning the room. Since these clinical labor tasks are associated with related codes typically reported at the same time, we also proposed to allocate minutes to these equipment items to account for their use immediately before and following the procedure. All of these proposed adjustments are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*. We also note that the proposed PE RVUs included in Addendum B reflect the proposed updates. We requested recommendations from the AMA RUC and other public commenters on the direct PE inputs for these services.

While we recognize that using these procedure time assumptions will result in payment reductions for these particular services, we believe such changes are necessary to appropriately value these services. Recent attention from popular media sources like the *Wall Street Journal* (*online.wsj.com/article/SB10001424052748703904804575631222900534954.html* December 7, 2010) and the *Washington Post* (*www.washingtonpost.com/wp-dyn/content/article/2011/02/28/AR2011022805378.html*) February 28, 2011 has encouraged us to consider the possibility that potential overuse of IMRT services may be partially attributable to financial incentives resulting from inappropriate payment rates. In its 2010 Report to Congress, MedPAC referenced concerns that financial incentives may influence how cancer patients are treated. In the context of the growth of ancillary services in physicians' offices, MedPAC recommended that improving payment accuracy for discrete services should be a primary tool used by CMS to mitigate incentives to increase volume (Report to Congress: Aligning Incentives in Medicare, June 2010, p. 225). We note that in recent years, PFS nonfacility payment rates for IMRT treatment delivery have exceeded the Medicare payment rate for the same service paid through the hospital Outpatient Prospective Payment System (OPPS), which includes packaged payment for image guidance also used in treatment delivery. We believe that such high-volume services that are furnished in both nonfacility and facility settings are unlikely to be more resource-intensive in freestanding radiation therapy centers or physicians' offices than when furnished in facilities like hospitals that generally incur higher overhead costs, maintain a 24 hour, 7 day per week capacity, are generally paid in larger bundles, and generally furnish services to higher acuity patients than the patients who receive services in physicians' offices or freestanding clinics. Given that the OPPS payment rates are based on auditable data on hospital costs, we believe the relationship between the OPPS and nonfacility PFS payment rates reflects inappropriate assumptions within the current direct PE inputs for CPT code 77418. The AMA RUC's most recent direct PE input recommendations reflect the same procedure time assumptions used in developing the recommendations for CY 2002. However, we believe that using procedure time assumptions that reflect the maximum times reported as typical to Medicare beneficiaries will improve the accuracy of those inputs and the resulting nonfacility payment rates.

We received many comments regarding our proposal to change the direct PE inputs for CPT codes 77418 and 77373 based on amended procedure time assumptions and consideration of the comments from the AMA RUC and other stakeholders to include the seven equipment items omitted from the previous AMA RUC recommendation for CPT code 77418. The following is summary of the comments we received and our responses to those comments.

Comment: Several commenters agreed with CMS' proposal to add the equipment items omitted from the AMA RUC recommendation for CPT code 77418 to the code.

Response: We appreciate the support for that aspect of the proposal.

Comment: Many commenters disagreed with CMS' proposal to adjust the procedure time assumptions for these services. Some of these commenters stated that 35 minutes was a more appropriate estimate, but none presented alternative sources of objective information for determining accurate procedure time assumptions. Many commenters objected to CMS' proposal on the basis that the agency used publicly available information to adjust procedure times assumptions instead of basing its proposal on information developed through the AMA RUC process. These commenters stated that CMS should not finalize its proposed procedure time assumptions for one of four reasons: publicly available procedure time information does not consider the time resources required prior to or following the procedure, that educational information for patients is an inappropriate data source because such material is not subject to the same degree of scrutiny by the medical community as the information presented to the AMA RUC, that CMS only has the authority to review or revalue PFS services through the AMA RUC process, or that time has been universally inflated by the AMA RUC so that using more accurate time assumptions in setting the RVUs for these services would distort their value relative to other PFS services.

Response: We appreciate the commenters' interest in CMS using the best available data to identify the time resources required to furnish services to Medicare beneficiaries. We address commenters' objections to using these patient education materials in the comment summaries and response paragraphs that follow.

Comment: Many commenters stated that patient education materials are not an appropriate source of data because the procedure times conveyed through such materials may not fully account for the time spent positioning the patient for treatment, performing safety checks or the work that occurs before and after treatment. Several commenters explicitly stated that it is highly likely

that the patient education materials describe only the time the patient is on the treatment table.

Response: We understand that the procedure times cited in the patient education materials may not include the full time for preparing the equipment, positioning the patient or other necessary work required prior to or following the procedure. The procedure time assumptions used in developing direct PE inputs only account for a portion of the service period minutes allocated to the clinical labor or the equipment direct PE inputs. For example, in our proposal to reduce procedure time assumptions for CPT code 77418, we allocated an additional seven minutes to the equipment beyond the procedure time assumption for additional tasks. These minutes reflect the standard minutes usually recommended by the RUC for these tasks. For example, for CY 2013 the AMA RUC recommended these minutes for direct PE inputs for CPT code 31231 (Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure), CPT code 52287 (Cystourethroscopy with injection(s) for chemodenervation of the bladder), CPT code 65800 (Paracentesis of anterior chamber of eye (separate procedure); with diagnostic aspiration of aqueous), and CPT code 11311 (Shaving of epidermal or dermal lesion, single lesion, face ears, eyelid, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm).

We also note that the direct PE inputs for codes describing imaging guidance services that are typically reported at the same time-include minutes for the radiation therapist to prepare the room, position the patient, and clean the room. Similarly, the proposed direct PE inputs for CPT code 77373 incorporate clinical labor and equipment minutes that exceed the minutes assumed for the procedure itself: 24 minutes of additional nurse time, 24 minutes of additional time for the radiation therapist, and 15 additional minutes for the medical physicist for pre-service and post-service tasks. On the basis of these tasks, the equipment associated with the code has also been allocated 24 minutes beyond the procedure time assumption for pre-service and post-service work. Therefore, we do not agree with commenters who suggested that our proposed revisions are inappropriate because the procedure time reported in the patient education materials may underestimate the procedure time assumptions used in developing direct PE inputs. Instead, we believe that the typical procedure time described in the patient education material is generally equivalent to the minutes incorporated in the service period for performing the procedure. We already have incorporated additional minutes of clinical labor time into the direct PE inputs for both CPT codes 77418 and 77373 to account for tasks like preparing the equipment and cleaning the room in addition to the minutes allocated for the procedure time assumptions. This reflects the direct PE inputs used for most services, where we allocate minutes to clinical labor and medical equipment for preparatory or follow-up tasks in addition to the equipment time allocated based on the procedure time assumption. While many commenters stated that the procedure times reported in the publicly available information do not include necessary preparatory or follow-up tasks, we received no comments with specific objections to the number of minutes allocated for such tasks in conjunction with our proposal.

Comment: The AMA RUC and some medical specialty societies expressed opposition to CMS using patient education materials in the process of setting Medicare payment rates. These commenters claimed that such information is not evaluated by the same standards applied to the extant data used as part of the AMA RUC process, so that CMS' use of these materials is ill-conceived.

Response: As we stated previously, we believe medical societies and practitioners strive to offer their cancer patients accurate information regarding the IMRT or SBRT treatment experience. We believe that such information, especially for high-volume services, is more likely to reflect typical treatment times than information proffered solely for the purpose of developing payment rates. While many commenters objected in principle to the validity of the patient education materials, we do not believe that medical specialty societies and providers of care would broadly inform their patients that IMRT treatment would last between 10 and 30 minutes per session if the typical treatment session actually lasted for one hour or that SBRT treatment would last for no more than one hour if it typically takes 90 minutes.

Comment: Many commenters claimed that CMS has the responsibility to conduct a comprehensive, empirical review of those procedure time assumptions utilizing the AMA RUC if CMS has concerns with those assumptions.

Response: We agree that AMA RUC review and recommendations are one important component in constructing payment rates under the physician fee schedule. While we do not agree with the commenters' statement that CMS has a responsibility to conduct all reviews of potentially misvalued codes through the AMA RUC process exclusively, we note the AMA RUC reviewed both CPT codes 77418 and 77373 as recently as 2010. Both of these services had been identified under our potentially misvalued code initiative. As noted above, the AMA RUC recommended minor revisions to the direct PE inputs for the code to eliminate duplicative clinical labor, supplies, and equipment to account for the frequency with which the code was billed with other codes. For CPT code 77373 (SBRT treatment delivery), the AMA RUC recommended no significant changes to the direct PE inputs. We note that in response to this proposal, the AMA RUC has recently informed us that since there is no physician work associated with these codes, it has asked the relevant specialty society to conduct a survey for clinical staff time, in order to ensure accurate procedure times.

Comment: Some commenters stated that CMS should only consider the accuracy of these procedure time assumptions relative to the procedure time estimates for other services. Some of these commenters claimed that procedure time assumptions for services across the PFS are inflated so that CMS should not use procedure time assumptions for these services that are also exaggerated.

Response: We appreciate the commenters' concerns with maintaining the relativity of time used in developing relative value units. We understand that procedure times may be overestimated for some other PFS services. While we agree that maintaining the resource relativity of services within the payment system is very important, we also believe that there is no practical means for CMS or stakeholders to engage in a complete simultaneous review of time assumptions across all payable codes. As such, we must evaluate times (and other factors) and make adjustments in smaller increments when we find that adjustments are warranted. We strive to maintain relativity by reviewing all RVU components for a code or reviewing all codes within families where appropriate. Furthermore, we believe that our proposal to use more accurate procedure time assumptions for these services should be considered in the context of broader efforts to improve the accuracy of PFS relative values, where time is a significant component of developing relative values.

Since MedPAC's March 2006 Report to the Congress, CMS has implemented a potentially misvalued codes initiative

and has taken significant steps to identify and address potentially misvalued codes, including establishing physician times that accurately reflect the resources involved in furnishing the service. For example, CMS has reduced the physician times for services that were originally valued in the inpatient setting but now are frequently performed in the outpatient setting, services that are frequently performed together or in multiple units, and services billed on the same day as an E/M service. Furthermore, in addition to our proposal to review services with stand-alone procedure time, in this CY 2013 PFS final rule with comment period, we also discuss recommendations on how best to accurately measure post-operative work in the global surgical period, and finalize several proposals to adjust times for services with anomalous times in the physician time file. Moreover, in September 2012, we entered into two contracts to assist us in validating RVUs of potentially misvalued codes, which may include the validation of physician time elements.

Additionally, we do not agree with the commenters' assertion that if time is distorted across the PFS, it is likely to be distorted with consistent proportionality. While the distortions may be relatively consistent for surveys taken at similar times or data gathered through similar methods, the procedure time assumptions used in developing practice expense inputs have not originated from consistent sources. The 60 minute procedure time assumption for IMRT treatment delivery, for example, was originally developed based on a specialty society survey for CY 2002.

Through our misvalued codes initiative and other efforts, we strive to prioritize and review values for codes each year and work toward achieving greater calibration of values across the PFS over time.

Comment: MedPAC commented that CMS should implement its proposal to reduce the time estimates for these codes based on the credible evidence presented in the proposed rule. The commission stated further that if stakeholders object to these changes, they should provide objective, valid evidence to CMS that the agency's proposed time estimates are too low. Furthermore, the commission expressed concerns about using physician surveys to develop time estimates since physician medical societies have a financial stake in the process. Therefore, MedPAC recommended that the AMA RUC should seek evidence other than the surveys conducted by specialty societies and that CMS may need to regularly collect data on service time and other variables to establish more accurate RVUs for practice expense and physician work.

Response: We appreciate MedPAC's support for the proposal. We agree that there are many means to measure time other than through survey methodology, and we are open to considering robust data on procedure time from many sources.

Comment: Many commenters objected to CMS' proposal to update the procedure time assumptions used in determining the direct PE inputs for these services since CMS did not propose corresponding updates to other direct PE inputs for the services.

Response: We appreciate the commenters' interest in CMS' use of the most accurate and up-to-date information in establishing practice expense RVUs for these services. We note that we recently received direct PE input recommendations from the AMA RUC for these services and used them to establish interim final direct PE inputs for CY 2012. We also note that in the CY 2011 PFS final rule (75 FR 73205 through 73207) we established a public process for updating prices for supplies and equipment used as direct PE inputs. Prior to making our CY 2013 proposal regarding procedure times for the IMRT and SBRT codes, we had received no requests to update prices for the inputs associated with these codes.

Comment: Several commenters submitted specific information regarding appropriate input revisions for CPT codes 77418 and 77373. Several commenters (including the AMA RUC) suggested that IMRT treatment requires two radiation therapists, working simultaneously, to furnish the service safely. Others suggested that the linear accelerator (ER010) and collimator (ER017) used as direct PE inputs for CPT code 77418 IMRT treatment are no longer typical. These commenters submitted evidence, consisting of a collection of paid invoices, that demonstrated that the typical accelerator used in IMRT includes the functionality of the collimator and should be priced at $ 2,641,783 and that the price of the ''laser, diode, for patient positioning (Probe)'' (ER040) should be $18,160. Several commenters also noted that two equipment items included in many other radiation treatment codes, the radiation treatment vault (ER056) and water chiller (ER065) ought to be included in the equipment inputs for IMRT and SBRT treatment delivery. Finally, several commenters suggested that the equipment items used in these treatment delivery services require practitioners to purchase maintenance and service contracts in addition to the price of the equipment itself.

Response: We appreciate all the submitted information to assist us in conducting a comprehensive update of the appropriate direct PE inputs for these services. We agree with the commenters that we should use the best information available in developing direct PE inputs for PFS services. Based on this information, we believe it would be appropriate to include two radiation therapists as direct PE inputs for CPT code 77418. We also believe it would be appropriate to update the current accelerator and collimator equipment inputs used in CPT code 77418 based on the invoices provided to us by commenters. While we generally urge stakeholders to submit such requests through the process we established for CY 2011, because we made a proposal specifically related to the equipment minutes allocated for these procedures, we believe it would be appropriate to consider the associated equipment and prices. We have observed that some other radiation treatment codes incorporate the water chiller and radiation treatment vault as direct PE inputs. We believe it would be appropriate to incorporate the water chiller as an equipment item into the IMRT and SBRT treatment delivery codes for the sake of consistency with the other radiation treatment codes. However, we question whether it is fully consistent with the principles underlying the PFS PE methodology to continue to classify the radiation treatment vault as medical equipment (a direct cost) since it is difficult to distinguish the cost of the construction of the vault from the cost of the construction of the building. The submitted architectural invoices for vault construction illustrate the difficulty in making that distinction. Furthermore, the typical circumstances of the vault's use are unclear, especially regarding whether or not the vault may be servicing multiple patients at the same time. However, we do not believe that it would be appropriate to remove the radiation treatment vault as a direct input for all PFS services for CY 2013. We expect to address the status of the radiation treatment vault as a direct PE input during CY 2014 rulemaking. For CY 2013, we believe that it would be appropriate to include the radiation treatment vault for CPT codes 77373 and 77418 to align the code with the similar radiation treatment delivery codes. In terms of the maintenance and service contract costs submitted to us by commenters, we remind stakeholders

that we have generally not considered such costs as direct costs attributable to furnishing services to individual Medicare beneficiaries and that our standard equipment cost per minute calculation includes a maintenance factor that adequately incorporates such costs in amortizing the cost of the equipment itself.

Comment: A few commenters suggested that CMS should re-price the capital equipment associated with CPT code 77373. However, none of these commenters submitted invoices.

Response: We urge commenters to submit invoices and other evidence appropriate for pricing the capital equipment used in SBRT delivery as part of our public process for updating supply and equipment prices. We direct interested stakeholders to the CY 2011 PFS final rule (75 FR 73205–73207) for information regarding that process. We also note that as we explained in the CY 2012 PFS final rule with comment period (76 FR 73214), we could not accept the invoices accompanying the AMA RUC's recommendation for CPT Code 77373 to update the price of the ''SRS system, SBRT, six systems, average'' equipment (ER083). Each of these invoices included line items that we would not accept as part of the cost of the equipment, such as costs for training technologists to use the equipment, and the prices for these items were not separately identifiable. Therefore, we did not update the equipment price for ER083 in establishing interim final direct PE inputs for CY 2012. Were we to receive updated invoices through the process established during CY 2012 that did not include embedded costs that we would not accept as part of the cost of the equipment, we would consider those invoices in rulemaking for CY 2014.

Comment: Many commenters suggested that reductions in Medicare payment rates for these services would put serious financial strain on community radiation oncology practices, and result in significant negative impact on patient access to life-saving cancer treatment, particularly in rural communities. One commenter provided the results of an informal study that suggested that if the proposed RVUs become effective for CY 2013, many providers will stop providing charity care, lay off staff, limit hours of operation, refrain from purchasing new equipment, limit or stop accepting Medicare patients, or consolidate or close practice locations.

Response: We appreciate and share commenters' concerns regarding Medicare beneficiaries' access to care for radiation treatment services. While we share these concerns in general, we believe that accurately valuing services promotes Medicare beneficiaries' access to many different kinds of important services paid under the PFS, including radiation treatment. We continue to be interested in information related to beneficiaries' access to these kinds of services, and we will monitor for evidence of such problems. We would welcome being alerted to access problems, should they arise. At present, we do not have reason to believe that the proposed changes in procedure time assumptions, in conjunction with other corresponding updates in the direct PE inputs for these services, will jeopardize access to care for Medicare beneficiaries. We note that the final PE RVUs for these services, based on direct PE inputs updated with information provided by commenters, are significantly greater than those reflected in the proposed rule. We also note that the specialty-level impact of this final rule with comment period is significantly reduced relative to the policy as proposed. We direct interested readers to the section VIII.C. of this final rule with comment period regarding the specialty-level impacts of this and other finalized policies.

Comment: Many commenters objected to CMS' assumptions that the services would be more costly for facilities such as hospital outpatient departments that generally have Emergency Medical Treatment and Labor Act (EMTALA) obligations and standby capacity than for free-standing centers or offices. These commenters stated that the cost structure and the services furnished in freestanding and hospital outpatient settings are the same. These commenters stated that, while outpatient hospital departments may have to maintain standby capacity, they do not typically furnish IMRT 24 hours per day, seven days a week nor do the radiation oncology departments of hospitals generally furnish radiation treatment to higher acuity patients than the patients who receive services in physicians' offices or freestanding clinics.

Several other commenters suggested that the payment decrease expected to result from this proposal will force patients into the more expensive hospital setting and patients will be steered toward treatment options that result in greater financial returns. These commenters stated that this migration will increase costs both to the Medicare program and to patients through higher co-insurance payments. Others suggested that significant differences between nonfacility PFS and OPPS payment are likely to result in consolidation of free-standing cancer centers and hospitals that will reduce competition, inhibit access to care, and undermine focused care for cancer patients.

Response: As we stated in the proposal, we continue to believe that high-volume services, such as IMRT, that are widely furnished in both nonfacility and facility settings are highly unlikely to be more resource-intensive in freestanding radiation therapy centers or physicians' offices than when furnished in facilities like hospitals. We agree with commenters that the direct costs of furnishing the service may be similar, but we continue to believe that hospitals are likely to incur additional indirect costs. For example, hospitals incur greater costs for maintaining the capacity to furnish services 7 days per week, 24 hours per day, even if IMRT delivery is not typically furnished during all of those hours. As we have already noted, the disparity between OPPS and PFS payment is even greater than a direct comparison of the payment rates would suggest. OPPS payment for CPT code 77148 includes packaged payment for image guidance, which is almost always furnished and billed with CPT code 77418. The PFS continues to make separate payment for several forms of image guidance.

We understand commenters' concerns regarding the inadvertent impact that financial incentives may make on the usual site of service for particular services. We believe that utilizing the most accurate cost inputs possible is a reasonable approach to mitigating the impact of such potential incentives.

As a result of the comments we received regarding our proposal to change the procedure time assumptions used in determining direct PE inputs for CPT codes 77418 and 77373, we are finalizing our proposals to adjust the procedure time assumption for IMRT delivery (CPT code 77418) to 30 minutes and to adjust the procedure time assumption for SBRT delivery (CPT code 77373) to 60 minutes. These codes continue to include clinical labor time for preparatory and follow-up tasks in addition to revisions to the procedure times. Based on comments received regarding additional updates to the direct PE inputs for these services, we are also adjusting other direct PE inputs for these services on an interim final basis for CY 2013. Based on comments received on our proposal, we are incorporating a second radiation therapist for CPT code 77418. The second therapist will be allocated 30 minutes of service period time, consistent with the first. Furthermore, we are incorporating a new equipment

item called ''IMRT accelerator'' to replace the linear accelerator (ER010) and collimator (ER017) used as current direct PE inputs for CPT code 77418. Based on the evidence submitted by commenters, the new equipment item will be priced at $2,641,783 in the direct PE input database. Additionally, we are incorporating the radiation treatment vault (ER056) and water chiller (ER065) as direct PE inputs for both CPT codes 77418 and 77373. We are also updating the price of the ''laser, diode, for patient positioning (Probe)'' (ER040) from $7,678 to $18,160. We are adopting these direct PE inputs on an interim basis for CY 2013 and these values are reflected in the CY 2013 PFS direct PE input database. That database is available under downloads for the CY 2013 PFS final rule with comment period on the CMS Web site at: *http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage*. We also note that the PE RVUs included in Addenda B and C reflect these interim direct PE inputs.

These two IMRT and SBRT treatment delivery codes are PE only codes and are fairly unique in that the resulting RVUs are largely comprised of resources for staff and equipment based on the minutes associated with clinical labor. There are several other codes on the PFS established through the same methodology. As we previously stated, we believe that the procedure time assumptions for these kinds of services have not been subject to all of the same mechanisms recently used by CMS in the valuation of the physician work component of PFS payment. In light of observations about publicly available procedure times for CPT codes 77418 (IMRT treatment delivery) and 77373 (SBRT treatment delivery) and public awareness of potential adverse financial incentives associated with IMRT treatment delivery in particular, we believe that similar codes may be potentially misvalued.

Therefore, consistent with the requirement in section 1848(c)(2)(K)(ii) of the Act to examine other codes determined to be appropriate by the Secretary, we proposed to review and make adjustments to CPT codes with stand-alone procedure time assumptions used in developing nonfacility PE RVUs. These procedure time assumptions are not based on physician time assumptions. We prioritized for review CPT codes that have annual Medicare allowed charges of $100,000 or more, include direct equipment inputs that amount to $100 or more, and have PE procedure times of greater than 5 minutes. We did not propose to include in this category services with payment rates subject to the OPPS cap (as specified in the statute under section 1848(b)(4) of the Act and listed in Addendum G to this proposed rule) or services with PE minutes established through code descriptors. (For example, an overnight monitoring code might contain 480 minutes of monitoring equipment time to account for 8 hours of overnight monitoring.) The CPT codes meeting these criteria appear in Table 8. We recognized that there are other CPT codes that are valued in the same manner. We may consider evaluating those services as potentially misvalued codes in future rulemaking.

For the services in Table 8, we requested recommendations from the AMA RUC and other public commenters on the appropriate direct PE inputs for these services. We encourage the use of valid and reliable alternative data sources when developing recommended values, including electronic medical records (with personally-identifiable information redacted) and other independent data sources. We note that many of the CPT codes in Table 8 have been identified through other potentially misvalued code screens and have been recently reviewed. Given our concerns with the inputs for the recently reviewed IMRT and SBRT direct PE inputs discussed above, we believe it is necessary to re-review other recently reviewed services with stand-alone PE procedure time.

TABLE 8—SERVICES WITH STAND-ALONE PE PROCEDURE TIME

CPT code	Short descriptor
77280	Set radiation therapy field.
77285	Set radiation therapy field.
77290	Set radiation therapy field.
77301	Radiotherapy dose plan imrt.
77338	Design mlc device for imrt.
77372	Srs linear based.
77373	Sbrt delivery.
77402	Radiation treatment delivery.
77403	Radiation treatment delivery.
77404	Radiation treatment delivery.
77406	Radiation treatment delivery.
77407	Radiation treatment delivery.
77408	Radiation treatment delivery.
77409	Radiation treatment delivery.
77412	Radiation treatment delivery.
77413	Radiation treatment delivery.
77414	Radiation treatment delivery.
77416	Radiation treatment delivery.
77418	Radiation tx delivery imrt.
77600	Hyperthermia treatment.
77785	Hdr brachytx 1 channel.
77786	Hdr brachytx 2–12 channel.
77787	Hdr brachytx over 12 chan.
88348	Electron microscopy.

Comment: Several commenters objected to our proposal to review these codes. Some of these commenters objected to the premise that the procedure time assumptions for these services have not been subject to the same scrutiny as for services with procedure time assumptions tied directly to physician time. One of these commenters explained that the AMA RUC process of reviewing direct practice expense inputs involves three main levels of expert panel review: specialty society expert panel review and attestation of the data provided; RUC Practice Expense Subcommittee review; and full RUC member review. Other commenters suggested that many of the identified services have procedure time assumptions related to physician time and therefore should be removed from the list. Another commenter claimed that services with professional and technical components should be removed from the list since services with professional components ought not to be considered ''stand-alone.'' Another commenter suggested that CPT code CPT Code 77600 should be removed from the list since few -TC claims had been submitted. One commenter claimed that the AMA RUC had extensive discussions regarding the procedure time assumptions used in developing direct PE inputs for some of the codes, so that those codes should be removed from the list.

Response: As we stated in the proposal, we believe that the procedure time assumptions used in developing direct PE inputs for these services have not been subject to the same rigor as other recently-reviewed services. Procedure time assumptions developed and validated by a series of expert panels have not generally been subject to the same scrutiny as the times developed through survey data or data gathered through electronic health records, for example. We identified the services by calling the services ''stand-alone PE procedure time,'' because they are services that include significant amounts of time resources allocated outside of physician time. We understand that some of these codes may be ''technical only'' codes and that in other cases these codes are used in reporting both the professional and technical component using the -TC or -26 modifiers, but we do not believe the divergent reporting mechanisms would mean that any services should be removed from the list. For CPT code 77600, we note that while few services were reported with the -TC modifier, many more services were billed globally in the nonfacility setting, so we continue to believe that the procedure time assumption that determines the inputs used in valuing the technical

component of the payment remains relevant for prioritization.

While we assume that the AMA RUC deliberated on the procedure time assumptions used in developing the direct PE input recommendations for these services, we do not believe that extensive committee discussions would mitigate the need for more extensive review of these services as potentially misvalued since the assumptions that were developed through discussion could benefit from the objective data of many kinds.

Comment: MedPAC supported CMS's proposal to review these services. However, it expressed concern that CMS exempted imaging services that are subject to the OPPS cap from this review. MedPAC pointed out that the procedure time assumptions used in several high-priced and high-expenditure imaging codes have not been reviewed by the AMA RUC since 2002 or 2003 and may be too high. MedPAC also noted that recent advances in CT and MRI machines have made it possible to scan patients faster and that even practitioners who are using older equipment could be performing studies in less time as they become more familiar with the procedures and equipment.

Response: We appreciate MedPAC's support for this proposal. We agree that the procedure time assumptions used in imaging codes subject to the OPPS cap may be inaccurate or outdated. We did not propose to prioritize review of these procedure time assumptions since the services are subject to the OPPS payment caps, but we will consider the appropriate means for reviewing the procedure time assumptions for those services in future rulemaking.

Based on the comments we received, we are finalizing our proposal to review and make adjustments to CPT codes with stand-alone procedure time assumptions used in developing nonfacility PE RVUs.

c. Services With Anomalous Time

Each year when we publish the PFS proposed and final rules, we publish on the CMS Web site several files that support annual PFS ratesetting. One of these supporting files is the physician time file, which lists the physician time associated with the HCPCS codes on the PFS. The physician time file associated with the CY 2013 PFS final rule with comment period is available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*.

As we stated in the CY 2013 PFS proposed rule, in our review of potentially misvalued codes and their inputs, we became aware of several HCPCS codes that have anomalous times in our physician time file. Physician work is a measure of physician time and intensity, so there should be no services that have payable physician work RVUs but no time in the physician time file, and there should be no payable services with time in the physician time file and no physician work RVUs. For CY 2013 we proposed to make the physician time file changes detailed below to address these anomalous time file entries.

(1) Review of Services With Physician Work and No Listed Physician Time

CPT code 94014 (Patient-initiated spirometric recording per 30-day period of time; includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and physician review and interpretation) has a physician work RVU of 0.52 and for CY 2012 was listed with 0 physician time. CPT code 94014 is a global service that includes CPT code 94015 (Patient-initiated spirometric recording per 30-day period of time; recording (includes hook-up, reinforced education, data transmission, data capture, trend analysis, and periodic recalibration)) (the technical component), and CPT code 94016 (Patient-initiated spirometric recording per 30-day period of time; physician review and interpretation only) (the professional component). We stated that we believe it is appropriate for the physician time of CPT code 94014 to match the physician time of the code's component professional service—CPT code 94016. As such, for CPT code 94014 for CY 2013, we proposed to assign 2 minutes of pre-service evaluation time, and 20 minutes of intra-service time, which matches the times associated with CPT code 94016.

HCPCS codes G0117 (Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist) and G0118 (Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist) both have physician work RVUs (0.45, and 0.17, respectively), but neither code was included in the CY 2012 physician time file. HCPCS codes G0117 and G0118 have a PFS procedure status indicator of T indicating that these services are only paid if there are no other services payable under the PFS billed on the same date by the same provider.

In the CY 2002 PFS final rule (66 FR 55274), we crosswalked the physician work of HCPCS code G0117 from CPT code 99212 (Level 2 office or other outpatient visit, established patient), and we crosswalked the physician work of HCPCS code G0118 from CPT code 99211 (Level 1 office or other outpatient visit, established patient). Based on these finalized physician work crosswalks, we proposed to assign HCPCS code G0117 physician times matching CPT code 99212, and HCPCS code G0118 physician times matching CPT code 99211. Specifically, we proposed 2 minutes of pre-service time, 10 minutes of intra-service time, and 4 minutes of immediate post-service time for HCPCS code G0117, and 5 minutes of intra-service time, and 2 minutes of immediate post-service time for HCPCS code G0118.

HCPCS code G0128 (Direct (face-to-face with patient) skilled nursing services of a registered nurse provided in a comprehensive outpatient rehabilitation facility, each 10 minutes beyond the first 5 minutes) currently has a physician work RVU (0.08), but was not listed in the CY 2012 physician time file. In the CY 2013 proposed rule we stated that, after review of this HCPCS code, we do not believe that HCPCS code G0128 describes a service that includes physician work. Time for a registered nurse to furnish the service is included in the PE for the code. As such, for CY 2013, we proposed to remove the physician work RVU for HCPCS code G0128. HCPCS code G0128 continues to have PE and malpractice expense RVUs.

HCPCS codes G0245 (Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: (1) The diagnosis of LOPS; (2) a patient history; (3) a physical examination that consists of at least the following elements: (a) Visual inspection of the forefoot, hindfoot and toe web spaces; (b) evaluation of a protective sensation; (c) evaluation of foot structure and biomechanics; (d) evaluation of vascular status and skin integrity; and (e) evaluation and recommendation of footwear; and (4) patient education), G0246 (Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: (1) A patient history; (2) a physical examination that includes: (a) Visual inspection of the forefoot, hindfoot and toe web spaces; (b) evaluation of protective sensation; (c) evaluation of foot structure and biomechanics; (d) evaluation of vascular status and skin integrity; and (e) evaluation and recommendation of

footwear; and (3) patient education), and G0247 (Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include, the local care of superficial wounds (that is, superficial to muscle and fascia) and at least the following if present: (1) Local care of superficial wounds; (2) debridement of corns and calluses; and (3) trimming and debridement of nails) have physician work RVUs of 0.88, 0.45, and 0.50, respectively, but were not listed in the CY 2012 physician time file. HCPCS codes G0245, G0246, and G0247 have a procedure status indicator of R on the PFS indicating that coverage of these services is restricted.

In the CY 2003 PFS final rule (67 FR 79990), we crosswalked the physician work of HCPCS code G0245 from CPT code 99202 (Level 2 office or other outpatient visits, new patient), we crosswalked the physician work of HCPCS code G0246 from CPT code 99212, and we crosswalked the physician work of HCPCS code G0257 from CPT code 11040 (Debridement; skin; partial thickness). Based on these finalized physician work crosswalks, we proposed to assign HCPCS code G0245 physician times matching CPT code 99202, HCPCS code G0246 physician times matching CPT code 99212, and HCPCS code G0247 physician times matching CPT code 11040. Specifically, for HCPCS code G0245 we proposed 2 minutes of pre-service time, 15 minutes of intra-service time, and 5 minutes of immediate post-service time. For HCPCS code G0246 we proposed 2 minutes of pre-service time, 10 minutes of intra-service time, and 4 minutes of immediate post-service time. For HCPCS code G0247 we proposed 7 minutes of pre-service time, 10 minutes of intra-service time, and 7 minutes of immediate post-service time.

HCPCS code G0250 (Physician review, interpretation, and patient management of home INR (International Normalized Ratio) testing for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include 4 tests) has a physician work RVU of 0.18 but was not listed in the CY 2012 physician time file. HCPCS code G0250 has a procedure status indicator of R on the PFS indicating that coverage of this service is restricted. In the CY 2003 final rule (67 FR 79991), we assigned HCPCS code G0250 a work RVU of 0.18, which corresponds to the work RVU of CPT code 99211. While we did not articulate this as a direct crosswalk in the CY 2003 final rule, after clinical review we believe that HCPCS code G0250 continues to require similar work as CPT code 99211, and should have the same amount of physician time as CPT code 99211. As such, we proposed to assign HCPCS code G0250 the same physician time as CPT code 99211. Specifically, for HCPCS code G0250 we proposed 5 minutes of intra-service time and 2 minutes of immediate post-service time.

During our annual review of new, revised, and potentially misvalued CPT codes, the assessment of physician time used to furnish a service is an important part of the clinical review when determining the appropriate work RVU for a service. However, the time in the physician time file is not used to automatically adjust the physician work RVUs outside of that clinical review process. As such, the proposed addition of physician time to the HCPCS codes discussed above will have no impact on the current physician work RVUs for these services.

The time data in the physician time file is used in the PE methodology described in section II.A.2. In creating the indirect practice cost index (IPCI), we calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services furnished by the specialty. The proposed addition of physician time to the HCPCS codes discussed above will affect the aggregate pools of indirect PE at the specialty level. However because the services discussed above have low utilization and low total time, the impact of the physician time changes on the IPCI is negligible, and likely would have a modest impact if any on the PE RVUs at the individual code level.

Below is a summary of the comments we received on our proposed changes for PFS services with physician work and no listed time in the physician time file.

Comment: Commenters agreed with our proposed time changes for these services. The AMA RUC noted that historically the AMA RUC has not provided work or time recommendations for HCPCS G-codes, but that they will update the AMA RUC database to reflect these new physician time components.

Response: We thank commenters for their input on the times associated with these services. We are finalizing our proposals without modification. These proposed adjustments are reflected in the physician time file associated with this CY 2013 final rule with comment period, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/.*

(2) Review of Services With No Physician Work and Listed Time in the Physician Time File

There are a number of services that have no physician work RVUs, yet include time in the physician time file. Many of these services are not payable under the PFS or are contractor priced services where the physician time is not used to nationally price the services on the PFS. We did not propose to remove the physician time from the time file for these services as the time has no effect on the calculation of RVUs for the PFS. However, there are several CPT codes, listed in Table 9, that are payable under the PFS and have no physician work RVUs yet include time in the physician time file. We proposed to remove the physician time from the time file for these seven CPT codes.

TABLE 9—PAYABLE CPT CODES WITH PHYSICIAN TIME AND NO PHYSICIAN WORK

CPT Code	Short descriptor	PFS Procedure status	CY 2012 Total physician time (minutes)
22841	Insert spine fixation device	B (Bundled, not separately payable)	5
51798	Us urine capacity measure	A (Active, payable)	9
95990	Spin/brain pump refill & main	A (Active, payable)	40
96904	Whole body photography	R (Restricted coverage)	80
96913	Photochemotherapy uv-a or b	A (Active, payable)	90
97545	Work hardening	R (Restricted coverage)	120

TABLE 9—PAYABLE CPT CODES WITH PHYSICIAN TIME AND NO PHYSICIAN WORK—Continued

CPT Code	Short descriptor	PFS Procedure status	CY 2012 Total physician time (minutes)
97602	Wound(s) care non-selective	B (Bundled, not separately payable)	36

As mentioned above and as discussed in section II.A.2. of this final rule with comment period, to create the IPCI used in the PE methodology, we calculated specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services performed by the specialty. As we stated in the CY 2013 PFS proposed rule, the proposed removal of physician time from the CPT codes discussed above will affect the aggregate pools of indirect PE at the specialty level. However because the services discussed above have low utilization and/or low total time, the impact of the physician time changes on the IPCI is negligible, and likely will have a modest impact if any on the PE RVUs at the individual code level.

Below is a summary of the comments we received on our proposed changes for PFS services with no physician work and listed time in the physician time file.

Comment: Commenters agreed with our proposal to remove the time listed in the physician time file for CPT codes 22841 (Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)), 95990 (Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump, when performed;), 96904 (Whole body integumentary photography, for monitoring of high risk patients with dysplastic nevus syndrome or a history of dysplastic nevi, or patients with a personal or familial history of melanoma), and 96913 (Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4–8 hours of care under direct supervision of the physician (includes application of medication and dressings)). Commenters noted that CPT code 51798 (Measurement of post-voiding residual urine and/or bladder capacity by ultrasound, non-imaging) likely had time listed in the physician time file because the AMA RUC had recommended work RVUs for the service however CMS assigned only practice expense. Similarly, commenters noted that CPT code 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) likely had time included in the physician time final because the AMA RUC HCPAC recommended work RVUs for the service, however CMS assigned CPT code 97602 a bundled procedure status. Commenters noted that CPT code 97545 (Work hardening/conditioning; initial 2 hours) has a restricted procedure status, but inherently involves 2 hours of work, and requested that CMS maintain the time entry in the physician time file for this service to assist other payers and stakeholder in making payment policy decisions.

Response: We thank commenters for their input on the times associated with these services. After reviewing the comments, we are finalizing our proposal to remove the time from the physician time file for CPT codes 22841, 51798, 95990, 96913, and 97602. We will maintain the time entry in the physician time file for CPT code 97545, as requested; while this CPT code has a restricted procedure status indicator, it is still payable in some circumstances. CPT code 96904 also has a restricted procedure status indicator and is payable in some circumstances. For consistent treatment of these two CPT codes, we will also maintain the time entry in the physician time file for CPT code 96904. These adjustments are reflected in the physician time file associated with this CY 2013 PFS final rule with comment period, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/.*

4. Expanding the Multiple Procedure Payment Reduction Policy

Medicare has long employed multiple procedure payment reduction (MPPR) policies to adjust payment to more appropriately reflect reduced resources involved with furnishing services that are frequently furnished together. Under these policies, we reduce payment for the second and subsequent services within the same MPPR category furnished in the same session or same day. These payment reductions reflect efficiencies that typically occur in either the practice expense (PE) or professional work or both when services are furnished together. With the exception of a few codes that are always reported along with another code, the Medicare PFS values services independently to recognize relative resources involved when the service is the only one furnished in a session. While our general policy for MPPRs precedes the Affordable Care Act, MPPRs address the fourth category of potentially misvalued codes identified in section 1848(c)(2)(K) of the Act which is ''multiple codes that are frequently billed in conjunction with furnishing a single service'' (see 75 FR 73216).

For CY 2013, we proposed to continue our work to recognize resource efficiencies when certain services are furnished together. We proposed to apply an MPPR to the technical component (TC) of certain cardiovascular and ophthalmology diagnostic tests. As discussed in the CY 2012 final rule with comment period (76 FR 73079), we are also proceeding with applying the current MPPR policy for imaging services to services furnished in the same session by physicians in the same group practice.

a. Background

Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same beneficiary by a single physician or physicians in the same group practice on the same day, largely based on the presence of efficiencies in the PE and pre- and post-surgical physician work. Effective January 1, 1995, the MPPR policy, with this same percentage reduction, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806, and 78807). In the CY 1995 PFS final rule with comment period (59 FR 63410), we indicated that we would consider applying the policy to other diagnostic tests in the future.

Consistent with recommendations of MedPAC in its March 2005 Report to the Congress on Medicare Payment Policy, for CY 2006 PFS, we extended the MPPR policy to the TC of certain

diagnostic imaging procedures furnished on contiguous areas of the body in a single session (70 FR 70261). This MPPR policy recognizes that for the second and subsequent imaging procedures furnished in the same session, there are some efficiencies in clinical labor, supplies, and equipment time. In particular, certain clinical labor activities and supplies are not duplicated for subsequent imaging services in the same session and, because equipment time and indirect costs are allocated based on clinical labor time, we also reduced those accordingly.

The imaging MPPR policy originally applied to computed tomography (CT) and computed tomographic angiography (CTA), magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA), and ultrasound services within 11 families of codes based on imaging modality and body region and only applied to procedures furnished in a single session involving contiguous body areas within a family of codes, not across families. Additionally, the MPPR policy originally applied to TC-only services and to the TC of global services, but not to professional component (PC) services.

There have been several revisions to this policy since it was originally adopted. Under the current imaging MPPR policy, full payment is made for the TC of the highest paid procedure, and payment for the TC is reduced by 50 percent for each additional procedure subject to this MPPR policy. We originally planned to phase in the imaging MPPR policy over a 2-year period, with a 25 percent reduction in CY 2006 and a 50 percent reduction in CY 2007 (70 FR 70263). However, the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) amended the statute to place a cap on the PFS payment amount for most imaging procedures at the amount paid under the hospital outpatient prospective payment system (OPPS). In view of this new OPPS payment cap, we decided in the PFS final rule with comment period for CY 2006 that it would be prudent to retain the imaging MPPR at 25 percent while we continued to examine the appropriate payment levels (71 FR 69659). The DRA also exempted reduced expenditures attributable to the imaging MPPR policy from the PFS BN provision. Effective July 1, 2010, section 1848(b)(4)(C) of the Act increased the MPPR on the TC of imaging services under the policy established in the CY 2006 PFS final rule with comment period from 25 to 50 percent. Section 1848(c)(2)(B)(v)(IV) of the Act exempted the reduced expenditures attributable to this further change from the PFS BN provision.

In the July 2009 U.S. Government Accountability Office (GAO) report entitled, *Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided Together,* the GAO recommended that we take further steps to ensure that fees for services paid under the PFS reflect efficiencies that occur when services are furnished by the same physician to the same beneficiary on the same day. The GAO recommended the following: (1) expanding the existing imaging MPPR policy for certain services to the PC to reflect efficiencies in physician work for certain imaging services; and (2) expanding the MPPR to reflect PE efficiencies that occur when certain nonsurgical, nonimaging services are furnished together. The GAO report also encouraged us to focus on service pairs that have the most impact on Medicare spending.

In its March 2010 report, MedPAC noted its concerns about mispricing of services under the PFS. MedPAC indicated that it would explore whether expanding the unit of payment through packaging or bundling would improve payment accuracy and encourage more efficient use of services. In the CYs 2009 and 2010 PFS proposed rules (73 FR 38586 and 74 FR 33554, respectively), we stated that we planned to analyze nonsurgical services commonly furnished together (for example, 60 to 75 percent of the time) to assess whether an expansion of the MPPR policy could be warranted. MedPAC encouraged us to consider duplicative physician work, as well as PE, in any expansion of the MPPR policy.

Section 1848(c)(2)(K) of the Act specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values. As a first step in applying this provision, in the CY 2010 final rule with comment period, we implemented a limited expansion of the imaging MPPR policy to additional combinations of imaging services.

Effective January 1, 2011, the imaging MPPR applies regardless of code family; that is, the policy applies to multiple imaging services furnished within the same family of codes or across families. This policy is consistent with the standard PFS MPPR policy for surgical procedures that does not group procedures by body region. The current imaging MPPR policy applies to CT and CTA, MRI and MRA, and ultrasound procedures furnished to the same beneficiary in the same session, regardless of the imaging modality, and is not limited to contiguous body areas.

As we noted in the CY 2011 PFS final rule with comment period (75 FR 73228), while section 1848(c)(2)(B)(v)(VI) of the Act specifies that reduced expenditures attributable to the increase in the imaging MPPR from 25 to 50 percent (effective for fee schedules established beginning with 2010 and for services furnished on or after July 1, 2010) are excluded from the PFS BN adjustment, it does not apply to reduced expenditures attributable to our policy change regarding additional code combinations across code families (noncontiguous body areas) that are subject to BN under the PFS. The complete list of codes subject to the CY 2011 MPPR policy for diagnostic imaging services is included in Addendum F.

As a further step in applying the provisions of section 1848(c)(2)(K) of the Act, on January 1, 2011, we implemented an MPPR for therapy services. The MPPR applies to separately payable ''always therapy'' services, that is, services that are only paid by Medicare when furnished under a therapy plan of care. As we explained in the CY 2011 PFS final rule with comment period (75 FR 73232), the therapy MPPR does not apply to contractor-priced codes, bundled codes, and add-on codes. The complete list of codes subject to the MPPR policy for therapy services is included in Addendum H.

This MPPR for therapy services was first proposed in the CY 2011 proposed rule (75 FR 44075) as a 50 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single beneficiary in a single day. It applies to services furnished by an individual or group practice or ''incident to'' a physician's service. However, in response to public comments, in the CY 2011 PFS final rule with comment period (75 FR 73232), we adopted a 25 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single beneficiary in a single day.

Subsequent to publication of the CY 2011 PFS final rule with comment period, section 3 of the Physician Payment and Therapy Relief Act of 2010 (PPTRA) (Pub. L. 111–286) revised the payment reduction percentage from 25 percent to 20 percent for therapy services for which payment is made under a fee schedule under section 1848 of the Act (which are services furnished

in office settings, or non-institutional services). The payment reduction percentage remains at 25 percent for therapy services furnished in institutional settings. Section 4 of the PPTRA exempted the reduced expenditures attributable to the therapy MPPR policy from the PFS BN provision. Under our current policy as amended by the PPTRA, for institutional services, full payment is made for the service or unit with the highest PE and payment for the PE component for the second and subsequent procedures or additional units of the same service is reduced by 25 percent. For non-institutional services, full payment is made for the service or unit with the highest PE and payment for the PE component for the second and subsequent procedures or additional units of the same service is reduced by 20 percent.

This MPPR policy applies to multiple units of the same therapy service, as well as to multiple different ''always therapy'' services, when furnished to the same beneficiary on the same day. The MPPR applies when multiple therapy services are billed on the same date of service for one beneficiary by the same practitioner or facility under the same National Provider Identifier (NPI), regardless of whether the services are furnished in one therapy discipline or multiple disciplines, including physical therapy, occupational therapy, or speech-language pathology.

The MPPR policy applies in all settings where outpatient therapy services are paid under Part B. This includes both services that are furnished in the office setting and paid under the PFS, as well as institutional services that are furnished by outpatient hospitals, home health agencies, comprehensive outpatient rehabilitation facilities (CORFs), and other entities that are paid for outpatient therapy services at rates based on the PFS.

In its June 2011 Report to Congress, MedPAC highlighted continued growth in ancillary services subject to the in-office ancillary services exception. The in-office ancillary exception to the general prohibition under section 1877 of the Act as amended by the Ethics in Patient Referrals Act, also known as the Stark law, allows physicians to refer Medicare beneficiaries for designated health services, including imaging, radiation therapy, home health care, durable medical equipment, clinical laboratory tests, and physical therapy, to entities with which they have a financial relationship under specific conditions. MedPAC recommended that we apply a MPPR to the PC of diagnostic imaging services furnished by the same practitioner in the same session as one means to curb excess self-referral for these services. The GAO already had made a similar recommendation in its July 2009 report.

In continuing to apply the provisions of section 1848(c)(2)(K) of the Act regarding potentially misvalued codes that result from ''multiple codes that are frequently billed in conjunction with furnishing a single service,'' in the CY 2012 final rule (76 FR 73071), we expanded the MPPR to the PC of Advanced Imaging Services (CT, MRI, and Ultrasound), that is, the same list of codes to which the MPPR on the TC of advanced imaging already applied (see Addendum F). Thus, this MPPR policy now applies to the PC and the TC of certain diagnostic imaging codes. Specifically, we expanded the payment reduction currently applied to the TC to apply also to the PC of the second and subsequent advanced imaging services furnished by the same physician (or by two or more physicians in the same group practice) to the same beneficiary in the same session on the same day. However, in response to public comments, in the CY 2012 PFS final rule with comment period, we adopted a 25 percent payment reduction to the PC component of the second and subsequent imaging services.

Under this policy, full payment is made for the PC of the highest paid advanced imaging service, and payment is reduced by 25 percent for the PC for each additional advanced imaging service furnished to the same beneficiary in the same session. This policy was based on the expected efficiencies in furnishing multiple services in the same session due to duplication of physician work, primarily in the pre- and post-service periods, but with some efficiencies in the intraservice period.

This policy is consistent with the statutory requirement for the Secretary to identify, review, and adjust the relative values of potentially misvalued services under the PFS as specified by section 1848(c)(2)(K) of the Act. This policy is also consistent both with our longstanding policy on surgical and nuclear medicine diagnostic procedures, under which we apply a 50 percent payment reduction to second and subsequent procedures. Furthermore, it was responsive to continued concerns about significant growth in imaging spending, and to MedPAC (March 2010 and June 2011) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies.

In the CY 2012 proposed rule (76 FR 42812), we also invited public comment on the following MPPR policies under consideration. We noted that any proposals would be presented in future rulemaking and subject to further public comment:

- Apply *the MPPR to the TC of All Imaging Services.* This approach would apply a payment reduction to the TC of the second and subsequent imaging services furnished in the same session. Such an approach could define imaging consistent with our existing definition of imaging for purposes of the statutory cap on PFS payment at the OPPS rate including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography. Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

Such an approach would be based on the expected efficiencies due to duplication of clinical labor activities, supplies, and equipment time when multiple services are furnished together. This approach would apply to approximately 530 HCPCS codes, including the 119 codes to which the current imaging MPPR applies. Savings would be redistributed to other PFS services as required by the statutory PFS BN provision.

- *Apply the MPPR to the PC of All Imaging Services.* This approach would apply a payment reduction to the PC of the second or subsequent imaging services furnished in the same encounter. Such an approach could define imaging consistent with our existing definition of imaging for the cap on payment at the OPPS rate. Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

Such an approach would be based on efficiencies due to duplication of physician work primarily in the pre- and post-service periods, with smaller efficiencies in the intraservice period, when multiple services are furnished together. This approach would apply to approximately 530 HCPCS codes, including the 119 codes to which the current imaging MPPR applies. Savings would be redistributed to other PFS services as required by the statutory PFS BN provision.

- *Apply the MPPR to the TC of All Diagnostic Tests.* This approach would apply a payment reduction to the TC of the second and subsequent diagnostic tests (such as radiology, cardiology, audiology, etc.) furnished in the same

encounter. Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

Such an approach would be based on the expected efficiencies due to duplication of clinical labor activities, supplies, and equipment time when multiple services are furnished together. The approach would apply to approximately 700 HCPCS codes, including the approximately 560 HCPCS codes that are currently subject to the OPPS cap. The savings would be redistributed to other PFS services as required by the statutory PFS BN provision.

b. MPPR Policy Clarifications

(1) Apply the MPPR to Two Nuclear Medicine Procedures

As indicated previously, effective January 1, 1995, we implemented an MPPR for six nuclear medicine codes. Under the current policy, full payment is made for the highest paid procedure, and payment is reduced by 50 percent for the second procedure furnished to the same beneficiary on the same day. As noted in the CY 2013 proposed rule (77 FR 44748), due to a technical error, the MPPR is not being applied to CPT codes 78306 (Bone imaging; whole body) when followed by CPT code 78320 (Bone imaging; SPECT). We will apply the MPPR to these procedures effective January 1, 2013. We received the following comment on this provision:

Comment: A commenter indicated that continuing to apply and extend the MPPR for nuclear medicine procedures is unwarranted and inconsistent with CMS' aim to improve payment accuracy. The commenter noted that decisions made in 1995 were based on qualitative assessments rather than on rigorous data analysis. The commenter believes that with the wealth of data now available, and improved techniques in data analysis, careful evaluation of the applicability of the MPPR for all six nuclear medicine procedures is merited.

Response: We acknowledge the commenter's concerns, but we neither proposed discontinuing the MPPR on nuclear medicine procedures, nor extending it to new codes. Rather, we noted that the MPPR under current policy was, for technical reasons, not being applied to CPT code 78306 (Bone imaging; whole body) when followed by CPT code 78320 (Bone imaging; SPECT), and provided notification that the MPPR would be applied effective January 1, 2013. Accordingly, we are finalizing this technical correction effective for services furnished on or after January 1, 2013.

(2) Apply the MPPR to the PC and TC of Advanced Imaging Procedures to Physicians in the Same Group Practice

As indicated in the CY 2012 final rule (76 FR 73077–73079), we finalized a policy to apply the MPPR to the PC and TC of the second and subsequent advanced imaging procedures furnished to the same beneficiary in the same session by a single physician or by multiple physicians in the same group practice. Due to operational limitations, we did not apply this MPPR to multiple physicians in the same group practice during CY 2012. In addition, after we issued the CY 2012 final rule with comment period, some commenters stated that they had not commented on the application of the MPPR to physicians in the same group practice because that policy was not explicit in the CY 2012 proposed rule discussion expanding the MPPR for advanced imaging to the PC. As noted in the CY 2013 proposed rule (77 FR 44748), we have resolved the operational problems and, therefore, for services furnished on or after January 1, 2013 we will apply the MPPR to both the PC and the TC of advanced imaging procedures to multiple physicians in the same group practice (same group NPI). Under this policy, the MPPR will apply when one or more physicians in the same group practice furnish services to the same beneficiary, in the same session, on the same day. This policy is consistent with other PFS MPPR policies for surgical and therapy procedures and, effective January 1, 2013, for diagnostic cardiovascular and ophthalmology procedures. We continue to believe that the typical efficiencies achieved when the same physician is furnishing multiple procedures also accrue when different physicians in the same group furnish multiple procedures involving the same beneficiary in the same session. While we agree with commenters that most physicians would not change the way they practice in order to avoid application of the MPPR, we believe application of the imaging MPPR to physicians in the same group practice will ensure that there is no financial incentive for physicians in a group practice to change their behavior to split imaging interpretation services for a beneficiary among different physicians in the group. It is our intention to apply this and future MPPRs to services furnished by one or more physicians in the same group unless we determine for a specific MPPR that the efficiencies associated with an individual physician furnishing multiple procedures do not extend to multiple physicians in the same group practice. We received the following comments on this provision:

Comment: Most commenters opposed applying the MPPR on diagnostic imaging to physicians in the same group practice, specifically to the PC. While many commenters acknowledged minimal efficiencies in the PC of second and subsequent procedures when furnished by the same physician, they maintained that no such efficiencies exist when furnished by multiple physicians.

Commenters maintained that CMS assumes efficiencies exist, but has not presented any clinical evidence or comprehensive resource use analysis to justify claims of efficiency. Commenters do not believe that substantial economy of time or of effort exist. According to commenters, each physician who reviews a beneficiary's imaging results must review the beneficiary's medical history, examine the imaging results, make diagnoses, draft a report, and enter communications with other physicians in the beneficiary's medical chart. Commenters note that none of these actions would take less time or effort when performed by a second physician in the same practice. Commenters do not believe this proposal reflects the true costs incurred by a practice when multiple physicians furnish advanced imaging services to the same beneficiary on the same day. Another commenter noted that cognitive medicine, such as diagnostic imaging cannot have global efficiencies, as every observer needs to independently investigate, collect data, formulate an educated opinion, and furnish a professional assessment.

Commenters maintained that clinical best practice dictates that the images are read by subspecialized, fellowship-trained radiologists, trained to read specific body parts. For example, they stated, radiologists are trained to read either breast, musculoskeletal, body, neurology or oncology images. Commenters indicated that the proposal would penalize or disincentivize practices from having the most appropriate radiologist read the study, which may subject beneficiaries to undue risks.

Commenters also noted that beneficiaries suffering from life-threatening conditions such as trauma, heart attacks, and cancer often require multiple imaging scans to accurately and fully assess extent of injury and monitor disease progression and/or any improvements in condition. This is not uncommon in an urban hospital serving high acuity beneficiaries. Commenters maintained that as the complexity of the

beneficiary case increases, the likelihood that multiple scans and/or series will be needed in a given day increases, and thus the number of physicians needed to review multiple scans and/or regions of the body in a series of scans increases, requiring a variety of sub-specialty-trained radiologists. Commenters concluded that the amount of work in the form of time, effort, and skill, does not diminish in this situation but rather has an additive effect, reflecting the clinical complexity of the beneficiary situation, not a duplication of efforts.

A commenter noted that multi-modality images on a beneficiary are not always interpreted at the same time or by the same physician. According to the commenter, the beneficiary encounter that includes multiple TCs is not directly related to the performance of the PCs by the interpreting physician(s). The commenter indicated that through the use of teleradiology, the interpretations often take place at separate locations and by separate physicians. Finally, the commenter noted that this process allows differently specialized radiologists to interpret different images.

A commenter maintained that CMS' reliance on both the July 2009 GAO report and the March 2010 MedPAC report to support its MPPR policies is fundamentally flawed because such sources do not appear to justify the proposals. The commenter noted that CMS also cites the June 2011 MedPAC report as further support for its MPPR application to the PC of diagnostic imaging services furnished by the same physician in the same session. The commenter indicated that the report's policy recommendation is for a multiple procedure payment reduction to the professional component of diagnostic imaging services furnished by the same practitioner in the same session. The commenter stated that it could be unfair to apply the MPPR to physicians who share a practice.

A commenter recommended that CMS focus on applying the results of the Medicare Imaging Demonstration, and pursuing options to encourage use of appropriateness criteria, as the best solution to any problems of under or overutilization of imaging.

Response: The policy of applying the imaging MPPR to physicians in the same group practice is consistent with other MPPR policies for surgical procedures and therapy services, and effective January 1, 2013, for diagnostic cardiovascular and diagnostic ophthalmology procedures under the PFS. We continue to believe that the typical efficiencies achieved when the same physician is furnishing multiple procedures also accrue when different physicians in the same group furnish multiple procedures involving the same beneficiary. We believe that efficiencies exist in the parts of the service that deal directly with patients, such as gowning and obtaining consent, as well as in the interpretation, where the first completed interpretation is commonly available to the second interpreting physician at the point of interpretation. Although efficiencies may be less when one physician is remote, we still believe that efficiencies are within the ranges that will typically be seen across the many varied combinations of imaging services subject to the MPPR.

We disagree that radiologists are routinely trained to only read organ specific or technology specific images. Radiologists receive broad training that allows them to provide services across multiple technologies and organ systems. Some may choose to more narrowly focus their practice, but in the typical radiology practice across the country, many radiologists continue to provide a broad range of imaging interpretation services.

We agree with the commenter that higher complexity patients may require multiple scans. However, we disagree that this higher complexity negates the efficiencies that are seen with less complex patients. Duplication in technical component, such as greeting and gowning, would continue irrespective of patient complexity. Higher complexity patients, receiving multiple scans, provide greater support for the proposed MPPR policy changes. Since interpretation of an image builds on the clinical framework that the radiologist(s) develops for each patient as she reviews each scan, we believe that interpretation of multiple additional scans require diminishing marginal effort.

Finally, while we agree with commenters that most physicians would not change the way they practice in order to avoid application of the MPPR, we believe application of the imaging MPPR to physicians in the same group practice will ensure that there is no financial incentive for physicians in a group practice to change their behavior to split imaging interpretation services for a beneficiary among different physicians in the group.

It is our intention to apply this and future MPPR policies to services furnished by one or more physicians in the same group. Future modifications may be appropriate if we collect or are provided with data that indicates that the efficiencies associated with an individual physician furnishing multiple procedures do not extend to multiple physicians in the same group practice.

We disagree that we have misinterpreted GAO and MedPAC policy recommendations. MedPAC's June 2011 recommendation for an MPPR on the professional component of imaging services is silent on application to the group practice, but since then, MedPAC has not opposed our proposal to apply the MPPR on the PC and TC of diagnostic imaging to physicians in the same group practice. Finally, the Medicare Imaging Demonstration is designed to test whether the use of decision support systems can improve quality of care by diminishing patient exposure to potentially harmful radiation caused by unnecessary over-utilization of advanced imaging services. The 2-year demonstration has recently completed its first year. The demonstration is a separate initiative and does not specifically address MPPR policy.

Comment: Many commenters noted that administrative considerations prevented us from implementing this policy effective January 1, 2012. Commenters indicated that we have not provided a detailed explanation of how such administrative concerns were rectified.

Response: Our administrative delay in implementing the policy did not involve the merits of the policy but the practicality of implementation. Medicare contractors were unable to make the necessary changes to their systems to effectively operationalize the policy for CY 2012. The necessary system changes have now been made in order for this policy to be operational beginning on January 1, 2013.

Comment: Commenters expressed concern that using the NPI to define a group practice may be inaccurate. Commenters indicated that some diagnostic imaging practice members may belong to more than one NPI group; whereas other practitioners may be part of a smaller NPI group than their corporate structure would suggest. Commenters maintained that attempts to apply the MPPR to physicians in the same group practice using the NPI could lead to unfair application simply due to corporate governance issues. Additionally, commenters noted that radiologists in a group practice may also independently contract to furnish outside interpretations for other groups. Finally, commenters indicated that reliance on the NPI in these cases may lead to confusion and potential compliance concerns.

Response: We have traditionally relied on the group NPI to identify

services furnished in the same group practice as a basis for group practice-level edits across the physician fee schedule. We plan to use the group NPI for applying the MPPR to advanced imaging services at the group practice level beginning in 2013. We appreciate commenter input on this issue and understand that physicians do not always furnish services within their group practice and that the group NPI may reflect several different organizational arrangements. Accordingly, we intend to further explore the issues the commenters raised regarding use of the group NPI to identify services furnished in the same group practice. For example, we could consider using a provider Tax Identification Number (TIN) as an alternative to the group NPI; however, we would need to determine whether this would create other operational problems. Medicare contractors would also require adequate time to make the necessary systems changes. We will consider these issues and make any changes in future rulemaking.

Comment: Various commenters had the following concerns about the definition of a ''session'' and the use of modifier 59:

- Physicians use the 59 modifier appropriately to bypass the MPPR when multiple services are furnished to the same beneficiary in separate sessions on the same day. However, the 59 modifier is also used for the Correct Coding Initiative (CCI) edits, creating a conflict between the two different uses of the modifier. For example, if an MRA of the head and brain are furnished to the same beneficiary on the same day, it may be appropriate to report modifier 59 to bypass the CCI edit. However, the modifier 59 may also be interpreted to bypass the MPPR, which would not be appropriate if the services were furnished in the same session. They stated that this presents a quandary for both radiology practices and Medicare Administrative Contractors.
- CMS has provided no guidance on what constitutes a separate session for professional interpretation, other than ''scans interpreted at widely different times,'' leaving radiology practices vulnerable to differing interpretations by Medicare contractors, including Recovery Audit Contractors.
- Whether CMS' use of the word ''encounter'' is synonymous with ''session.''
- Multiple physicians furnishing the PC on different studies to the same beneficiary on the same day should constitute separate sessions by definition.
- Software programs in use for medical billing do not adequately capture interpretation times, and therefore, do not track whether the PC was performed in the same or different sessions and when the 59 modifier is appropriate. Commenters expressed concern that they will not be able to routinely identify when a Medicare beneficiary has had multiple imaging scans on the same day, especially if reports are generated in different locations, by different physicians, at different times of day. Radiology workflow systems triage studies to subspecialty radiologists who each separately interpret the studies and generate reports. Billing systems submit separate claims for each study. If two physicians read studies on the same beneficiary, coders and billing systems will have significant difficulty attaching the 59 modifier to the appropriate study, even if they are able to recognize that the 59 modifier should be applied. Hospital-based radiologists rely on data feeds provided by their hospitals' information systems. These data-feeds typically include beneficiary demographic information but not image interpretation times. Because they are unable to track the time of interpretation, coders and billers will be required to re-create the timing of interpretative sessions to determine whether or not the interpretation occurred in the same session.
- Radiologists in small practices, or rural hospitals and imaging facilities, are more likely to have only a few radiologists in the office. Frequently in small practices, there will be instances where beneficiaries have multiple advanced imaging services that are in clinically separate sessions, but interpreted by the individual members of the same small group of radiologists. It is not clear that there will be a way for coders, CMS contractors and auditors to understand and validate that these separate encounters constitute separate sessions.
- Contrary to CMS' claim, commenters expect there would be frequent circumstances requiring the use of the 59 modifier, that is, a distinct procedural service.

Response: We are aware of the conflict between use of modifier 59 for CCI edits and for purposes of bypassing the MPPR when multiple procedures are furnished. We are considering creating a new modifier for the MPPR to resolve this problem. In creating a new MPPR modifier, we would refine the definition of what constitutes a session. We believe that radiology imaging systems currently capture the time of each image and that image time can be provided to the interpreting radiologist(s). We also believe that radiology medical record systems currently capture the time of each professional comment or interpretation, and that the interpretation of the radiologist should contain any clinical information necessary to identify when a separate session has occurred. We believe that where billing systems currently do not capture this information in a readily usable form, that they will adapt to this policy and make this necessary billing information readily accessible to coders. Thus, we believe that coders will be able to determine when a separate session has occurred and will be able to append a 59 modifier (or new MPPR modifier for different session) to the claim line when such a modifier is justified.

Alternatively, we may consider modifying the MPPR policy to apply to procedures furnished on the same day, rather than in the same session. This would resolve some of the operational difficulties with the use of ''session'' and conform to the policy for all other MPPRs. If we were to modify this MPPR to apply to procedures furnished on the same day rather than in the same session, we would do so through future rulemaking and subject to public comment.

Comment: Commenters indicated that applying the MPPR for the PC of advanced imaging procedures to physicians in the same group practice would result in a payment reduction that would adversely affect both the quality of care and access to care.

Response: We have no evidence to suggest any adverse impacts on either the quality of care or the access to care have resulted from the implementation of the MPPR to the TC of imaging in 2006 or the PC of imaging in 2012. We have no evidence that beneficiaries have been unable to obtain needed imaging, and we will continue to monitor access to care. MedPAC's analysis in its June 2011 report indicates there has been continued high annual growth in the use of imaging through 2009. Further, in the absence of any evidence of inadequate access or safety and quality concerns, declining growth in imaging services could be interpreted as a return to a more appropriate level of imaging utilization. Based on our experience with the MPPR on both the TC and PC of advanced diagnostic imaging services, we have no reason to believe that extending the imaging MPPR to physicians in the same group practice will have a negative impact on quality or access to care.

c. Proposed MPPR for the TC of Cardiovascular and Ophthalmology Services

As noted above, we continue to examine whether it would be appropriate to apply MPPR policies to other categories of services that are frequently billed together, including the TC for diagnostic services other than advanced imaging services. For CY 2013, we examined other diagnostic services to determine whether there typically are efficiencies in the technical component when multiple diagnostic services are furnished together on the same day. We have conducted an analysis of the most frequently furnished code combinations for all diagnostic services using CY 2011 claims data. Of the several areas of diagnostic tests that we examined, we found that billing patterns and PE inputs indicated that multiple cardiovascular and ophthalmology diagnostic procedures, respectively, are frequently furnished together and that there is some duplication in PE inputs when this occurs. For cardiovascular diagnostic services, we reviewed the code pair/combinations with the highest utilization in the CPT code ranges of 75600 through 75893, 78414 through 78496, and 93000 through 93990. For ophthalmology diagnostic services, we reviewed the code pair/combinations with the highest utilization in the CPT code ranges of 76510 through 76529 and 92002 through 92371. The cardiovascular and ophthalmology diagnostic code combinations identified as most frequently billed together are listed in Tables 14 and 15.

Under the resource-based PE methodology, specific PE inputs of clinical labor, supplies, and equipment are used to calculate PE RVUs for each individual service. When multiple diagnostic tests are furnished to the same beneficiary on the same day, most of the clinical labor activities and some supplies are not furnished twice. We have identified the following clinical labor activities that typically would not be duplicated for subsequent procedures:

- Greeting and gowning the patient.
- Preparing the room, equipment and supplies.
- Education and consent.
- Completing diagnostic forms.
- Preparing charts.
- Taking history.
- Taking vitals.
- Preparing and positioning the patient.
- Cleaning the room.
- Monitoring the patient.
- Downloading, filing, identifying and storing photos
- Developing film.
- Collating data.
- Quality Assurance documentation.
- Making phone calls.
- Reviewing prior X-rays, lab and echocardiograms.

We analyzed the CY 2011 claims data for the most frequently billed cardiovascular and ophthalmology diagnostic code combinations to determine the level of duplication present when multiple services are furnished to the same beneficiary on the same day. Our MPPR determination excludes the clinical staff minutes associated with the activities that are not duplicated for subsequent procedures. For purposes of this analysis, we retained the higher number of minutes for each duplicated clinical activity, regardless of the code in the pair with which those clinical labor minutes were associated. For example, if code A and B had 6 and 3 minutes, respectively, of clinical labor for preparing and positioning the beneficiary, we removed 3 minutes. If code A and B had 2 and 4 minutes, respectively, of clinical labor for preparing room, equipment and supplies, we removed 2 minutes. The lower number of minutes was removed, regardless of the code. If one code had no minutes for a particular clinical labor activity, then no minutes were removed for that activity. Equipment time and indirect costs are allocated based on clinical labor time; therefore, these inputs were reduced accordingly. While we observed that some supplies are duplicated, we did not factor these into our calculations because they were low cost and had little impact on our estimate of the level of duplication for each code pair.

When we removed the PE inputs for activities that are not duplicated, and adjusted the equipment time and indirect costs, we found support for payment reductions ranging from 8 to 57 percent for second and subsequent cardiovascular procedures (volume-adjusted average reduction across all code pairs of 25 percent); and payment reductions ranging from 9 to 62 percent for second and subsequent ophthalmology procedures (volume-adjusted average reduction across all code pairs of 32 percent). Because we found a relatively wide range of reductions by code pair, we believed that an across-the-board reduction of 25 percent for second and subsequent procedures (which is approximately the average reduction supported by our analysis) would be appropriate. In the CY 2013 proposed rule (77 FR 44748–44752), we proposed to apply an MPPR to TC-only services and to the TC portion of global services for the procedures listed in Tables 12 and 13. The MPPR would apply independently to second and subsequent cardiovascular services and to second and subsequent ophthalmology services. We proposed to make full payment for the TC of the highest priced procedure and to make payment at 75 percent (that is, a 25 percent reduction) of the TC for each additional procedure furnished by the same physician (or physicians in the same group practice, that is, the same group practice NPI) to the same beneficiary on the same day. We did not propose to apply an MPPR to the PC for cardiovascular and ophthalmology services at this time.

We believe that the proposed MPPR percentage represents an appropriate reduction for the typical delivery of multiple cardiovascular and ophthalmology services on the same day. Because the reduction is based on discounting the specific PE inputs that are not duplicated for second and subsequent services, the proposal is consistent with our longstanding policies on surgical, nuclear medicine diagnostic procedures, and advanced imaging procedures, which apply a 50 percent reduction to second and subsequent procedures, and our more recent policy on therapy services, which applies a 20 or 25 percent reduction depending on the setting.

Furthermore, it is consistent with section 1848(c)(2)(K) of the Act, which specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values.

Finally, it is responsive to continued concerns about significant growth in spending on imaging and other diagnostic services, and to MedPAC (March 2010) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies. Savings resulting from this proposal would be redistributed to other PFS services as required by the general statutory PFS BN provision.

In summary, we proposed that for services furnished on or after January 1, 2013, we will apply the MPPR to nuclear medicine procedures to CPT code 78306 (Bone imaging; whole body) when followed by CPT code 78320 (Bone imaging; SPECT). We will apply the MPPR to the PC and the TC of advanced imaging procedures when furnished by multiple physicians in the same group practice (same group NPI). Therefore, the MPPR will apply when

one or more physicians in the same group practice furnish services to the same beneficiary, in the same session, on the same day. Finally, we proposed to apply an MPPR to TC-only services and to the TC portion of global services for diagnostic cardiovascular and ophthalmology procedures. The reduction would apply independently to cardiovascular and ophthalmology services. We proposed to make full payment for the TC of the highest priced procedure and payment at 75 percent of the TC for each additional procedure furnished by the same physician (or physicians in the same group practice, that is, the same group practice NPI) to the same beneficiary on the same day.

The following is a summary of the comments we received on this proposal to apply the MPPR to diagnostic cardiovascular and ophthalmology procedures:

Comment: MedPAC supported the proposal to expand the MPPR to cardiovascular and ophthalmology diagnostic services. Furthermore, MedPAC encouraged CMS to examine whether there are efficiencies in physician work that occur when multiple tests are furnished in the same session that would justify applying the MPPR to the PC of these services. For example, when multiple tests are performed together, certain physician activities (such as reviewing the beneficiary's medical records and discussing the findings with the referring physician) are likely to occur only once.

In the PFS proposed rule for CY 2012 (76 FR 42812–42813), CMS solicited comments on whether the MPPR should be applied to the TC of all diagnostic tests, rather than just imaging procedures. In response, MedPAC examined Part B claims data from 2010 to look for diagnostic tests that are frequently furnished more than once on the same day by the same physician for the same beneficiary. MedPAC found that several surgical pathology codes are frequently billed with more than one unit of service on the same date. For example, one-third of the claims for CPT code 88305 (Level IV, surgical pathology, gross and microscopic examination) contained more than one unit of service for that code. In addition, 57 percent of the claims for CPT code 88342 (immunohistochemistry, each antibody) contained more than one unit of service for that code. In these cases, it appears that multiple specimens from the same beneficiary were examined at the same time by the same pathologist. MedPAC indicated that CMS should analyze whether there are efficiencies in practice expense or physician work that occur when multiple units of the same test are performed at the same time. If so, MedPAC suggested that CMS should consider applying the MPPR policy to these services or creating bundled codes that include multiple units of the same test. MedPAC noted that these services account for a substantial and growing amount of Medicare spending. In 2010, Medicare spent $1.3 billion on CPT code 88305 and $241 million on CPT code 88342.

MedPAC noted that it has recommended expanding the MPPR to both the TC and PC of all imaging services to account for efficiencies in practice expense and physician work that occur when multiple studies are furnished in the same session.

A few additional commenters either agreed with the principle of applying the MPPR to cardiovascular and ophthalmology services or concurred with our findings that efficiencies exist when multiple diagnostic services are furnished on the same beneficiary on the same day. Those commenters agreed that the application of the MPPR to the additional cardiovascular and ophthalmic diagnostic procedures is an appropriate way to recognize such efficiencies.

Response: We appreciate the support of MedPAC and other commenters for our proposal to apply the MPPR to cardiovascular and ophthalmology services. We agree that the MPPR is an appropriate mechanism to account for efficiencies when multiple procedures are furnished to the same beneficiary on the same day in order to ensure more accurate payments.

Comment: Most commenters opposed applying the MPPR to the TC of diagnostic cardiovascular and ophthalmology services. Commenters maintained that the assumption that there is major duplication in clinical labor activities is false when two studies are done in the same session, and especially when these services are done in separate sessions on the same day. Commenters stated that CMS' methodology of eliminating the smaller number of minutes assigned to one code in the frequently performed together code pairs for clinical staff and equipment is not appropriate for pairs of services that are: (1) Furnished by different types of clinical staff, with different expertise and training (for example, radiology technologists and sonographers); (2) furnished in different types of rooms (for example, angiography suites and vascular ultrasound lab rooms); and (3) stocked with unique equipment. According to commenters, many of the clinical labor activities considered redundant are performed multiple times, at different times of day, and in different rooms.

As examples, commenters referenced the sample payment reduction calculations in the proposed rule for cardiovascular and ophthalmology services. Concerning CPT code 93306 (transthoracic echocardiography) and CPT code 78452 (myocardial perfusion single-photon emission computed tomography (SPECT)), commenters noted that different physicians, each supported by separately specialized clinical staff perform the service in different rooms on two different types of equipment.

Commenters indicated that clinical teams for each test independently greet and gown the patient, provide education, obtain consent, review previous exam results and studies and position the patient for the test. Commenters noted that the patient is positioned multiple times on different exam tables. According to commenters, two different clinical staff will independently review prior x-ray, laboratory, echocardiography studies, and other studies. Also, separate notes are made in the patient's records, different diagnostic forms are completed, and different quality assurance regulatory compliance information must be documented for each test. Commenters noted that two different rooms with different specialized equipment in two different parts of the facility are prepared and cleaned for the two unique and different services. Finally, two different machines are utilized by two differently credentialed support staff to acquire independent and unrelated clinical testing data.

Concerning CPT code 92235 (Fluorescein Angiography) and CPT code 92250 (Fundus Photography), commenters maintained that the proposal was based on an erroneous understanding of how services vary. Commenters noted that ophthalmic diagnostic tests are not equivalent to x-ray or fluoroscopic imaging, where the technician simply repositions the same device over a nearby area of the patient's body. Commenters noted that ophthalmic diagnostic tests range from imaging to psychophysical tests using a number of different technologies and instruments that require patient participation by responding to various stimuli to achieve an objective functional measurement of the anatomical structures within the eye. For such tests the patient must be taken to a second instrument and positioned, substantially reducing any redundancy in direct practice expenses.

Another commenter indicated that visual field testing equipment, and other eye diagnostic equipment, do not share interfaces, space or patient information. The commenter noted that each machine requires independent input from the testing technician; including patient name, date, birth date, verification of the eye being tested, and there is no shared registration of data between the two services.

According to the commenter, visual field testing requires a dedicated space and is typically not performed at the same time as other diagnostic tests. Patients need a quiet area away from other testing and patients to complete the test. Both eyes are tested, each with their own input and varying lenses that must be inserted into the equipment. The commenter maintained that these tests require substantial clinical staff time, patient instruction and interaction. Ophthalmology patients are typically elderly, often visually impaired and in need of mobility and positioning assistance in order to perform diagnostic eye testing. Finally, the commenter highlighted that the AMA RUC recently removed clinical staff time from some of the codes reviewed in our analysis.

Commenters disagreed that diagnostic test resource utilization for multiple diagnostic tests is comparable to those required for multiple surgeries. Commenters noted that surgical procedures generally have a 90-day global period where more than 50 percent of the payment is related to postoperative care. Commenters also noted that in large multi-specialty practice, technical resources are located in different physical locations.

Commenters recommended that CMS conduct its study with a new methodology that takes into account both the frequency and the different types of clinical staff, and the different types of rooms involved in the services that are performed together on the same day.

Finally, commenters noted that CMS' own analysis reveals payment reductions as low as 8 percent, indicating that a payment reduction of 25 percent would be excessive for some of these services. A commenter expressed concern that taking this ''average'' approach would have the effect of discouraging cardiologists and ophthalmologists from performing certain low overhead diagnostic procedures as the payment will be far less than the practice costs. The commenter suggested that in previous cases the identified savings were closer to the mean on average and would not result in such dramatic effects. Other commenters recommended that the MPPR reduction percentage should be code-specific up to a maximum reduction of 25 percent.

Response: We appreciate the many comments submitted on this proposal. However, we disagree with commenters' statements that there are minimal or no efficiencies in the TC of diagnostic cardiovascular and ophthalmology services.

Concerning CPT code 93306 (transthoracic echocardiography) and CPT code 78452 (myocardial perfusion single-photon emission computed tomography (SPECT)) referenced by commenters, we agree that some cardiovascular centers might choose to employ two differently specialized technicians; that is, nuclear medicine and echocardiography; to allow two different clinical staff to independently perform the studies; and to locate the different specialized equipment in two different parts of the practice. However, we continue to believe that is not the typical cardiovascular center or practice. We believe that the typical cardiovascular center performing these diagnostic tests commonly cross-train technicians to perform both procedures and that a single cardiologist often performs both tests for a single patient. In addition, we continue to believe that much of the pre-service work such as greeting and gowning the patient and reviewing medical records and previous images is redundant. We believe that some of the equipment used in the top code pairs is portable and can be used in the treatment room or other diagnostic room. We also do not believe that multiple rooms dedicated to individual testing equipment is typical such that room preparation, greeting and gowning, and cleaning the room are never duplicated. Overall, commenters provided general descriptions of practices using multiple rooms and technicians to furnish these services, without sufficient information supporting a multiple room, dedicated clinical labor model as typical outside the facility setting. We would review generalizable, robust data demonstrating that an extensive practice model of multiple rooms dedicated to individual tests and distinct dedicated technicians trained is typical practice.

Concerning CPT code 92235 (Fluorescein Angiography) and CPT code 92250 (Fundus Photography), we acknowledge that these tests are not equivalent to other imaging procedures. However, we believe there are still efficiencies when furnished to the same patient due to some duplication of clinical labor. Concerning visual field testing, we agree that this is an interactive test, requiring the technician to teach the patient how to perform the test; however, the most intense instruction only occurs the first time a patient has visual field testing. Although not considered in our analysis, we also note that once a patient is diagnosed with glaucoma the patient usually undergo visual field testing for the rest of their life, and their familiarity with the test reduces the clinical labor associated with providing this service overtime. As for the other ophthalmology tests, we understand them to be mostly passive with minimal patient instruction.

Commenters expressed concerns that there is wide variation in the potential efficiencies among different code pairs; that such variability precludes broad application of a single percentage reduction; and, that establishing new combined codes is the only mechanism for capturing accurate payment for multiple imaging services. In general, we believe that MPPR policies capture efficiencies when several services of the same type are furnished in the same session and that it is appropriate to apply a single percentage reduction to second and subsequent procedures to capture those efficiencies. Because of the myriad potential combinations of diagnostic services, establishing new combined codes for each combination of advanced imaging scans is unwieldy and impractical. An MPPR policy reflects efficiencies in the aggregate, such as common patient history, application of multiple tests to the same anatomical structures by the same clinical labor, frequently with the same modality, for the same patient.

As previously noted, we found support for payment reductions ranging from 8 to 57 percent for second and subsequent cardiovascular procedures (volume-adjusted average reduction across all code pairs of 25 percent); and payment reductions ranging from 9 to 62 percent for second and subsequent ophthalmology procedures (volume-adjusted average reduction across all code pairs of 32 percent). Based on this analysis, and because we found a relatively wide range of reductions by code pair, we believed that an across-the-board reduction of 25 percent for second and subsequent procedures, which is approximately the average reduction supported by our analysis, would be appropriate. Based on subsequent public comments, we have conducted additional analysis on ophthalmology code pairs discussed below. In response to comment that this MPPR application to ophthalmic and cardiovascular diagnostic testing is not the same as the MPPR for global surgery,

we agree. We have provided our analysis for why we proposed a 25 percent reduction on second and subsequent diagnostic tests rather than a 50 percent reduction. We note that, as with many of our policies, we will continue to review this MPPR policy and refine it as needed in future years to ensure that we continue to provide accurate payments under the PFS.

Comment: A commenter noted that several ophthalmology codes included in our analysis have been reviewed by the AMA RUC within the last year, which resulted in the recommended removal of several minutes of clinical staff time for activities that the AMA RUC determined are also included within an accompanying office visit code. The commenter indicated that CMS' acceptance of the AMA RUC recommendation, as well as applying the MPPR, would effectively double the practice expense reductions. The codes reviewed by the AMA RUC for CY 2013 were: CPT codes 92081–92083 (Visual field examinations), CPT code 92235 (Fluorescein angiography) and CPT code 92286 (Internal eye photography). As discussed above, commenters noted that visual field testing equipment and other eye diagnostic equipment do not share interfaces, space or patient information, that there is no shared information with other tests, that the tests required separate staff time and clinical instruction, and that visual field testing happens in a dedicated space away from other testing.

The commenter requested that any ophthalmic tests that had their time reduced because of duplication with an office visit should be removed from the list of codes subject to the MPPR. Specifically, the commenter requested that the three visual field tests CPT codes 92081, 92082 and 92083 and CPT code 92235 (Fluorescein angiography) and CPT code 92286 (Internal eye photography) for which minutes were reduced that were not reflected in the CMS analysis should be removed from the list. Additionally, the commenter indicated that CPT codes 92133, 92134 and 92285 all had their clinical staff labor times previously reduced during the AMA RUC consideration and should not be included in the MPPR.

Commenters also expressed concern about CPT codes that have recently been reviewed or are in the process of being reviewed under the various misvalued services screens. Commenters noted that these codes have already been subjected to a process where duplicative minutes have been reduced. Therefore, they requested that any codes for procedures where the AMA RUC has reviewed the PE inputs in the last 2 years be removed from this proposed list of services.

Response: Our original proposed rule analysis for the subject ophthalmology codes was based on the latest AMA RUC PE worksheets available at that time. The PE worksheets are the basis for the direct practice expense inputs used in the PE methodology. They delineate minutes of the clinical staff time, equipment, and supplies for each clinical labor activity, for each CPT code. We subsequently reviewed the CY 2013 PE worksheets for the subject codes, which appeared in many of the ophthalmology code combinations reviewed. The AMA RUC did not reduce clinical labor minutes for CY 2013 for two of the reviewed code pairs (76514 with 92286 and 92081 with 92285). The most significant change in clinical labor activities for the other reviewed code pairs was the reduction of time for preparing and positioning the patient from either 7 or 10 minutes to 2 minutes. Because we never reduced this activity by more than 2 minutes, the AMA RUC changes to this clinical labor activity had no effect on our calculation. In all cases, the subject codes are the highest paid codes in the code combination. The payment reductions range from 9 to 62 percent for second and subsequent ophthalmology procedures, noted in the proposed rule, remains unchanged. However, the volume-adjusted average reduction across all code pairs, originally calculated at 32 percent is revised to 22 percent.

We disagree that recently reviewed codes should be exempt from the MPPR. However, we agree that the analysis establishing an MPPR should be based on the most current practice expense data available, and that the recent clinical labor reductions made to the subject codes should be taken into account. Therefore, based on our revised analysis, we are reducing the final MPPR on ophthalmology services from 25 percent to 20 percent to more accurately reflect the new data.

Comment: Commenters expressed concern about the lack of transparency in the methodology and data sets used to develop the proposed MPPR. Commenters noted that CMS did not post basic data files on its Web site until August 10, 2012, less than 30 calendar days from the comment deadline. Commenters also indicated that the posted data did not enable them to understand the cuts or replicate the data used to form the basis of the proposed MPPR. Commenters believed that this unfairly hampered their ability to fully analyze the proposal. Commenters urged us not to implement this proposed policy until full access to the data used to develop the policy is provided.

Response: We have provided full access to the data that we used to develop the policy. We have listed every code pair reviewed and every clinical labor activity considered for duplication. In addition, we provided a description of how the analysis was conducted, the range of reductions found and the adjusted average reduction determined for cardiovascular and ophthalmology services. We acknowledge that the PE worksheets were not made available simultaneously with the publication of the proposed rule. Upon receiving requests from various specialty groups to supplement the information we provided in the proposed rule, we posted the PE worksheets used in the analysis on our Web site. We posted these data in August 2012, approximately one month before the comment period ended. We believe the information provided in the proposed rule would have been sufficient to permit full consideration of our proposed policy, but agreed to provide greater detail to assist commenters in further evaluating the proposal.

Comment: Commenters indicated that we stated in the proposed rule that the code pairs published the MPPR analysis are frequently billed together. However, the AMA RUC determined that only four of the cardiology pairs (CPT codes 93320–93325, 93320–93351, 93965–93970 and 78452TC–93017), and only one ophthalmology code pair (CPT codes 92235 and 92250), are typically reported together on the same date of service. Commenters stated that the computerized ophthalmic diagnostic imaging codes (92133 and 923134) were created in 2011 and were not included in this analysis.

Commenters further noted that every other code pair is reported together at or below 40 percent of the time, with over half below 20 percent. They stated that not only are these services not commonly billed together, they are not performed on contiguous body parts and are not always performed on the same type of equipment or even in the same room. Further, the services would sometimes be performed by different physicians in the same group practice.

In addition, commenters indicated that a broader analysis of the claims data for all the analyzed codes pairs for cardiovascular and ophthalmology suggest that only roughly four percent of the code combinations are typically performed together on the same date of service. Given that these services are rarely performed on the same day

together, it is unreasonable to assume there would be efficiencies gained when these services are performed together.

Commenters maintained that efficiencies in practice expense are potentially created only when the two services are similar, use the same instrument, and are commonly performed together. Commenters indicated, however, that for more low-volume code pairs, the practice will not have the same level of familiarity, including the office equipment set up, to conduct these services. Commenters further noted that the differences between these services are such that even if all these services were commonly billed together, physician staff could not provide noticeable efficiencies.

Response: In the CY 2013 proposed rule (77 FR 44748), we indicated that we analyzed the CY 2011 claims data for the most frequently billed cardiovascular and ophthalmology diagnostic code combinations to determine the level of duplication present when multiple services are furnished to the same patient on the same day. For cardiovascular diagnostic services, we reviewed the code pair/combinations with the highest utilization in code ranges 75600 through 75893, 78414 through 78496, and 93000 through 93990. For ophthalmology diagnostic services, we reviewed the code pair/combinations with the highest utilization in code ranges 76510 through 76529 and 92002 through 92371.

The frequency of code combinations reviewed for cardiovascular services ranged from 260 to 207,573 and for ophthalmology services from 4,193 to 553,502. Although utilization was low for some code combinations reviewed, we examined the top highest frequency code combinations for each of the five code groups examined (three for cardiovascular and two for ophthalmology). The frequency with which a code combination is furnished does not diminish the potential efficiencies in clinical labor activities that will occur when that code combination is furnished. All MPPR policies (surgery, diagnostic imaging and therapy) apply to all code combinations of procedures subject to the policy, regardless of the frequency that the code combination was furnished. Therefore, we believe it is appropriate to apply the MPPR regardless of the frequency which the code combination is billed. Applying the MPPR to code combinations furnished infrequently will have a minimal effect on overall payments for imaging services. Finally, we based our final recommended percent reduction on the volume-adjusted average reduction observed in our code pair analysis, which ensures that when the MPPR is applied, the reduction adjustment is more likely to reflect the actual reduction for the code pair. MPPR policies have been consistently applied to all multiple procedures and are not restricted to those with the highest frequency of billings.

Comment: Commenters noted that the MPPR is partly designed to address the growth in imaging and diagnostic services, as noted by MedPAC. Commenters further noted that in recent years the rate of imaging growth for both Medicare and private payor patients has slowed considerably, and concluded that additional payment reductions are unwarranted and unnecessary. Commenters cited an article in the August 2012 issue of *Health Affairs* further confirming this trend, noting that the growth rate of advanced diagnostic imaging slowed to single digits beginning in 2006. The study concluded that the use of MRI in Medicare slowed to an average 2.6 percent annual growth rate from 2006–2009. In addition, commenters maintained that 2008 and 2009 data from MedPAC and the AMA demonstrate that the rate of volume growth for diagnostic imaging services overall is now generally lower than the rate of growth for all other physicians' services. Commenters further maintained that the volume of all physicians' services grew by 3.6 percent in 2008 and 2009 while the volume of diagnostic imaging services rose by 3.3 percent in 2008 and 2.2 percent in 2009.

Another commenter noted that ultrasound services have never experienced rapid growth, but rather, have experienced only moderate growth. The commenter cited GAO's September 2008 report to Congress that found that after the implementation of DRA cap, which for vascular ultrasound services resulted in reductions of greater than 40 percent, the disparity in utilization between ultrasound and expensive, advanced imaging modalities continued to grow. The commenter noted that this is reflected by the Congressional Budget Office's (CBO) December 2008 recommendations to Congress in which it excluded ultrasound and other inexpensive imaging modalities from its policy recommendations on advanced imaging services. Commenters concluded that imaging has absorbed numerous payment reductions and that it is illogical to target procedures for reduction that do not demonstrate a pattern of rapid growth.

Response: MedPAC's analysis in its June 2011 report indicates there has been continued annual growth in the use of imaging. While overall growth may be lower than it was in the last decade, declining growth in imaging services could be interpreted as a return to a more appropriate level of imaging utilization without any accompanying evidence of inadequate access or safety and quality concerns. As indicated previously, MedPAC has expressed support for the MPPR on diagnostic cardiovascular and ophthalmology services.

Comment: A commenter noted that many of the code pair combinations identified by CMS for the MPPR on cardiovascular services are not cardiovascular services, specifically, CPT 75600–75893, 78414–78496, and 93000–93990. The commenter further noted that it is highly unlikely that these codes would be furnished to the same patient on the same day by the same physician. For example, the AMA RUC database indicates CPT code 93980 for penile vascular study was provided by cardiologists less than 1 percent of the time to Medicare patients in 2011. The commenter did not recommend removing the codes from the MPPR list because their presence produces no impact. However, the commenter indicated that the inclusion of codes unrelated to cardiovascular creates doubts about the thoroughness and validity of the analysis underlying the proposal.

Response: In reviewing the group of codes that we refer to as cardiovascular services, we looked at services involving the heart and vessels, regardless of the specialty that furnishes them. For example, penile vascular services are vascular services. Whereas we would not expect a urologist to perform trans-esophageal echoes, nor would we expect a cardiologist to perform penile studies, we would not be surprised to find some generalists, or even general vascular surgeons, evaluating the penile vasculature along with, for example, the vasculature of the lower extremities. And even if, as the commenter suggested, it would be unlikely for certain codes to be billed by the same physician on the same day, then the MPPR simply would not apply.

Comment: Commenters questioned how the MPPR on cardiovascular services would apply to remote monitoring CPT codes 93279–93296. Specifically, they indicated that it is unclear whether the date of service is: (1) The day the patient transmits their data; (2) the day the data is received in the physician's office for technician review, technical support and

distribution of results; or (3) the day the physician reviews the data; all of which may represent different dates of service. The commenters indicated that because there is no specific identification of the date of service within the CPT description, applying the MPPR is likely to create confusion among physicians. Commenters recommended that we either remove these codes from the list subject to the MPPR or issue instructions that specifically indicate how dates of service within the 90-day monitoring period should be addressed.

Another commenter noted that CPT codes 93293 (Transtelephonic rhythm strip pacemaker evaluation(s) single, dual, or multiple lead pacemaker system, includes recording with and without magnet application with analysis, review and report(s) by a physician or other qualified health care professional, up to 90 days), 93296 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system or implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results), and 93299 (Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results) describe the TC for remote interrogation of the devices, meaning that the patient is not physically present when the service is furnished. The commenter questioned how it is possible for efficiencies to exist in the rare circumstance these services were furnished on the same date as a cardiovascular diagnostic service. The commenter indicated that the inclusion of these codes demonstrates a lack of understanding of how diagnostic services are furnished to beneficiaries.

Response: The appropriate date of service used to bill codes subject to the MPPR is the same as required by Medicare billing instructions. We note that codes in the range of CPT codes 92293 through 92299 should be consistently treated regarding application of the MPPR. Since we did not propose to include all codes in this range for the MPPR, we have removed remote monitoring codes CPT codes 93293 and 93296 from the list of procedures subject to the MPPR. We note that CPT code 93299 was not on the proposed list.

Comment: A commenter noted that diagnostic ultrasound offers a number of important advantages compared to CT and MRI, in terms of safety and effectiveness. For example, ultrasound is non-invasive and offers real-time imaging, allowing for examinations of structures at rest and in motion and does not use ionizing radiation. Although not always a good substitute for other advanced imaging modalities, ultrasound is an effective diagnostic tool in many cases.

The commenter further noted that, due to the relatively low payment rates for ultrasound procedures, they are one of the most cost-effective diagnostic imaging modalities. The commenter indicated that analyses performed by GAO in 2008 and others have shown that lower cost imaging modalities such as ultrasound have declined in use relative to more expensive imaging modalities, negatively impacting the quality and cost of their health care.

The commenter concluded that payment reductions to ultrasound services have threatened the ability to furnish such services. Therefore, the commenter requested removal of all ultrasound procedures from the list of procedures subject to the MPPR on cardiovascular services.

Another commenter noted that the June 2011 MedPAC report focused on advanced diagnostic imaging services and supported increasing, rather than decreasing, the payments for ultrasound services. The commenter indicated that the report suggests reforming the Medicare fee-for-service system to encourage the use of high-value services and discourage the use of low-value services. In describing what is meant by low-valued services, MedPAC points to situations where two services may be equally safe and effective, yet one is more expensive than the other. The commenter indicates that this is the situation with ultrasound as compared to other, more expensive imaging services. Finally, the commenter noted that the report suggested that services that can potentially harm patients, for example, overexposure to radiation, should be considered low-value. The commenter indicates that ultrasound, which is non-ionizing, poses less risk to patients than other modalities.

Response: The MPPR on diagnostic imaging procedures has included CT, MRI and ultrasound since 2006. MedPAC, as noted in its comment above, has supported our previous MPPR proposals and has not recommended excluding ultrasound from MPPR on diagnostic cardiovascular and ophthalmology services. MPPR policies are resource-based. MPPR policies for the TC reduce payment in situations where there is overlap in resources employed in the delivery of multiple services, with comparable practice expense inputs, when those resources are only employed once. We do not apply the MPPR to ultrasound used in place of other modalities, only when it is used in addition to, other modalities in the same session. We do not expect the MPPR to encourage radiologists to forego ultrasound imaging in favor of advanced imaging modalities.

Comment: Commenters noted that the AMA RUC and the CPT Editorial Panels have been working to combine services frequently billed together into comprehensive codes and to remove overlapping physicians' services from the payment rates. Commenters indicated that the effort to combine codes and reduce payment for duplicate services has been accelerated by CMS after the threshold for analyzing services billed together was reduced from 95 percent to 75 percent overlap.

Commenters urged CMS to be mindful of this work and to fully take into account the AMA RUC review of the code pairs. Commenters found it contradictory for CMS to utilize the AMA RUC process and accept the PE payment principle, only to disregard the methodology in applying an MPPR; and suggested that duplication of work in services performed on the same date of service should be addressed at the individual code level rather than through an MPPR.

Another commenter recommended that CMS ask the AMA RUC to review the codes and make code-specific recommendations and claimed that implementing payment reductions that are not specific does a disservice to the entire AMA RUC process and all of the physicians who are paid under the PFS.

Commenters disputed the assumption that an MPPR is a valid and accurate mechanism to value services when performed on the same date of service. Commenters indicated that, historically, the AMA RUC has recognized that efficiencies can be gained when services are commonly performed by the same physician on the same date of service, but only when explicit criteria are met. The commenters indicated that the proposal fails to meet these criteria because the services are not commonly billed together, are not analogous services performed on contiguous body parts, and applies to both individual physicians and physicians in the same group practice.

Commenters maintained that the vague justification for selecting particular codes in the CY 2013 rule stands in stark contrast to the AMA RUC. According to commenters, the AMA RUC process set a clear and

distinct threshold for analyzing codes billed together, that is, 75 percent of the time. In contrast, according to commenters, the proposal fails to define ''frequently billed'' thus creating a substantial barrier to a clear comprehension of the MPPR expansion.

Response: As we have indicated previously (76 FR 73077–73078), the MPPR is not intended to supersede the AMA RUC process of developing recommended values for services described by CPT codes. We continue to appreciate the work done by the AMA RUC and encourage the AMA RUC to continue examining code pairs for duplication based upon the typical case, and appropriately valuing new comprehensive codes for bundled services that are established by the CPT Editorial Panel. We view the AMA RUC process and the MPPR policy as complimentary and equally reasonable means to the appropriate valuation and payment for services under the PFS. We note that as more code combinations are bundled into a single complete service reported by one CPT code, the MPPR policy would no longer apply to the combined services. At the same time, the adoption of the MPPR for the TC of diagnostic cardiovascular and ophthalmology services will address duplications in the PE to ensure that Medicare payment for multiple diagnostic services better reflects the resources involved in providing those services.

As noted previously, although less precise than creating new comprehensive codes to capture each unique combination of diagnostic services that could be performed together, we believe that an MPPR policy appropriately addresses efficiencies present when multiple diagnostic services are furnished together. Moreover, we believe it would be unwieldy and impractical to develop unique codes and values for the myriad of procedure combinations that could be furnished together. In addition, we believe that the expansion of the MPPR policy to the TC of diagnostic cardiovascular and ophthalmology services is consistent with both the GAO and MedPAC recommendations. Finally, we already have discussed information on the determination of frequently billed services in response to comments on this rule concerning the most frequently billed cardiovascular and ophthalmology diagnostic code combinations used in our analysis.

Comment: A commenter indicated that the statutory authority cited by CMS for the proposed MPPR expansion and new MPPR policy only grants CMS the authority to modify the reimbursement for ''codes'' and does not provide CMS with the authority to implement multiple service reductions. The commenter maintains that Congress bestowed CMS with specific and limited authority to implement multiple service reductions in another part of the Act and that this confirms that Congress did not intend to provide the authority that CMS claims under the ''misevaluation'' clause. The commenter stated that the misvalued codes section of the Act that addresses multiple services frequently billed together as potentially misvalued does not give CMS the authority to implement either of its proposed MPPR policies. The commenter did not believe that the codes are ''misvalued'' within the meaning of the statutory provision CMS cites, and maintains that CMS has effectively conceded this point, as it continues to use the existing relative value units (RVUs) for single services. The commenter maintains that CMS is not contending that the activities and items described in the RVUs are not, in fact, part of the service; but rather, CMS is attempting to effectively reset the conversion factor based on its assumption that costs can be saved in multiple procedure scenarios, but the statute does not permit CMS to institute multiple conversion factors. Another commenter merely suggested that there was inadequate legal basis for the proposal.

Another commenter noted that payment rates for x-rays under the OPPS are significantly higher than payment rates under the PFS. The commenter indicated that application of the MPPR in a non-hospital setting will cause procedures to shift to the hospital setting. The commenter recommended paying the lower of (1) full payment under the OPPS rate for procedure with the higher fee, and 50 percent of the OPPS rate for the second procedure, or (2) full payment for both procedures under the PFS.

Response: We believe that the application of the MPPR to the PC of second and subsequent advanced imaging services furnished in the same session to the same patient is fully consistent with section 1848(c)(2)(K) of the Act, especially given our authority to adopt ancillary policies under section 1848(c)(4). We also note that we have had several MPPR policies in place for many years before the enactment of section 1848(c)(2)(K) of the Act.

As explained previously, section 1848(c)(2)(K)(i) of the Act requires the Secretary to identify services within several specific categories as being potentially misvalued and to make appropriate adjustments to their relative values. One of the specific categories listed under section 1834(c)(2)(K)(ii) of the Act is ''multiple codes that are frequently billed in conjunction with furnishing a single service.'' Although some code pair combinations will occur infrequently, the codes subject to the MPPR are frequently found in groups of multiple codes that are billed in conjunction with furnishing a single service. Section 1848(c)(2)(K)(ii) of the Act specifies that we should examine not only individual codes, but also families of codes. We believe the MPPR policy contributes to fulfilling our statutory obligations under section 1848(c) of the Act by more appropriately valuing combinations of imaging services furnished to patients and paid under the PFS.

As previously noted, Medicare has a long-standing policy of applying an MPPR to surgical procedures. While the various MPPRs have been adopted through notice and comment rulemaking as administrative actions, the Congress has acknowledged our authority to adopt MPPRs by directly modifying several of them, and by exempting the payment changes relating to several others from budget neutrality adjustment under the PFS. For example, section 5102(a) of the DRA exempted from the PFS budget neutrality adjustment the changes in expenditures resulting from the MPPR on the TC of diagnostic imaging. Section 3135(b) of the Affordable Care Act increased the MPPR reduction percentage on the TC of diagnostic imaging from 25 to 50 percent. Sections 3 and 4 of the PPATRA decreased the MPPR reduction percentage on the PE of therapy services from 25 to 20 percent for therapy services furnished in office settings, and exempted from budget neutrality the change in expenditures resulting from the MPPR on therapy services from budget neutrality.

We appreciate the commenter's suggestions concerning alternate payment methodologies, that is, payments based on the OPPS rate, and we will consider them further for possible rulemaking in the future.

Comment: A commenter noted that the proposed list of cardiovascular procedures subject to the MPPR did not include the global services that have different procedure codes than the corresponding technical services, which are on the list. The commenter specifically mentioned CPT codes 93005, 93016, 93040, and 93224, representing global services for electrocardiograms, cardiac stress tests, rhythm electrocardiograms, and Holter monitors, respectively. Lastly, the commenter noted that, because such codes were not proposed for inclusion

in the MPPR, it would violate the Administrative Procedure Act to subject them to the MPPR through this final rule.

Response: The commenter is correct that we had not specifically identified global services that have different CPT codes than the corresponding TC on the proposed cardiovascular MPPR code list. However, we indicated in the proposed rule (77 FR 44749) that the MPPR applies to TC services and the TC of global services. As such, it is consistent with the proposed policy (which we are finalizing in this final rule with comment period as described here), and not inconsistent with the Administrative Procedure Act, to include these codes on the list of codes to which the MPPR will apply. In response to the comment, we have added the following global services to the cardiovascular MPPR list: CPT code 93000 (Electrocardiogram complete); CPT code 93015 (Cardiovascular stress test); CPT code 93040 (Rhythm ECG with report); CPT code 93224 (Ecg monit/reprt up to 48 hrs); CPT code 93268 (ECG record/review); and CPT code 93784 (Ambulatory BP monitoring). The technical portion(s) of such codes will be subject to the MPPR. We note that CPT code 93005 (Electrocardiogram tracing) is a TC service already on the list, and CPT code 93016 (Cardiovascular stress test) is a PC service not subject to the MPPR.

Comment: Several commenters noted that the following add-on codes were included on the list of procedures subject to the MPPR on cardiovascular procedures: CPT code 75774 (Artery x-ray each vessel); CPT code 78496 (Heart first pass add-on); CPT code 93320 (Doppler echo exam heart); CPT code 93321 (Doppler echo exam heart); and CPT code 93325 (Doppler color flow add-on). Commenters indicated that such codes have already been valued to reflect efficiencies.

Response: We agree that these codes should not be subject to the MMPR and have removed them from the list. While three of these codes were included in our analysis, their inclusion had no effect on the results. For example, CPT codes 93320 and 93325 contain none of the clinical labor activities that might be duplicated. While duplicated clinical labor was noted in the code combinations including CPT code 77774, it affected neither the payment reduction range of 8 to 57 percent for second and subsequent procedures, nor, due to the extremely low utilization, the volume-adjusted average reduction across all code pairs of 25 percent.

Comment: Commenters noted that it was unclear exactly how we adjusted the equipment minutes in calculating the MPPR reduction and requested additional details.

Response: In general, the minutes allocated to particular direct PE equipment items are based on the amount of time clinical labor would use the equipment for a typical service. When the clinical labor minutes were reduced in our analysis, and those minutes had been used to allocate minutes to the equipment, we made corresponding reductions to the equipment minutes so that the equipment minutes matched the adjusted clinical labor times.

Comment: One commenter expressed concern that because pediatric cardiologists assess multiple aspects of a patient's cardiovascular status, the MPPR on cardiovascular services has an unjust impact on pediatric cardiology practices in the diagnosis and treatment of congenital heart diseases. The commenter noted that the functional and structural assessment of these multiple aspects requires the pediatric cardiologist to perform multiple procedures on the pediatric patient. It also requires special training and more time than a non-congenital adult assessment. According to the commenter, an echocardiogram performed to evaluate for congenital heart disease includes multiple types of different procedures/assessments which require a unique level of skill, training, and time when compared to the adult non-congenital assessment.

The commenter urged us to exclude the following codes from the MPPR on cardiovascular services: CPT codes 93303 and 93304 (Congenital transthoracic echocardiography); CPT code 93308 (Limited non-congenital code used for follow-up studies); and CPT codes 93320, 93321 and 93325 (Spectral and Color Doppler). The commenter maintained that excluding these codes would have no demonstrable effect on Medicare utilization of cardiology services since cardiologists treating adult patients rarely bill the congenital echocardiography codes to Medicare. The commenter noted that because most adult non-congenital transthoracic echocardiography studies that are billed to Medicare have been bundled into CPT code 93306 (including non-congenital echocardiography CPT codes 93307, 93320 and 93325), the significant decrease in payment for the subject codes would disproportionately impact pediatric cardiologists.

The commenter further noted that state Medicaid agencies and private sector health insurance payors use Medicare guidelines and RVU valuations to establish their own payment protocols. Therefore, the repercussions of these reductions will extend across all payor sources for pediatric cardiology practices and have a materially significant impact on the financial viability of many practices. Finally, the commenter indicated that the inclusion of the subject codes in the proposed MPPR would exacerbate the current shortage of available fellowship positions that recruit medical residents into pediatric cardiology, and will impair their ability to provide patient access to this life-saving specialty care, especially to medically underserved areas.

Response: We appreciate the commenter's concerns as to the impact of this policy on pediatricians. While we recognize that echocardiography training for congenital cardiovascular abnormalities may be different from that for adults, we are not convinced that the MPPR does is not equally applicable to pediatric and adult cardiologists. The purpose of the MPPR policy is to account for the efficiencies inherent when multiple procedures are furnished together. We do not believe that those efficiencies differ significantly from diagnostic testing on adults versus pediatric patients for these code pairs.

We considered the specific scenarios presented by the commenter's in the context of MPPR methodology and identified the same or similar efficiencies regardless of whether the multiple diagnostic procedures were targeted at abnormal flow in response to congenital structural abnormalities or were targeted at functional abnormalities in response to primary vascular disease. We also noted that, whereas practitioners who perform more services that are reported separately will be impacted more by the MPPR, practitioners who report more services that have recently been bundled together will have a similar impact due to the efficiencies that were considered by CMS in the valuation of those new bundled codes. Finally, we note that the codes are not specific to pediatric patients so it is not possible to exclude them for pediatric cardiologists alone.

In response to the commenters concerns that other insurers may adopt our policies, we do not modify Medicare payment policy based on the fact that Medicaid and other payors may adopt such policies. We understand that other payors have their own unique payment systems and consider the appropriateness of CMS valuations in their decisions to accept, modify or ignore our payments. We continue to believe that the MPPR policy that we are

adopting in this final rule with comment period is appropriate for Medicare. Therefore, we are not excluding these codes from the MPPR.

Comment: Several commenters maintained that the policy could result in the following unintended consequences:

- Create a disincentive for specialists to provide efficient, high quality and continuous care to their patients. Penalize the use of the appropriate sub-specialist, resulting in generalist physicians conducting multiple reads, leading to a degradation of diagnostic interpretation quality.
- Have a negative impact on investment in new advanced imaging technology and stifle innovation. New equipment offers more precise images and the addition of highly-trained personnel to a medical practice is integral to high quality patient care. Inhibit staff training and the addition of staff in a state of uncertainty.
- Lead to a forced reduction in necessary services, compromising patient access to life-saving diagnostic imaging services in all settings, including independent practices, community hospitals, and large academic medical centers.
- Drive more services out of physicians' offices and into more expensive hospital settings, fragment care, and increase patient costs.
- Reduce the efficiency of patient care and inconvenience patients because many would be scheduled for multiple procedures over multiple days instead of just one day. This would particularly disadvantage patients with serious medical conditions, such as multiple traumas, heart attacks, strokes, and cancer, who require frequent and multiple imaging.
- Disproportionally affect radiologists in academic medical centers who are often part of large group practices and who furnish care to a more complex patient population. These patients are often suffering from acute trauma or undergoing treatment for cancer and are more likely to have multiple examinations on the same day.
- Contradict the goal to focus more on preventive care, as diagnostic tests enable the early detection of potentially serious conditions.

Response: We have no reason to believe that appropriately valuing services for payment under the PFS by revising payment to reflect duplication in the TC of diagnostic cardiovascular and ophthalmology multiple services would negatively impact quality of care, be counter-productive to the goal of promoting preventive care, or limit patients' access to medically reasonable and necessary imaging services, or disproportionally affect certain groups. We have no evidence to suggest any of the adverse impacts identified by the commenters have resulted from the implementation of the MPPR on the TC of imaging in 2006. In fact, to the contrary, the analysis in MedPAC's June 2011 report indicates there has been continued high annual growth in the use of imaging. Further, it is worth noting that, without any accompanying evidence of inadequate access or safety and quality concerns, declining growth in imaging services could be interpreted as a return to a more appropriate level of imaging utilization.

For the ordering and scheduling of cardiovascular or ophthalmology services for Medicare beneficiaries, we require that Medicare-covered services be appropriate to beneficiary needs. We would not expect the adoption of an MPPR for the TC of diagnostic cardiovascular and ophthalmology services to result in services being furnished on separate days by one physician merely so that the physician may garner increased payment. We agree with the commenters who noted that such an unprofessional response on the part of practitioners would be inefficient and inappropriate care for the beneficiary. We will monitor access to care and patterns of delivery for cardiovascular and ophthalmology services to beneficiaries, with particular attention focused on identifying any clinically inappropriate changes in timing of the delivery of such services.

In summary, after consideration of the public comments received, we are adopting our CY 2013 proposal to apply an MPPR to the TC of diagnostic cardiovascular and ophthalmology services, with a modification to apply a 20 percent reduction for diagnostic ophthalmology services rather than the 25 percent reduction we had proposed. The reduction percentage for diagnostic cardiovascular services remains at 25 percent, as proposed. We continue to believe that efficiencies exist in the TC of multiple diagnostic cardiovascular and ophthalmology services and we will continue to monitor code combinations for possible future adjustments to the reduction percentage applied through this MPPR policy.

Specifically, beginning in CY 2013 we are adopting an MPPR that applies a 25 percent reduction to the TC of second and subsequent diagnostic cardiovascular, and a 20 percent reduction to the TC of second and subsequent diagnostic ophthalmology services, furnished by the same physician (or physicians in the same group practice) to the same beneficiary, on the same day. In Table 10, we provide examples illustrating the current and CY 2013 payment amounts:

TABLE 10—ILLUSTRATION OF CURRENT AND CY 2013 PAYMENTS

	Code 78452	Code 93306	Total current payment	Total CY 2013 payment	Payment calculation
Sample Cardiovascular Payment Reduction *					
PC	$77.00	$65.00	$142.00	$142.00	no reduction.
TC	427.00	148.00	575.00	538.00	$427 + (.75 × $148).
Global	504.00	213.00	717.00	680.00	$142 + $427 + (.75 × $148).
	Code 92235	Code 92250	Total current payment	Total CY 2013 payment	Payment calculation
Sample Ophthalmology Payment Reduction *					
PC	$46.00	$23.00	$69.00	$69.00	no reduction.
TC	92.00	53.00	145.00	134.40	$92 + (.80 × $53).
Global	138.00	76.00	214.00	203.40	$69 + $92 + (.80 × $53).

* Dollar amounts are for illustrative purposes and do not reflect actual payment amounts.

No changes have been made to the proposed list for diagnostic ophthalmology services. We have revised the proposed list for diagnostic cardiovascular services by removing codes deleted for CY 2013, add-on codes, and remote monitoring codes, and adding global codes corresponding to technical-only codes already on the list:

TABLE 11—CHANGES TO THE PROPOSED LIST OF PROCEDURES SUBJECT TO THE MPPR ON DIAGNOSTIC CARDIOVASCULAR SERVICES

Code	Descriptor	Added/deleted	Reason
75650	Artery x-rays head & neck	Deleted	Deleted for CY 2013.
75660	Artery x-rays head & neck	Deleted	Deleted for CY 2013.
75662	Artery x-rays head & neck	Deleted	Deleted for CY 2013.
75665	Artery x-rays head & neck	Deleted	Deleted for CY 2013.
75671	Artery x-rays head & neck	Deleted	Deleted for CY 2013.
75676	Artery x-rays neck	Deleted	Deleted for CY 2013.
75680	Artery x-rays neck	Deleted	Deleted for CY 2013.
75685	Artery x-rays spine	Deleted	Deleted for CY 2013.
75774	Artery x-ray each vessel	Deleted	Add-on Code.
78496	Heart first pass add-on	Deleted	Add-on Code.
93000	Electrocardiogram complete	Added	Global Code.
93015	Cardiovascular stress test	Added	Global Code.
93040	Rhythm ECG with report	Added	Global Code.
93224	Ecg monit/reprt up to 48 hrs	Added	Global Code.
93268	ECG record/review	Added	Global Code.
93293	Pm phone r-strip device eval	Deleted	Remote monitoring code.
93296	Pm/icd remote tech serv	Deleted	Remote monitoring code.
93320	Doppler echo exam heart	Deleted	Add-on Code.
93321	Doppler echo exam heart	Deleted	Add-on Code.
93325	Doppler color flow add-on	Deleted	Add-on Code.
93784	Ambulatory BP monitoring	Added	Global Code.

The complete list of services subject to the MPPR for the TC of diagnostic cardiovascular and ophthalmology services is shown in Addendum X. The PFS budget neutrality provision is applicable to the new MPPR for the TC of diagnostic cardiovascular and ophthalmology services. Therefore, the estimated reduced expenditures for such services have been redistributed to increase payment for other PFS services. We refer readers to section VIII.C. of this final rule with comment period for further discussion of the impact of this policy.

TABLE 12—DIAGNOSTIC CARDIOVASCULAR SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION

Code	Short descriptor
75600	Contrast x-ray exam of aorta.
75605	Contrast x-ray exam of aorta.
75625	Contrast x-ray exam of aorta.
75630	X-ray aorta leg arteries.
75658	Artery x-rays arm.
75705	Artery x-rays spine.
75710	Artery x-rays arm/leg.
75716	Artery x-rays arms/legs.
75726	Artery x-rays abdomen.
75731	Artery x-rays adrenal gland.
75733	Artery x-rays adrenals.
75736	Artery x-rays pelvis.
75741	Artery x-rays lung.

TABLE 12—DIAGNOSTIC CARDIOVASCULAR SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION—Continued

Code	Short descriptor
75743	Artery x-rays lungs.
75746	Artery x-rays lung.
75756	Artery x-rays chest.
75791	Av dialysis shunt imaging.
75809	Nonvascular shunt x-ray.
75820	Vein x-ray arm/leg.
75822	Vein x-ray arms/legs.
75825	Vein x-ray trunk.
75827	Vein x-ray chest.
75831	Vein x-ray kidney.
75833	Vein x-ray kidneys.
75840	Vein x-ray adrenal gland.
75842	Vein x-ray adrenal glands.
75860	Vein x-ray neck.
75870	Vein x-ray skull.
75872	Vein x-ray skull.
75880	Vein x-ray eye socket.
75885	Vein x-ray liver.
75887	Vein x-ray liver.
75889	Vein x-ray liver.
75891	Vein x-ray liver.
75893	Venous sampling by catheter.
78428	Cardiac shunt imaging.
78445	Vascular flow imaging.
78451	Ht muscle image spect sing.
78452	Ht muscle image spect mult.
78453	Ht muscle image planar sing.
78454	Ht musc image planar mult.
78456	Acute venous thrombus image.
78457	Venous thrombosis imaging.
78458	Ven thrombosis images bilat.

TABLE 12—DIAGNOSTIC CARDIOVASCULAR SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION—Continued

Code	Short descriptor
78466	Heart infarct image.
78468	Heart infarct image (ef).
78469	Heart infarct image (3D).
78472	Gated heart planar single.
78473	Gated heart multiple.
78481	Heart first pass single.
78483	Heart first pass multiple.
78494	Heart image spect.
93000	Electrocardiogram complete.
93005	Electrocardiogram tracing.
93015	Cardiovascular stress test.
93017	Cardiovascular stress test.
93024	Cardiac drug stress test.
93025	Microvolt t-wave assess.
93040	Rhythm ECG with report.
93041	Rhythm ecg tracing.
93224	Ecg monit/reprt up to 48 hrs.
93225	Ecg monit/reprt up to 48 hrs.
93226	Ecg monit/reprt up to 48 hrs.
93229	Remote 30 day ecg tech supp.
93268	ECG record/review.
93270	Remote 30 day ecg rev/report.
93271	Ecg/monitoring and analysis.
93278	ECG/signal-averaged.
93279	Pm device progr eval sngl.
93280	Pm device progr eval dual.
93281	Pm device progr eval multi.
93282	Icd device prog eval 1 sngl.
93283	Icd device progr eval dual.
93284	Icd device progr eval mult.
93285	Ilr device eval progr.
93286	Pre-op pm device eval.

TABLE 12—DIAGNOSTIC CARDIOVASCULAR SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION—Continued

Code	Short descriptor
93287	Pre-op icd device eval.
93288	Pm device eval in person.
93289	Icd device interrogate.
93290	Icm device eval.
93291	Ilr device interrogate.
93292	Wcd device interrogate.
93303	Echo transthoracic.
93304	Echo transthoracic.
93306	Tte w/doppler complete.
93307	Tte w/o doppler complete.
93308	Tte f-up or lmtd.
93312	Echo transesophageal.
93314	Echo transesophageal.
93318	Echo transesophageal intraop.
93350	Stress tte only.
93351	Stress tte complete.
93701	Bioimpedance cv analysis.
93724	Analyze pacemaker system.
93784	Ambulatory BP monitoring.
93786	Ambulatory BP recording.
93788	Ambulatory BP analysis.
93880	Extracranial study.
93882	Extracranial study.
93886	Intracranial study.
93888	Intracranial study.
93890	Tcd vasoreactivity study.
93892	Tcd emboli detect w/o inj.
93893	Tcd emboli detect w/inj.

TABLE 12—DIAGNOSTIC CARDIOVASCULAR SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION—Continued

Code	Short descriptor
93922	Upr/l xtremity art 2 levels.
93923	Upr/lxtr art stdy 3+ lvls.
93924	Lwr xtr vasc stdy bilat.
93925	Lower extremity study.
93926	Lower extremity study.
93930	Upper extremity study.
93931	Upper extremity study.
93965	Extremity study.
93970	Extremity study.
93971	Extremity study.
93975	Vascular study.
93976	Vascular study.
93978	Vascular study.
93979	Vascular study.
93980	Penile vascular study.
93981	Penile vascular study.
93990	Doppler flow testing.

TABLE 13—DIAGNOSTIC OPHTHALMOLOGY SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION

Code	Descriptor
76510	Ophth us b & quant a.
76511	Ophth us quant a only.
76512	Ophth us b w/non-quant a.

TABLE 13—DIAGNOSTIC OPHTHALMOLOGY SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION—Continued

Code	Descriptor
76513	Echo exam of eye water bath.
76514	Echo exam of eye thickness.
76516	Echo exam of eye.
76519	Echo exam of eye.
92025	Corneal topography.
92060	Special eye evaluation.
92081	Visual field examination(s).
92082	Visual field examination(s).
92083	Visual field examination(s).
92132	Cmptr ophth dx img ant segmt.
92133	Cmptr ophth img optic nerve.
92134	Cptr ophth dx img post segmt.
92136	Ophthalmic biometry.
92228	Remote retinal imaging mgmt.
92235	Eye exam with photos.
92240	Icg angiography.
92250	Eye exam with photos.
92265	Eye muscle evaluation.
92270	Electro-oculography.
92275	Electroretinography.
92283	Color vision examination.
92284	Dark adaptation eye exam.
92285	Eye photography.
92286	Internal eye photography.

TABLE 14—FREQUENTLY BILLED DIAGNOSTIC CARDIOVASCULAR COMBINATIONS

Code	Descriptor	Code	Descriptor	Code	Descriptor	Code	Descriptor
Code Range 75600–75893							
75710	Artery x-rays arm/leg.	75791	Av dialysis shunt imaging.				
75625	Contrast x-ray exam of aorta.	75716	Artery x-rays arms/legs.				
75625	Contrast x-ray exam of aorta.	75716	Artery x-rays arms/legs.	75774	Artery x-ray each vessel.		
75820	Vein x-ray arm/leg ..	75827	Vein x-ray chest.				
75625	Contrast x-ray exam of aorta.	75710	Artery x-rays arm/leg.				
75791	Av dialysis shunt imaging.	75827	Vein x-ray chest.				
75658	Artery x-rays arm	75791	Av dialysis shunt imaging.	75820	Vein x-ray arm/leg ..	75827	Vein x-ray chest.
75710	Artery x-rays arm/leg.	75774	Artery x-ray each vessel.				
75820	Vein x-ray arm/leg ..	93931	Upper extremity study.				
75791	Av dialysis shunt imaging.	75820	Vein x-ray arm/leg.				
Code Range 78414–78496							
78452	Ht muscle image spect mult.	93306	Tte w/doppler complete.				
78452	Ht muscle image spect mult.	93017	Cardiovascular stress test.				
78452	Ht muscle image spect mult.	93306	Tte w/doppler complete.	93880	Extracranial study.		
78452TC	Ht muscle image spect mult.	93017	Cardiovascular stress test.				
78452	Ht muscle image spect mult.	93880	Extracranial study.				

TABLE 14—FREQUENTLY BILLED DIAGNOSTIC CARDIOVASCULAR COMBINATIONS—Continued

Code	Descriptor	Code	Descriptor	Code	Descriptor	Code	Descriptor
78452TC	Ht muscle image spect mult.	93306	Tte w/doppler complete.				
78452	Ht muscle image spect mult.	93017	Cardiovascular stress test.	93306	Tte w/doppler complete.		
78451	Ht muscle image spect sing.	93306	Tte w/doppler complete.				
78452TC	Ht muscle image spect mult.	93306TC	Tte w/doppler complete.				
78452	Ht muscle image spect mult.	93306	Tte w/doppler complete.	93880	Extracranial study	93978	Vascular study.
Code Range 93000–93990							
93306	Tte w/doppler complete.	93880	Extracranial study.				
93320	Doppler echo exam heart.	93325	Lower extremity study.	93351	Stress tte complete.		
93922	Upr/l xtremity art 2 levels.	93925	Lower extremity study.				
93923	Upr/lxtr art stdy 3+ lvls.	93925	Lower extremity study.				
93306TC	Tte w/doppler complete.	93880TC	Extracranial study.				
93880	Extracranial study	93978	Vascular study.				
93284	Icd device progr eval mult.	93290	Icm device eval.				
93922	Upr/l xtremity art 2 levels.	93926	Lower extremity study.				
93965	Extremity study	93970	Extremity study.				
93925	Lower extremity study.	93970	Extremity study.				

TABLE 15—FREQUENTLY BILLED DIAGNOSTIC OPHTHALMOLOGY COMBINATIONS

Code	Descriptor	Code	Descriptor	Code	Descriptor
Code Range 76510–76529					
76514	Echo exam of eye thickness	92133	Cmptr ophth img optic nerve.		
76514	Echo exam of eye thickness	92083	Visual field examination(s)	92133	Cmptr ophth img optic nerve.
76514	Echo exam of eye thickness	92083	Visual field examination(s).		
76514	Echo exam of eye thickness	92250	Eye exam with photos.		
76514	Echo exam of eye thickness	92083	Visual field examination(s)	92250	Eye exam with photos.
76512	Ophth us b w/non-quant a	92134	Cptr ophth dx img post segmt.		
76512	Ophth us b w/non-quant a	92250	Eye exam with photos.		
76514	Echo exam of eye thickness	92286	Internal eye photography.		
76514	Echo exam of eye thickness	92134	Cptr ophth dx img post segmt.		
76512	Ophth us b w/non-quant a	92235	Eye exam with photos	92250	Eye exam with photos.
Code Range 92002–92371					
92083	Visual field examination(s)	92133	Cmptr ophth img optic nerve.		
92235	Eye exam with photos	92250	Eye exam with photos.		
92083	Visual field examination(s)	92250	Eye exam with photos.		
92083	Visual field examination(s)	92134	Cptr ophth dx img post segmt.		
92134	Cptr ophth dx img post segmt	92235	Eye exam with photos.		
92134	Cptr ophth dx img post segmt	92250	Eye exam with photos.		
92134	Cptr ophth dx img post segmt	92235	Eye exam with photos	92250	Eye exam with photos.
92250	Eye exam with photos	92285	Eye photography.		
92082	Visual field examination(s)	92250	Eye exam with photos.		
92081	Visual field examination(s)	92285	Eye photography.		

d. Procedures Subject to the OPPS Cap

We are proposing to add the new codes in Table 16 to the list of procedures subject to the OPPS cap, effective January 1, 2013. Some of these codes are replacement codes for codes deleted for CY 2013. These procedures meet the definition of imaging under section 5102(b) of the DRA. These codes are being added on an interim final basis and their addition as procedures subject to the OPPS cap is open to public comment in this final rule with comment period.

TABLE 16—ADDITIONS AND DELETIONS TO THE LIST OF PROCEDURE SUBJECT TO THE OPPS CAP ON IMAGING SERVICES

Additions		Deletions	
Code	Descriptor	Code	Descriptor
31620	Endobronchial us add-on	71040	Contrast x-ray of bronchi.
36221	Place cath thoracic aorta	71060	Contrast x-ray of bronchi.
36222	Place cath carotd/inom art	75650	Artery x-rays head & neck.
36223	Place cath carotd/inom art	75660	Artery x-rays head & neck.
36224	Place cath carotd art	75662	Artery x-rays head & neck.
36225	Place cath subclavian art	75665	Artery x-rays head & neck.
36226	Place cath vertebral art	75671	Artery x-rays head & neck.
36227	Place cath xtrnl carotid	75676	Artery x-rays neck.
36228	Place cath intracranial art	75680	Artery x-rays neck.
43206	Esoph optical endomicroscopy	75685	Artery x-rays spine.
43252	Upper GI optical endomicroscopy	75900	Intravascular cath exchange.
77080	DXA bone density axial	75961	Retrieval broken catheter.
77082	DXA bone density vert fx	77424	Intraoperative radiation delivery.
78013	Thyroid imaging w/blood flow	78006	Thyroid imaging with uptake.
78014	Thyroid imaging w/blood flow	78007	Thyroid image mult uptakes.
78070	Parathyroid planar imaging	78010	Thyroid imaging.
78071	Parathyroid planar imaging w/o subtrj	78011	Thyroid imaging with flow.
78072	Parathyroid imaging w/spect & ct.		
88375	Optical endomicroscopy interp.		
91110	GI tract capsule endoscopy.		
91111	Esophageal capsule endoscopy.		
92287	Internal eye photography.		

C. Overview of the Methodology for the Calculation of Malpractice RVUs

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: work, PE, and malpractice. From 1992 to 1999, malpractice RVUs were charge-based, using weighted specialty-specific malpractice expense percentages and 1991 average allowed charges. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 4505(f) of the BBA, which amended section 1848(c) of the Act, required us to implement resource-based malpractice RVUs for services furnished beginning in 2000. Therefore, initial implementation of resource-based malpractice RVUs occurred in 2000.

The statute also requires that we review and, if necessary, adjust RVUs no less often than every 5 years. The first review and update of resource-based malpractice RVUs was addressed in the CY 2005 PFS final rule with comment period (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). In the CY 2010 PFS final rule with comment period, we implemented the second review and update of malpractice RVUs. For a discussion of the second review and update of malpractice RVUs, see the CY 2010 PFS proposed rule (74 FR 33537) and final rule with comment period (74 FR 61758).

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), malpractice RVUs for new and revised codes effective before the next Five-Year Review of Malpractice (for example, effective CY 2011 through CY 2014, assuming that the next review of malpractice RVUs occurs for CY 2015) are determined either by a direct crosswalk to a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjust (or ''scale'') the malpractice RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work value (or, if greater, the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code is 10 percent higher than the work RVU for its source code, the malpractice RVU for the revised code would be increased by 10 percent over the source code malpractice RVU. This approach presumes the same risk factor for the new/revised code and source code but uses the work RVU for the new/revised code to adjust for risk-of-service.

As we indicated in the CY 2013 PFS proposed rule, we will continue our current approach for determining malpractice RVUs for new/revised codes. In section II.M.2. of this final rule with comment period, we have published a list of new/revised codes and the malpractice crosswalk(s) used for determining their malpractice RVUs. These malpractice RVUs for new/revised codes will be implemented for CY 2013 on an interim final basis and the malpractice crosswalks are subject to public comment. We will respond to comments and finalize the malpractice crosswalks for the majority of these codes in the CY 2014 PFS final rule with comment period.

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice). While requiring that the PE and MP GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states beginning January 1, 2011.

Section 1848 (e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2011. The statute was amended by section 303 of the Temporary Payroll

Tax Cut Continuation Act of 2011 (TPTCCA) (Pub. L. 112–78) to extend the 1.0 floor for the work GPCIs through February 29, 2012. The statute was again amended by section 3004 of the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA) (P.L. 112–399) to extend the 1.0 work floor for GPCIs throughout the remainder of CY 2012 (that is, for services furnished no later than December 31, 2012). During the development of the CY 2012 PFS final rule with comment period, neither TPTCCA nor MCTRJCA had been enacted and, because the work GPCI floor was set to expire at the end of 2011, the GPCIs published in Addendum E of the CY 2012 PFS final rule with comment period did not reflect the 1.0 work floor. Following the enactment of the legislation, appropriate changes to the CY 2012 GPCIs to reflect the 1.0 work floor required by section 303 of the TPTCCA and section 3004 of the MCTRJCA.

Since the 1.0 work GPCI floor provided in section 1848 (e)(1)(E) of the Act is set to expire prior to the implementation of the CY 2013 updates to the PFS, the proposed CY 2013 work GPCIs and summarized geographic adjustment factors (GAFs) published in addendums D and E of this CY 2013 PFS proposed rule do not reflect the 1.0 work GPCI floor for CY 2013. As required by section 1848 (e)(1)(G) and section1848 (e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are applicable in CY 2013 and are reflected in addendums D and E.

In the CY 2012 PFS final rule with comment period, we made several refinements to the GPCIs (76 FR 73081 through 73092), including revising the sixth GPCI update to reflect the most recent data, with modifications. Specifically, we finalized our proposal to change the GPCI cost share weights for CY 2012 to reflect the most recent rebased and revised Medicare Economic Index (MEI). As a result, the cost share weight for the work GPCI (as a percentage of the total) was changed from 52.466 percent to 48.266 percent, and the cost share weight for the PE GPCI was revised from 43.669 percent to 47.439 percent with a change in the employee compensation component from 18.654 to 19.153 percentage points. The cost share weight for the office rent component of the PE GPCI was changed from 12.209 percent to 10.223 percentage points (fixed capital with utilities), and the medical equipment, supplies, and other miscellaneous expenses component was changed from 12.806 percent to 9.968 percentage points. In addition, we finalized the weight for purchased services at 8.095 percentage points, of which 5.011 percentage points are adjusted for geographic cost differences. Lastly, the cost share weight for the malpractice GPCI was revised from 3.865 percent to 4.295 percent. Table 17 displays the cost share weights that were finalized in the CY 2012 final rule with comment period. Note that the employee compensation; office rent; purchased services; and equipment supplies and other cost share weights sum to the total PE GPCI cost share weights of 47.439 percent.

TABLE 17—COST SHARE WEIGHTS FINALIZED IN CY 2012 GPCI UPDATE

Expense category	Cost share weights %
Work	48.266
Practice Expense	47.439
Employee Compensation	19.153
Office Rent	10.223
Purchased Services	8.095
Equipment, Supplies, and Other	9.968
Malpractice Insurance	4.295

We also finalized several other policies in the CY 2012 final rule with comment period including the use of 2006 through 2008 American Community Survey (ACS) two-bedroom rental data as a proxy for the relative cost difference in physician office rent. In addition, we created a purchased services index to account for labor-related services within the ''all other services'' and ''other professional expenses'' MEI components. In response to public commenters who recommended that we use Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) data to capture the ''full range'' of occupations included in the offices of physician industry to calculate the nonphysician employee wage component (also referred to as the employee wage index) of the PE GPCI, we finalized a policy of using 100 percent of the total wage share of nonphysician occupations in the offices of physicians' industry to calculate the nonphysician employee wage component of the PE GPCI.

2. Recommendations From the Institute of Medicine

Concurrent with our CY 2012 rulemaking cycle, the Institute of Medicine released the final version of its first of two anticipated reports entitled *''Geographic Adjustment in Medicare Payment: Phase I: Improving Accuracy, Second Edition''* on September 28, 2011. This report included an evaluation of the accuracy of GAFs for the hospital wage index and the GPCIs, as well as the methodology and data used to calculate them. Several of the policies that we finalized in CY 2012 rulemaking addressed recommendations contained in the Institute of Medicine's first report. Because we did not have adequate time to completely address the Institute of Medicine's Phase I report recommendations during CY 2012 rulemaking, we included a discussion in the CY 2013 proposed rule (77 FR 44756) about the recommendations that were not implemented or discussed in the CY 2012 final rule with comment period.

As we anticipated in the CY 2013 proposed rule, the Institute of Medicine's second report, entitled ''*Geographic Adjustment in Medicare Payment—Phase II: Implications for Access, Quality, and Efficiency,*'' was released July 17, 2012. The Phase II report evaluates the effects of GAFs (hospital wage index and GPCIs) on the distribution of the healthcare workforce, quality of care, population health, and the ability to provide efficient, high value care. Once we have had an opportunity to fully evaluate the report and its recommendations we will respond to its recommendations in subsequent rulemaking.

3. GPCI Discussion for CY 2013

CY 2013 is the final year of the sixth GPCI update and, because we will propose updates next year, we did not include any proposals related to the GPCIs for the CY 2013 PFS. In response to public inquiries about exceptions to the calculated GPCIs, we provided a brief discussion about the permanent 1.0 PE floor for frontier states, the 1.5 work floor for Alaska, the GPCIs for the Puerto Rico payment locality, and the expiration of the GPCI 1.0 work floor required under section 1848 (e)(1)(E) of the Act. We also discussed recommendations from the first Institute of Medicine report that were not addressed during CY 2012 rulemaking in the CY 2013 proposed rule. We have included this discussion below.

a. Alaska Work Floor and PE GPCI Floor for Frontier States

Section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009. Therefore, the 1.5 work floor for Alaska will remain in effect in CY 2013. In addition, section 1848(e)(1)(I) of the Act establishes a 1.0 PE GPCI floor for physicians' services furnished in frontier states effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act,

beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in states determined to be frontier states. The following states met the statutory criteria to be considered frontier states for CY 2012: Montana, North Dakota, Nevada, South Dakota, and Wyoming. There are no changes to those states identified as frontier states for CY 2013.

b. GPCI Assignments for the Puerto Rico Payment Locality

As noted in the CY 2013 proposed rule, we have received inquiries from representatives of the Puerto Rico medical community regarding our policies for determining the GPCIs for the Puerto Rico payment locality. While we did not make any proposals related to the GPCIs for Puerto Rico, in response to those inquiries, we provided the following discussion regarding the GPCIs assigned to the Puerto Rico payment locality. We anticipate recalculating all the GPCIs in the seventh GPCI update, currently anticipated to be implemented for CY 2014.

As noted above, we are required by section 1848(e)(1)(A) of the Act to develop separate GPCIs to measure relative resource cost differences among localities compared to the national average for each of the three fee schedule components: Work, PE and malpractice expense. To calculate these GPCI values, we rely on three primary data sources. We currently use the 2006–2008 BLS OES data to calculate the work GPCI, the nonphysician employee wage component of PE GPCI, and the labor costs associated with the purchased services component of PE GPCI. We use 2006–2008 ACS data to calculate the office rent component of the PE GPCI. Finally, we use 2006–2007 malpractice premium data to calculate the malpractice GPCI. For all localities, including Puerto Rico, we assume equipment, supplies, and other expenses are purchased in a national market and that the costs do not vary by geographic location. Therefore, we do not use data on the price of equipment, supplies, and expenses across localities in calculating PE GPCIs. With the exception of the malpractice GPCI, we have current data from the applicable sources allowing us to calculate the work and PE GPCIs for the Puerto Rico payment locality. The 2006–2008 BLS OES data and rental values derived from the 2006–2008 ACS indicate that the costs associated with operating a physician practice in Puerto Rico are the lowest among all payment localities.

To calculate the malpractice GPCI for the various Medicare PFS localities, we collect malpractice insurance market share and premium data from state departments of insurance and from state rate filings. As discussed in our contractor's report (Final Report on the Sixth Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule page. 41), for the fourth, fifth, and sixth GPCI updates we were not able to collect this data for the Puerto Rico payment locality. Therefore, we carried over the malpractice GPCI value of 0.249 from previous GPCI updates when malpractice premium data were last available. It is important to note that we have a source for more current malpractice premium data for Puerto Rico for use in the upcoming seventh GPCI update. We are working with the relevant officials in Puerto Rico to acquire these data for use in future rulemaking.

For a detailed discussion regarding the methodology used to calculate the various components of the Puerto Rico GPCIs, we referred readers to our contractor's report from November of 2010 entitled ''Final Report on the Sixth Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule'' available on our Web site at *www.cms.gov/PhysicianFeeSched/downloads/GPCI_Report.pdf.*

In the CY 2013 proposed rule, we also encouraged comments from stakeholders regarding potential data sources that may be available for calculating the Puerto Rico malpractice GPCI.

Comment: In response to our inquiry regarding potential sources for data that could be used in calculating a malpractice GPCI for Puerto Rico, we received numerous comments about the costs of practicing medicine in Puerto Rico. The commenters primarily expressed concern about the PE GPCI (with emphases on the rent component) and the malpractice GPCI. The commenters stated that the current GPCI values for Puerto Rico are low in comparison to other PFS localities and that this disparity may create incentives for doctors to move their practices to the continental United States. As a result, the commenters explained that access to both primary and specialty care for Medicare beneficiaries residing in Puerto Rico could be compromised. Several stakeholders provided a report on a comprehensive study entitled *''Cost of Medical Services in Puerto Rico.''* The report included results from a physician survey on the costs of operating a medical practice in Puerto Rico, including the cost for obtaining malpractice insurance. For example, the report included information about the leading malpractice insurers in Puerto Rico, the amount of malpractice insurance coverage typically purchased by physicians, and the cost of malpractice insurance by primary and specialty care providers. In addition to malpractice insurance costs, the report also included information on the cost of employees, contracted services, rent and utilities, medical equipment and supplies in Puerto Rico as well as information on the major concerns, demographics, and work patterns of the doctors currently practicing medicine in Puerto Rico and the doctors that have moved from Puerto Rico now practicing in the United States.

Response: As noted in the proposed rule, we will be adjusting the GPCIs for CY 2014. Given that we did not make any proposals to modify the malpractice GPCI calculation methodology or values for CY 2013, it would not be appropriate to make changes to the GPCIs in this final rule. We appreciate the physician survey information on the cost of malpractice insurance. We will review the information submitted on the cost of obtaining malpractice insurance in Puerto Rico as we prepare for the seventh GPCI update. We would note that the GPCIs are based upon changes in the relative costs of obtaining malpractice insurance so any changes in the GPCI for Puerto Rico will be based not only on data reflecting the costs on Puerto Rico, but also those in other localities.

c. Expiration of GPCI Work Floor

The work GPCIs are designed to capture the relative costs of physician labor by Medicare PFS locality. Previously, the work GPCIs were developed using the median hourly earnings from the 2000 Census of workers in seven professional specialty occupation categories that we used as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories because Medicare payments are a key determinant of physicians' earnings. That is, including physicians' wages in the work GPCIs would effectively make the indices dependent upon Medicare payments. As required by law, the work GPCIs reflect one quarter of the relative wage differences for each locality compared to the national average. The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. For the sixth GPCI update in CY 2011, we used the 2006 through 2008 BLS OES data as a replacement for the 2000 Census data.

Although we did not propose any changes to the data or methodology used to calculate the work GPCI for CY

2013, we note that addenda D and E will reflect the expiration of the statutory 1.0 work GPCI floor which as noted above, is set to expire on December 31, 2012 in accordance with section 1848 (e)(1)(E) of the Act.

Comment: A few commenters requested an extension of the 1.0 work GPCI floor stating that the statutorily-mandated work GPCI floor will expire on December 31, 2012.

Response: As discussed above (and noted by the commenters) the 1.0 work GPCI floor is set to expire on December 31, 2012 and we do not have authority to extend the 1.0 work GPCI floor beyond December 31, 2012.

4. Institute of Medicine Phase I Report

a. Background

At our request, the Institute of Medicine conducted a study of the geographic adjustment factors in Medicare payment. It is a comprehensive empirical study of the geographic adjustment factors established under sections 1848(e) (GPCI) and 1886(d)(3)(E) (hospital wage index) of the Act. These adjustments are designed to ensure Medicare payments reflect differences in input costs across geographic areas. The factors the Institute of Medicine evaluated include the following:

- Accuracy of the adjustment factors;
- Methodology used to determine the adjustment factors; and
- Sources of data and the degree to which such data are representative.

Within the context of the U.S. healthcare marketplace, the Institute of Medicine also evaluated and considered the—

- Effect of the adjustment factors on the level and distribution of the health care workforce and resources, including—

++ Recruitment and retention taking into account mobility between urban and rural areas;

++ Ability of hospitals and other facilities to maintain an adequate and skilled workforce; and

++ Patient access to providers and needed medical technologies;

- Effect of adjustment factors on population health and quality of care; and
- Effect of the adjustment factors on the ability of providers to furnish efficient, high value care.

The Institute of Medicine's first report entitled ''*Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy*'' evaluated the accuracy of geographic adjustment factors and the methodology and data used to calculate them. The recommendations included in the Institute of Medicine's Phase I report that relate to or would have an effect on the methodologies used to calculate the GPCIs and the configuration of Medicare PFS payment locality structure are summarized as follows:

- Recommendation 2–1: The same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Metropolitan statistical areas and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets.
- Recommendation 2–2: The data used to construct the hospital wage index and the physician geographic adjustment factor should come from all health care employers.
- Recommendation 5–1: The GPCI cost share weights for adjusting fee-for-service payments to practitioners should continue to be national, including the three GPCIs (work, PE, and liability insurance) and the categories within the PE (office rent and personnel).
- Recommendation 5–2: Proxies should continue to be used to measure geographic variation in the physician work adjustment, but CMS should determine whether the seven proxies currently in use should be modified.
- Recommendation 5–3: CMS should consider an alternative method for setting the percentage of the work adjustment based on a systematic empirical process.
- Recommendation 5–4: The PE GPCI should be constructed with the full range of occupations employed in physicians' offices, each with a fixed national weight based on the hours of each occupation employed in physicians' offices nationwide.
- Recommendation 5–5: CMS and the Bureau of Labor Statistics should develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for CMS.
- Recommendation 5–6: A new source of information should be developed to determine the variation in the price of commercial office rent per square foot.
- Recommendation 5–7: Nonclinical labor-related expenses currently included under PE office expenses should be geographically adjusted as part of the wage component of the PE.

This report can be accessed on the Institute of Medicine 's Web site at *www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx*.

As previously noted in this section, the Institute of Medicine also considered the role of Medicare payments on matters such as the distribution of the healthcare workforce, population health, and the ability of providers to produce high-value, high-quality health care in its final report July 17, 2012. We were not able to evaluate the recommendations contained in the Institute of Medicine's Phase II report, in time for discussion in the proposed rule. The Phase II report can be accessed on the Institute of Medicine's Web site at *www.iom.edu/Reports/2012/Geographic-Adjustment-in-Medicare-Payment-Phase-II.aspx*.

b. Institute of Medicine Recommendations Implemented in CY 2012

In the CY 2012 PFS final rule with comment period, we addressed three of the recommendations offered by the Institute of Medicine in its Phase I report. Specifically, the final CY 2012 GPCIs utilized the full range of nonphysician occupations in the employee wage calculation consistent with Institute of Medicine recommendation 5–4. Additionally, we created a new purchased service index to account for nonclinical labor related expenses similar to Institute of Medicine recommendation 5–7. Lastly, we have consistently used national cost share weights to determine the appropriate weight attributed to each GPCI component, which is supported by Institute of Medicine recommendation 5–1 (76 FR 73081 through 73092). In order to facilitate a public discussion regarding the Institute of Medicine's remaining Phase I recommendations, we provided a summary analysis of these recommendations in the CY 2013 proposed rule, which has also been included in this final rule with comment period below. We provided our technical analyses of the remaining Institute of Medicine Phase I recommendations in a report released on the PFS Web site at *www.cms.gov/PhysicianFeeSched*. Since we have not yet had an opportunity to review the recommendations in the Institute of Medicine's Phase II report, these analyses focus exclusively on the recommendations as presented in the Institute of Medicine's Phase I report.

c. Discussion of Remaining Institute of Medicine's Phase I Recommendations

(1) Institute of Medicine Recommendation Summaries

(A) *Institute of Medicine recommendation 2–1:* The same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Metropolitan statistical areas and

statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pages 2–1 thru 2–29)

(i) Locality Background

The current PFS locality structure was developed and implemented in 1997. There are currently 89 total PFS localities; 34 localities are statewide areas (that is, only one locality for the entire state). There are 52 localities in the other 16 states, with 10 states having 2 localities, 2 states having 3 localities, 1 state having 4 localities, and 3 states having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 89 localities. The development of the current locality structure is described in detail in the CY 1997 PFS proposed rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494).

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments were based on the charging patterns of physicians. This resulted in large differences among types of services, geographic payment areas, and physician specialties. Recognizing this, the Congress replaced the reasonable charge system with the Medicare PFS in the Omnibus Budget Reconciliation Act (OBRA) of 1989, effective January 1, 1992. Payments under the fee schedule are based on the relative resources used in furnishing services and vary among areas as resource costs vary geographically as measured by the GPCIs.

Payment localities were established under the reasonable charge system by local Medicare carriers based on their knowledge of local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. As a result, a study was begun in 1994 that resulted in a comprehensive locality revision, which was implemented in 1997 (61 FR 59494).

The revised locality structure reduced the number of localities from 210 to the current 89 and the number of statewide localities increased from 22 to 34. The revised localities were based on locality resource cost differences as reflected by the GPCIs. A full discussion of the methodology can be found in the CY 1997 PFS final rule with comment period (61 FR 59494). The current 89 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS.

As was stated in the CY 2011 final rule with comment period (75 FR 73261), we require that changes to the PFS locality structure be done in a budget neutral manner within a state. For many years, we have sought consensus for any locality changes among the professionals whose payments would be affected. We have also considered more comprehensive changes to locality configurations. In 2008, we issued a draft comprehensive report detailing four different locality configuration options (*www.cms.gov/physicianfeesched/downloads/ReviewOfAltGPCIs.pdf*). The alternative locality configurations in the report are described below.

- *Option 1: CMS Core-Based Statistical Area (CBSA) Payment Locality Configuration:* CBSAs are a combination of Office of Management and Budget (OMB's) Metropolitan Statistical Areas (MSAs) and their Micropolitan Statistical Areas. Under this option, MSAs would be considered as urban CBSAs. Micropolitan Statistical Areas (as defined by OMB) and rural areas would be considered as non-urban (rest of state) CBSAs. This approach would be consistent with the areas used in the Inpatient Prospective Payment System (IPPS) pre-reclassification wage index, which is the hospital wage index for a geographic area (CBSA or non-CBSA) calculated from submitted hospital cost report data before statutory adjustments reconfigure, or ''reclassify'' a hospital to an area other than its geographic location, to adjust payments for difference in local resource costs in other Medicare payment systems. Based on data used in the 2008 locality report, this option would increase the number of PFS localities from 89 to 439.
- *Option 2: Separate High-Cost Counties from Existing Localities (Separate Counties):* Under this approach, higher cost counties are removed from their existing locality structure, and they would each be placed into their own locality. This option would increase the number of PFS localities from 89 to 214, using a 5 percent GAF differential to separate high-cost counties.
- *Option 3: Separate MSAs from Statewide Localities (Separate MSAs):* This option begins with statewide localities and creates separate localities for higher cost MSAs (rather than removing higher cost counties from their existing locality as described in Option 2). This option would increase the number of PFS localities from 89 to 130, using a 5 percent GAF differential to separate high-cost MSAs.
- *Option 4: Group Counties Within a State Into Locality Tiers Based on Costs (Statewide Tiers):* This option creates tiers of counties (within each state) that may or may not be contiguous but share similar practice costs. This option would increase the number of PFS localities from 89 to 140, using a 5 percent GAF differential to group similar counties into statewide tiers.

For a detailed discussion of the public comments on the contractor's 2008 draft report detailing four different locality configurations, we refer readers to the CY 2010 PFS proposed rule (74 FR 33534) and subsequent final rule with comment period (74 FR 61757). There was no public consensus on the options, although a number of commenters expressed support for Option 3 (separate MSAs from statewide localities) because the commenters believed this alternative would improve payment accuracy and could mitigate potential reductions to rural areas compared to Option 1 (CMS CBSAs).

In response to some public comments regarding the third of the four locality options, we had our contractor conduct an analysis of the impacts that would result from the application of Option 3. Those results were displayed in the final locality report released in 2011. The final report, entitled ''*Review of Alternative GPCI Payment Locality Structures—Final Report,*'' may be accessed directly from the CMS Web site at *www.cms.gov/PhysicianFeeSched/downloads/Alt_GPCI_Payment_Locality_Structures_Review.pdf*.

(ii) Institute of Medicine Recommendations on PFS Locality Structure Discussion

The Institute of Medicine recommends altering the current locality structure that was originally based on areas set by local contractors and, in 1996, reduced from 210 to current 89 using a systematic iterative methodology. Rather than using the current uniform fee schedule areas in adjusting for relative cost differences as compared to the national average, the Institute of Medicine recommends a three-tiered system for defining fee schedule areas. In the first tier, the

Institute of Medicine proposes applying county-based fee schedule areas to calculate the employee wage component of the PE GPCI. Although the Institute of Medicine's report states that it recommends that ''Metropolitan statistical areas and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets,'' the Institute of Medicine also recommends applying an out-commuting adjustment, which would permit employee wage index values to vary by county. Since the employee wage index is one component of the PE GPCI, these values also would vary by county under the Institute of Medicine's proposal.

To understand why the employee wage index would vary by county under the Institute of Medicine's recommendation, consider the three steps that would be required to calculate the employee wage index. The first step calculates the average hourly wage (AHW) for workers employed in each MSA or residual (rest of state) area. The wages of workers in each occupation are weighted by the number of workers employed in physicians' offices nationally. The second step applies a commuting-based smoothing adjustment to create area index wages for each county. The commuting-adjusted county index wages are equal to a weighted average of the AHW values calculated in the first step, where the weights are county-to-MSA out-commuting patterns. The Institute of Medicine's out-commuting-based weights equal the share of health care workers that live in a county where a physician's office is located who commute out of the county to work in a physician's office in each MSA. The third step sets each physician's employee index wage equal to the estimated area index wage (calculated in Step 2) of the county in which the physician's office is located. Because the out-commuting adjustment envisioned by the Institute of Medicine in the second step varies by county, the employee wage index value—and thus the PE GPCI as a whole—would also potentially vary by county depending on the smoothing option chosen. If implemented, the number of employee wage index payment areas could potentially increase from 89 to over 3,000.

The Institute of Medicine's second tier of fee schedule areas would use an MSA-based approach. The Institute of Medicine proposes using the MSA-based system for the work GPCI, the office rent index and the purchased services index of the PE GPCI, and the MP GPCI. An MSA is made up of one or more counties, including the counties that contain the core urban area with a population of 50,000 or more, as well as surrounding counties that exhibit a high degree of social and economic integration (as measured by commuting patterns) with the urban core. MSAs are designed to be socially and economically integrated units based on the share of workers who commute to work within the urban core of each MSA. Implementing an MSA-based locality structure would expand the number of fee schedule areas from 89 to upwards of 400 plus additional MSAs for U.S. territories (for example, Virgin Islands, American Samoa, Guam, Northern Marianna Islands).

In its third payment area tier, the Institute of Medicine proposes creating a national payment area for the ''equipment, supplies and other'' index. We currently do not adjust PEs associated with supplies and equipment since we believe they are typically purchased in a national market. Thus, this approach is equivalent to using a national fee schedule area to define this index. The Institute of Medicine proposes no change to the fee schedule area used to compute the ''equipment, supplies and other'' index.

Based on our contractor's analysis, there would be significant redistributive impacts if we were to implement a policy that would reconfigure the PFS localities based on the Institute of Medicine's three-tiered recommendation. Many rural areas would see substantial decreases in their corresponding GAF and GPCI values as higher cost counties are removed from current ''rest of state'' payment areas. Conversely, many urban areas, especially those areas that are currently designated as ''rest of state'' but reside within higher cost MSAs, would experience increases in their applicable GPCIs and GAFs.

The localities used to calculate the GPCIs have been a subject of substantial discussion and debate since the implementation of the PFS. The intensity of those discussions has increased since the last comprehensive update to the locality structure in 1997. Physicians and other suppliers in areas such as Santa Cruz County, California and Prince William County, Virginia have expressed concern that the current locality structure does not appropriately capture economic and demographic shifts that have taken place since the last PFS locality update. On the other hand, rural practitioners have argued that revisions to the current PFS payment localities will reduce their payments and exacerbate the problems of attracting physicians and other practitioners to rural areas. In the past, we have also heard concerns from representatives of some statewide localities regarding the potential implications of adopting an alternative locality structure that would change their current statewide payment area (74 FR 33536).

The Institute of Medicine stated in its Phase I report regarding its locality recommendation that, ''While the payment areas would stay the same for the HWI (hospital wage index), implementing this recommendation would mean that the GPCI payment areas would expand from 89 to 441 areas, which would be a significant change. The impact of the change in payment areas will be assessed in the Phase II report.'' (''*Geographic Adjustment in Medicare Payment: Phase I: Improving Accuracy, Second Edition'' on September 28, 2011 page 5–6.*) Moreover, the Institute of Medicine's Phase II report will evaluate the effects of geographic adjustment factors on the distribution of the healthcare workforce, quality of care, population health, and the ability to provide efficient, high value care. Over the years, commenters that have opposed revisions to localities have claimed that changes to the PFS areas could have a significant impact on the ability of rural areas to attract physicians. Certainly, one of our major goals when we last comprehensively revised the Medicare PFS localities in 1996 was to avoid excessively large urban/rural payment differences (61 FR 59494). In 1996, we were hopeful that the revisions would improve access to care for rural areas (61 FR 59494). Some areas may have experienced both economic and demographic shifts since the last comprehensive locality update. Before moving forward with the Institute of Medicine's three-tiered locality recommendation, or any other potential locality revision, we would need to assess, and prepare to inform the public of, the impact of any change for all Medicare stakeholders. The Institute of Medicine's Phase II report, released July 17, 2012, contains an evaluation of many of these important factors including:

- The effect of the adjustment factors on the level and distribution of the health care workforce and resources, including—

++ Recruitment and retention taking into account mobility between urban and rural areas;

++ Ability for hospitals and other facilities to maintain an adequate and skilled workforce;

++ Patient access to providers and needed medical technologies;

++ Effect of adjustment factors on population health and quality of care; and

++ Effect of adjustment factors on the ability of providers to furnish efficient, high value care.

To fully assess the broader public policy implications associated with the Institute of Medicine's locality recommendation, we must first fully assess and analyze the recommendations contained in the Institute of Medicine's Phase II report. Accordingly, we believe that it would be premature to make any statements about potential changes we would consider making to the PFS localities at this time. Any changes to PFS fee schedule areas would be made through future notice and comment rulemaking.

In the event that we develop a specific proposal for changing the locality configuration during future rulemaking, we would provide detailed analysis on the impact of the changes for physicians in each county. We would also provide opportunities for public input (for example, Town Hall meetings or Open Door Forums), as well as opportunities for public comments afforded by the rulemaking process.

While we did not propose to change the current locality configuration for CY 2013, we requested public comments regarding the Institute of Medicine's recommended three-tiered PFS payment locality definition. In addition, as stated above we, made our technical analyses of the Institute of Medicine locality recommendations, specific to the Phase I report, available on the CMS Web site at *www.cms.gov/PhysicianFeeSched/*.

The following is a summary of the comments we received regarding the Institute of Medicine's recommended three-tiered PFS payment locality definition.

Comment: We received several comments on the Institute of Medicine's recommendation for a three-tiered PFS payment locality definition. Commenters from rural areas opposed increasing the number of payment localities, as would happen under an MSA-based PFS locality structure, because it would redistribute payments from rural to urban areas. Additionally, commenters who opposed the Institute of Medicine's three-tiered locality approach argued that increasing the number of PFS payment localities would reduce their payment amounts and exacerbate problems of attracting physicians and other practitioners to rural areas.

A few commenters supported the Institute of Medicine's recommendation to move toward an MSA-based locality configuration and urged us to make updating the PFS locality configuration a priority in CY 2013. Commenters supporting an MSA-based locality configuration contend that significant economic and demographic shifts have occurred since the last reconfiguration, making the current locality assignments outdated. One state medical association expressed disappointment that we did not propose an MSA-based locality structure for CY 2013. The commenter urged us ''to adopt a transition plan to update the PFS localities'' and stressed that the ''transition plan must take into account the negative impact on physicians practicing in rural areas and work to mitigate the reductions in these regions.''

Response: We appreciate the comments received on the Institute of Medicine's recommendation to adopt an MSA-based approach for defining PFS localities. We will continue to evaluate the comments received on the Institute of Medicine's recommendations for revising the PFS locality structure, along with the impacts of such recommendations as discussed in the Phase II report.

(B) *Institute of Medicine Recommendation 2–2:* Employee Wage Index of the PE GPCI. The data used to construct the hospital wage index and the physician geographic adjustment factor should come from all healthcare employers (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pages 2–1 thru 2–29) and Recommendation 5–5: CMS and the Bureau of Labor Statistics should develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for the Centers for Medicare and Medicaid Services. (*Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy* page 5–38.)

The Institute of Medicine recommends altering the data used to calculate the employee wage index. Specifically, Institute of Medicine recommends using wage data for workers in the healthcare industry rather than wage data for workers across all-industries. Although all-industry wage data has the largest sample size, the Institute of Medicine ''* * * is concerned that the [all-industry] sample does not represent physician offices.'' BLS OES occupation wage data by MSA, however, are not publicly available for the healthcare industry. Using healthcare-industry wages would require the use of confidential BLS OES data. While CMS could potentially secure access to the confidential BLS OES data, the general public may not be able to. Although the Institute of Medicine recommends that CMS secure an agreement with BLS to use the confidential wage data, the current employee wage index relies on publicly-available all-industry wage data.

In the CY 2013 proposed rule we requested comments on the use of confidential employee wage index data rather than the publicly available all-industry wage data. However, we did not receive specific comments as to whether we should pursue the acquisition of confidential employee wage index data (as a replacement for the publically available all-industry wage data) for purposes of determining the employee wage index component of the PE GPCI.

Regardless of whether healthcare-industry or all-industry wage data is used, the Institute of Medicine recommends following the current approach adopted by CMS in CY 2012 for calculating the employee wage index. This approach constructs the employee wage index as a weighted average of occupation wages for the full-range of occupations employed in physicians' offices, where the weights are equal to the fixed national weight based on the hours of each occupation employed in physicians' offices nationwide. We adopted this approach for calculating the GPCI employee wage index in the CY 2012 PFS final rule with comment period (76 FR 73088).

(C) Institute of Medicine Recommendation 5–2: Work GPCI Methodology

Proxies should continue to be used to measure geographic variation in the physician work adjustment, but CMS should determine whether the seven proxies currently in use should be modified (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy page 5–36) and; Recommendation 5–3: CMS should consider an alternative method for setting the percentage of the work adjustment based on a systematic empirical process. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pages 5–36 thru 5–37)

The Institute of Medicine recommends replacing the current work GPCI methodology with a regression-based approach. We currently use three steps to calculate the work GPCI. These steps include:

(1) Selecting the proxy occupations and calculating an occupation-specific index for each proxy;

(2) Assigning weights to each proxy-occupation index based on each occupation's share of total national wages to create an aggregate proxy-occupation index; and

(3) Adjusting the aggregate proxy-occupation index by a physician inclusion factor to calculate the final work GPCI.

By using this approach, the current methodology reduces the circularity problem that occurs when work GPCI values are based on direct measurements of physician earnings. Because physician earnings are made up of both wages and a return on investment from ownership of the physician practice, calculating the work GPCI using physician earnings information would assign areas where physician practices are more profitable higher work GPCI values. Although the Institute of Medicine recommends that we continue to use proxy occupations in the work GPCI methodology, its regression-based approach alters each of the three steps described above.

To modify the first step, the Institute of Medicine recommends that we empirically evaluate the validity of seven proxy occupations we currently use. The current proxy occupations in the work GPCI are intended to represent highly educated, professional employee categories. Although the Institute of Medicine recommends re-evaluating the proxy occupations used in the work GPCI, it does not define specific criteria to use for this purpose.

To modify the second step, the Institute of Medicine recommends using a regression-based approach to weight the selected proxy occupation indices based on their correlation with physician earnings. This Institute of Medicine proposal would replace the current approach where occupations are weighted by the size of their share of total national wages. Such an approach presumes that wages for proxy occupations are not related to physician profits.

Finally, the Institute of Medicine proposes an empirically-based approach to determine the inclusion factor for work. The inclusion factor for work refers to section 1848(e)(1)(A)(iii) of the Act requiring that the work GPCI reflect only 25 percent of the difference between the relative value of physicians' work effort in each locality and the national average of such work effort. Therefore, under current law, only one quarter of the measured regional variation in physician wages is incorporated into the work GPCI. The Institute of Medicine recommends calculating an inclusion factor based on the predicted values of the regression described above. Under the Institute of Medicine's approach, the inclusion factor is larger when the proxy occupations have a higher correlation with physicians' earnings and smaller when the proxy occupations have a lower correlation with physicians' earnings. We note that using such an empirical approach to weight the proxy occupation indices and to estimate the inclusion factor requires the identification of a viable source of physician wage information in addition to the wage information of proxy occupations to accurately measure regional variation in physician wages.

We requested comments on the Institute of Medicine's recommendations to revise the work GPCI methodology.

The following is a summary of the comments we received regarding the Institute of Medicine's recommendations to revise the work GPCI methodology.

Comment: A few commenters stated that the physician work GPCI should not be adjusted at all for geographic cost differences. However, the same commenters stated that if geographic payments adjustments must be applied under the PFS, the current proxy occupations used for calculating the work GPCI should be replaced with actual physician salary survey data to determine the true cost (market price) of physician labor. To that end, the commenters suggested that third parties who hire physicians, for example hospitals, would be a good source for obtaining ''market based'' physician salary data. Additionally, one commenter encouraged us to work with the AMA and the Medical Group Management Association (MGMA) to evaluate the validity of the current proxy occupational data sources and to determine methods for gathering reliable physician cost data.

Response: We appreciate the comments received on the Institute of Medicine's recommendations to revise the work GPCI methodology. We will continue to evaluate the comments received on the methodology used for determining the physician work GPCI in preparation for the seventh update to the GPCIs, which is scheduled to be implemented in CY 2014. We also look forward to the MedPAC study on this issue, which is required under section 3004 of the MCTRJCA. This study will assess whether any geographic adjustment to physician work is appropriate and, if so, what the level should be and where it should be applied.

(D) *Institute of Medicine Recommendation 5–6:* Office Rent Component of PE GPCI. A new source of information should be developed to determine the variation in the price of commercial office rent per square foot. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pages 5–38 thru 5–39)

The Institute of Medicine recommends the development of a new source of data to determine the variation in the price of commercial office rent per square foot. However, the Institute of Medicine does not explicitly recommend where the data should come from or how it should be collected. Before coming to this recommendation, the Institute of Medicine identified and evaluated several public and commercially available sources of data to determine whether an accurate alternative is available to replace the residential rent data currently used as a proxy to measure regional variation in physicians' cost to rent office space in the PE GPCI; these sources include rental data from the U.S. Department of Housing and Urban Development, American Housing Survey, General Services Administration, Basic Allowance for Housing (U.S. Department of Defense), U.S. Postal Service, MGMA (MGMA), and REIS, Inc. The Institute of Medicine concluded that these sources had substantial limitations, including lack of representativeness of the market in which physicians rent space, small sample size, low response rates, and sample biases. Although we agree that a suitable source for commercial office rent data would be preferable to the use of residential rent data in our PE office rent methodology, we have still been unable to identify an adequate commercial rent source that sufficiently covers rural and urban areas.

We will continue to evaluate possible commercial rent data sources for potential use in the office rent calculation. To that end, we encouraged public commenters to notify us of any publicly available commercial rent data sources, with adequate data representation of urban and rural areas that could potentially be used in the calculation of the office rent component of PE. However, we did not receive comments on specific data sources for commercial rent for purposes of determining the office rent component of the PE GPCI.

Comment: We received several comments that were not within the scope of the CY 2013 proposed rule. For example, a few commenters expressed concerns about the methodology used for determining the CY 2012 GPCI values and the impact of the current PFS locality configuration on specific PFS localities.

Response: We appreciate the comments regarding the methodology used for determining the CY 2012 GPCI values and the impact they have on

specific PFS localities. As discussed above, we did not make any proposed changes to the GPCI calculation methodology or values for CY 2013. Therefore, it would not be appropriate to consider making new adjustments to the GPCI values for a specific locality without providing the public an opportunity to comment. We will consider the commenters' suggestions as we implement the seventh GPCI update anticipated in CY 2014.

Result of Evaluation of Comments

We appreciate the comments received on the Institute of Medicine's recommendations regarding the PFS locality structure and the data sources and methodology used to calculate GPCI values. We will consider the commenters' suggestions as we continue to evaluate options for reconfiguring the PFS locality structure and as we implement the seventh update to the GPCIs scheduled for CY 2014. We also look forward to conducting a full review and assessment of the Institute of Medicine's additional PFS locality recommendations (as discussed in their Phase II report), as well as the MedPAC study on the physician work GPCI under the PFS that is required by section 3004 of the MCTRJCA.

E. Medicare Telehealth Services for the Physician Fee Schedule

1. Billing and Payment for Telehealth Services

a. History

Prior to January 1, 1999, Medicare coverage for services delivered via a telecommunications system was limited to services that did not require a face-to-face encounter under the traditional model of medical care. Examples of these services included interpretation of an x-ray, or electrocardiogram, or electroencephalogram tracing, and cardiac pacemaker analysis.

Section 4206 of the BBA provided for coverage of, and payment for, consultation services delivered via a telecommunications system to Medicare beneficiaries residing in rural health professional shortage areas (HPSAs) as defined by the Public Health Service Act. Additionally, the BBA required that a Medicare practitioner (telepresenter) be with the patient at the time of a teleconsultation. Further, the BBA specified that payment for a teleconsultation had to be shared between the consulting practitioner and the referring practitioner and could not exceed the fee schedule payment which would have been made to the consultant for the service furnished. The BBA prohibited payment for any telephone line charges or facility fees associated with the teleconsultation. We implemented this provision in the CY 1999 PFS final rule with comment period (63 FR 58814).

Effective October 1, 2001, section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554) (BIPA) added a new section, 1834(m), to the Act which significantly expanded Medicare telehealth services. Section 1834(m)(4)(F)(i) of the Act defines *Medicare telehealth* services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when delivered via a telecommunications system. We first implemented this provision in the CY 2002 PFS final rule with comment period (66 FR 55246). Section 1834(m)(4)(F)(ii) of the Act required the Secretary to establish a process that provides for annual updates to the list of Medicare telehealth services. We established this process in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified in regulations at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real time interactive communication between the patient and the practitioner at the distant site. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system. An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act does allow the use of asynchronous ''store-and-forward'' technology in delivering these services when the originating site is a federal telemedicine demonstration program in Alaska or Hawaii. As specified in regulations at § 410.78(a)(1), store and forward means the asynchronous transmission of medical information from an originating site to be reviewed at a later time by the practitioner at the distant site.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the individual practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual means an individual enrolled under Part B who receives a telehealth service furnished at an originating site. Under the BIPA, originating sites were limited under section 1834(m)(3)(C) of the Act to specified medical facilities located in specific geographic areas. The initial list of telehealth originating sites included the office of a practitioner, a critical access hospital (CAH), a rural health clinic (RHC), a federally qualified health center (FQHC) and a hospital (as defined in Section 1861(e) of the Act). More recently, section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) expanded the list of telehealth originating sites to include hospital-based renal dialysis centers, skilled nursing facilities (SNFs), and community mental health centers (CMHCs). In order to serve as a telehealth originating site, these sites must be located in an area designated as a rural health professional shortage area (HPSA), in a county that is not in a metropolitan statistical area (MSA), or must be an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000. Finally, section 1834(m) of the Act does not require the eligible telehealth individual to be presented by a practitioner at the originating site.

b. Current Telehealth Billing and Payment Policies

As noted previously, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in an originating site. An originating site is defined as one of the specified sites where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system. In general, originating sites must be located in a rural HPSA or in a county outside of an MSA. The originating sites authorized by the statute are as follows:

- Offices of a physician or practitioner;
- Hospitals;
- CAHs;
- RHCs;
- FQHCs;
- Hospital-Based or Critical Access Hospital-Based Renal Dialysis Centers (including Satellites);
- SNFs;
- CMHCs.

Currently approved Medicare telehealth services include the following:

- Initial inpatient consultations;
- Follow-up inpatient consultations;
- Office or other outpatient visits;
- Individual psychotherapy;
- Pharmacologic management;

- Psychiatric diagnostic interview examination;
- End-stage renal disease (ESRD) related services;
- Individual and group medical nutrition therapy (MNT);
- Neurobehavioral status exam;
- Individual and group health and behavior assessment and intervention (HBAI);
- Subsequent hospital care;
- Subsequent nursing facility care;
- Individual and group kidney disease education (KDE);
- Individual and group diabetes self-management training (DSMT); and
- Smoking cessation services.

In general, the practitioner at the distant site may be any of the following, provided that the practitioner is licensed under state law to furnish the service via a telecommunications system:

- Physician;
- Physician assistant (PA);
- Nurse practitioner (NP);
- Clinical nurse specialist (CNS);
- Nurse-midwife;
- Clinical psychologist;
- Clinical social worker;
- Registered dietitian or nutrition professional.

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system. Distant site practitioners must submit the appropriate HCPCS procedure code for a covered professional telehealth service, appended with the –GT (Via interactive audio and video telecommunications system) or –GQ (Via asynchronous telecommunications system) modifier. By reporting the –GT or –GQ modifier with a covered telehealth procedure code, the distant site practitioner certifies that the beneficiary was present at a telehealth originating site when the telehealth service was furnished. The usual Medicare deductible and coinsurance policies apply to the telehealth services reported by distant site practitioners.

Section 1834(m)(2)(B) of the Act provides for payment of a facility fee to the originating site. To be paid the originating site facility fee, the provider or supplier where the eligible telehealth individual is located must submit a claim with HCPCS code Q3014 (Telehealth originating site facility fee), and the provider or supplier is paid according to the applicable payment methodology for that facility or location. The usual Medicare deductible and coinsurance policies apply to HCPCS code Q3014. By submitting HCPCS code Q3014, the originating site certifies that it is located in either a rural HPSA or non-MSA county or is an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000 as specified in section 1834(m)(4)(C)(i)(III) of the Act.

As previously described, certain professional services that are commonly furnished remotely using telecommunications technology, but that do not require the patient to be present in-person with the practitioner when they are furnished, are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in-person at the medical facility furnishing care to the patient. Such services typically involve circumstances where a practitioner is able to visualize some aspect of the patient's condition without the patient being present and without the interposition of a third person's judgment. Visualization by the practitioner can be possible by means of x-rays, electrocardiogram or electroencephalogram tracings, tissue samples, etc. For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted via telephone (that is, electronically, rather than by means of a verbal description) is a covered physician's service. These remote services are not Medicare telehealth services as defined under section 1834(m) of the Act. Rather, these remote services that utilize telecommunications technology are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way (that is, without the –GT or –GQ modifier appended).

2. Requests for Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. We assign any request to make additions to the list of telehealth services to one of two categories. In the November 28, 2011 **Federal Register** (76 FR 73102), we finalized revisions to criteria that we use to review requests in the second category. The two categories are:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. In reviewing these requests, we look for evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions

(for example, due to reduced rate of recurrence of the disease process).

- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

Since establishing the process to add or remove services from the list of approved telehealth services, we have added the following to the list of Medicare telehealth services: individual and group HBAI services; psychiatric diagnostic interview examination; ESRD services with 2 to 3 visits per month and 4 or more visits per month (although we require at least 1 visit a month to be furnished in-person by a physician, CNS, NP, or PA in order to examine the vascular access site); individual and group MNT; neurobehavioral status exam; initial and follow-up inpatient telehealth consultations for beneficiaries in hospitals and skilled nursing facilities (SNFs); subsequent hospital care (with the limitation of one telehealth visit every 3 days); subsequent nursing facility care (with the limitation of one telehealth visit every 30 days); individual and group KDE; and individual and group DSMT (with a minimum of 1 hour of in-person instruction to ensure effective injection training), and smoking cessation services.

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, requests submitted before the end of CY 2012 will be considered for the CY 2014 proposed rule. Each request for adding a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *www.cms.gov/telehealth/*.

3. Submitted Request and Other Additions to the List of Telehealth Services for CY 2013

We received a request in CY 2011 to add alcohol and/or substance abuse and brief intervention services as Medicare telehealth services effective for CY 2013. The following presents a discussion of this request, and our proposals for additions to the CY 2013 telehealth list.

a. Alcohol and/or Substance Abuse and Brief Intervention Services

The American Telemedicine Association submitted a request to add alcohol and/or substance abuse and brief intervention services, reported by CPT codes 99408 (Alcohol and/or substance (other than tobacco) abuse structured screening (for example, AUDIT, DAST), and brief intervention (SBI) services; 15 to 30 minutes) and 99409 (Alcohol and/or substance (other than tobacco) abuse structured screening (for example, AUDIT, DAST), and brief intervention (SBI) services; greater than 30 minutes) to the list of approved telehealth services for CY 2013 on a category 1 basis.

We note that we assigned a status indicator of ''N'' (Noncovered) to CPT codes 99408 and 99409 as explained in the CY 2008 PFS final rule with comment period (72 FR 66371). At the time, we stated that because Medicare only provides payment for certain screening services with an explicit benefit category, and these CPT codes incorporate screening services along with intervention services, we believed that these codes were ineligible for payment under the PFS. We continue to believe that these codes are ineligible for payment under PFS and, additionally, under the telehealth benefit. We do not believe it would be appropriate to make payment for claims using these CPT codes for the services furnished via telehealth, but not when furnished in person. Because CPT codes 99408 and 99409 are currently assigned a noncovered status indicator, and because we continue to believe this assignment is appropriate, we did not propose adding these CPT codes to the list of Medicare Telehealth Services for CY 2013.

However, we created two parallel G-codes for 2008 that allow for appropriate Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not furnished as screening services, but that are furnished in the context of the diagnosis or treatment of illness or injury. The codes are HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (for example, AUDIT, DAST) and brief intervention, 15 to 30 minutes) and HCPCS code G0397, (Alcohol and/or substance (other than tobacco) abuse structured assessment (for example, AUDIT, DAST) and intervention greater than 30 minutes). Since these codes are used to report comparable alcohol and substance abuse services under certain conditions, we believed that it would be appropriate to consider the ATA's request as it applies to these services when appropriately reported by the G-codes. The ATA asked that CMS consider this request as a category 1 addition based on the similarities between these services and CPT codes 99406 (Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes) and 99407 (Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes). We agree that the interaction between a practitioner and a beneficiary receiving alcohol and substance abuse assessment and intervention services is similar to their interaction in smoking cessation services. We also believe that the interaction between a practitioner and a beneficiary receiving alcohol and substance abuse assessment and intervention services is similar to the assessment and intervention elements of CPT code 96152 (health and behavior intervention, each 15 minutes, face-to-face; individual), which also is currently on the telehealth list.

Therefore, we proposed to add HCPCS codes G0396 and G0397 to the list of telehealth services for CY 2013 on a category 1 basis. Consistent with this proposal, we also proposed to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include alcohol and substance abuse assessment and intervention services as Medicare telehealth services.

b. Preventive Services

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list with respect to the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 proposed rule (76 FR 42826), we believe that the category 1 criteria not only streamline our review process for publically requested services that fall into this category, the criteria also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

During CY 2012, CMS added coverage for several preventive services through the national coverage determination (NCD) process as authorized by section 1861(ddd) of the Act. These services add to Medicare's existing portfolio of preventive services that are now

available without cost sharing under the Affordable Care Act. We believe that for several of these services, the interactions between the furnishing practitioner and the beneficiary are similar to services currently on the list of Medicare telehealth services. Specifically, we believe that the assessment, education, and counseling elements of the following services are similar to existing telehealth services:

- Screening and behavioral counseling interventions in primary care to reduce alcohol misuse, reported by HCPCS codes G0442 (Annual alcohol misuse screening, 15 minutes) and G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes).
- Screening for depression in adults, reported by HCPCS code G0444 (Annual Depression Screening, 15 minutes).
- Screening for sexually transmitted infections (STIs) and high-intensity behavioral counseling (HIBC) to prevent STIs, reported by HCPCS code G0445 (High-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior, performed semi-annually, 30 minutes).
- Intensive behavioral therapy for cardiovascular disease, reported by HCPCS code G0446 (Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes).
- Intensive behavioral therapy for obesity, reported by HCPCS code G0447 (Face-to-face behavioral counseling for obesity, 15 minutes).

We believe that the interactions between practitioners and beneficiaries receiving these services are similar to individual KDE services reported by HCPCS code G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour), individual MNT reported by HCPCS code G0270 (Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in the same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face-to-face with the patient, each 15 minutes); CPT code 97802 (Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes); and CPT code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes), and HBAI reported by CPT code 96150 (Health and behavior assessment (for example, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment); CPT code 96151 (Health and behavior assessment (for example, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient re-assessment); CPT code 96152 (Health and behavior intervention, each 15 minutes, face-to-face; Individual); CPT code 96153 (Health and behavior intervention, each 15 minutes, face-to-face; Group (2 or more patients)); CPT code 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)), all services that are currently on the telehealth list.

Therefore, we proposed to add HCPCS codes G0442, G0443, G0444, G0445, G0446, and G0447 to the list of telehealth services for CY 2013 on a category 1 basis. We note that all coverage guidelines specific to the services would continue to apply when these services are furnished via telehealth. For example, when the national coverage determination requires that the service be furnished to beneficiaries in a primary care setting, the qualifying originating telehealth site must also qualify as a primary care setting. Similarly, when the national coverage determination requires that the service be furnished by a primary care practitioner, the qualifying primary distant site practitioner must also qualify as primary care practitioner. For more detailed information on coverage requirements for these services, we refer readers to the Medicare National Coverage Determinations Manual, Pub. 100–03, Chapter 1, Section 210, available at *http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf*. Consistent with this proposal, we also proposed to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include these preventive services as Medicare telehealth services.

Comment: All commenters expressed support for CMS' proposals to add alcohol and/or substance abuse structured assessment and brief intervention services and the several preventive services established through the national coverage determination (NCD) process to the list of Medicare telehealth services for CY 2013. One commenter stated particular support for CMS' approach to ensure that coverage guidelines continue to apply when these services are furnished via telehealth and expressed the intention to support CMS' efforts to help educate practitioners about these preventive telehealth services newly available in 2013. Another commenter stated that the proposal to add these services to this list was an integral step forward for telehealth, but that the current breadth and level of services covered under the telehealth benefit is inadequate to support more robust telehealth capabilities sought by some practitioners.

Response: We appreciate the broad support for the proposed additions to the list of Medicare telehealth services and the efforts of stakeholders to ensure that practitioners are educated about the addition of these services to the list of Medicare telehealth services. We believe that the delivery of services via telehealth can help reduce barriers to health care access faced by some beneficiaries, and we remind all interested stakeholders that we are currently soliciting public requests to add services to the list of Medicare telehealth services. To be considered during PFS rulemaking for CY 2014, these requests must be submitted and received by December 31, 2012 or the close of the comment period for this final rule with comment period. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *www.cms.gov/telehealth/*.

After consideration of the public comments received, we are finalizing our CY 2013 proposal to add HCPCS codes G0396, G0397, G0442, G0443, G0444, G0445, G0446, and G0447 to the list of telehealth services for CY 2013 on a category 1 basis. We note that all coverage guidelines specific to the services will continue to apply when these services are furnished via telehealth. For example, when the national coverage determination requires that the service be furnished to beneficiaries in a primary care setting, the telehealth originating site must also qualify as a primary care setting under the terms of the national coverage determination. Similarly, when the national coverage determination requires that the service be furnished by a primary care practitioner, the distant site practitioner who furnishes the telehealth service must also qualify as primary care practitioner under the terms of the national coverage

determination. For more detailed information on coverage requirements for these services, we refer readers to the Medicare National Coverage Determinations Manual, Pub. 100–03, Chapter 1, Section 210, available at *www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf*. Consistent with this proposal, we are also revising our regulations at § 410.78(b) and § 414.65(a)(1) to include alcohol and/or substance abuse structured assessment and intervention services and the preventive services as Medicare telehealth services.

4. Technical Correction To Include Emergency Department Telehealth Consultations in Regulation

In the CY 2012 PFS final rule with comment period (76 FR 73103), we finalized our proposal to change the code descriptors for initial inpatient telehealth consultation G-codes to reflect telehealth consultations furnished to emergency department patients in addition to inpatient telehealth consultations effective January 1, 2012. However, we did not amend the description of the services within the regulation at § 414.65(a)(1)(i). Therefore, we proposed to make a technical revision to our regulation at § 414.65(a)(1)(i) to reflect telehealth consultations furnished to emergency department patients in addition to hospital and SNF inpatients.

We received no comments regarding our proposal to make this technical revision. Therefore, we are finalizing our proposal to make a technical revision to our regulation at § 414.65(a)(1)(i) to reflect telehealth consultations furnished to emergency department patients in addition to hospital and SNF inpatients.

5. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001, through December 31, 2002, at $20. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2013 is 0.8 percent. Therefore, for CY 2013, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $24.43. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in Table 18.

TABLE 18—THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE AND MEI INCREASE BY THE APPLICABLE TIME PERIOD

Facility fee	MEI increase	Period
$20.00 ...	N/A	10/01/2001–12/31/2002
$20.60 ...	3.0%	01/01/2003–12/31/2003
$21.20 ...	2.9%	01/01/2004–12/31/2004
$21.86 ...	3.1%	01/01/2005–12/31/2005
$22.47 ...	2.8%	01/01/2006–12/31/2006
$22.94 ...	2.1%	01/01/2007–12/31/2007
$23.35 ...	1.8%	01/01/2008–12/31/2008
$23.72 ...	1.6%	01/01/2009–12/31/2009
$24.00 ...	1.2%	01/01/2010–12/31/2010
$24.10 ...	0.4%	01/01/2011–12/31/2011
$24.24 ...	0.6%	01/01/2012–12/31/2012
$24.43 ...	0.8%	01/01/2013–12/31/2013

F. Extension of Payment for Technical Component of Certain Physician Pathology Services

1. Background and Statutory Authority

Section 542(c) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provided payment to independent laboratories furnishing the technical component (TC) of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital for a 2-year period beginning on January 1, 2000. This section was subsequently amended by section 732 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), section 104 of division B of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), section 104 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), section 136 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), section 3104 of the Affordable Care Act (Pub. L. 111–148), section 105 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309), section 305 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78) and section 3006 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96) to continue payment to independent laboratories furnishing the technical component (TC) of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital for various time periods. As discussed in detail below, Congress most recently acted to continue this payment through June 30, 2012. The TC of physician pathology services refers to the preparation of the slide involving tissue or cells that a pathologist interprets. The professional component (PC) of physician pathology services refers to the pathologist's interpretation of the slide.

When the hospital pathologist furnishes the PC service for a hospital patient, the PC service is separately billable by the pathologist. When an independent laboratory's pathologist furnishes the PC service, the PC service is usually billed with the TC service as a combined or global service.

Historically, any independent laboratory could bill the Medicare contractor under the PFS for the TC of physician pathology services for hospital patients even though the payment for the costs of furnishing the pathology service (but not its interpretation) was already included in the bundled inpatient stay payment to the hospital. In the CY 2000 PFS final rule with comment period (64 FR 59408 and 59409), we stated that this policy has contributed to the Medicare program paying twice for the TC service: (1) To the hospital, through the inpatient prospective payment rate, when the patient is an inpatient; and (2) To the independent laboratory that bills the Medicare contractor, instead of the hospital, for the TC service. While the policy also permits the independent laboratory to bill for the TC of physician pathology services for hospital outpatients, in this case, there generally would not be duplicate payment because we would expect the hospital to not also bill for the pathology service, which would be paid separately to the hospital only if the hospital were to specifically bill for it. We further indicated that we would implement a policy to pay only the hospital for the TC of physician pathology services furnished to its inpatients.

Therefore, in the CY 2000 PFS final rule with comment period, we revised § 415.130(c) to state that for physician pathology services furnished on or after January 1, 2001 by an independent laboratory, payment is made only to the hospital for the TC of physician pathology services furnished to a hospital inpatient. Ordinarily, the provisions in the PFS final rule with comment period are implemented in the following year. However, the change to § 415.130 was delayed 1-year (until January 1, 2001), at the request of the industry, to allow independent laboratories and hospitals sufficient time to negotiate arrangements.

Full implementation of § 415.130 was further delayed by section 542 of the

BIPA and section 732 of the MMA, which directed us to continue payment to independent laboratories for the TC of physician pathology services for hospital patients for a 2-year period beginning on January 1, 2001 and for CYs 2005 and 2006, respectively. In the CY 2007 PFS final rule with comment period (71 FR 69788), we amended § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the TC of physician pathology services furnished to a hospital inpatient or outpatient. However, section 104 of the MIEA–TRHCA continued payment to independent laboratories for the TC of physician pathology services for hospital patients through CY 2007, and section 104 of the MMSEA further extended such payment through the first 6 months of CY 2008.

Section 136 of the MIPPA extended the payment through CY 2009. Section 3104 of the Affordable Care Act amended the prior legislation to extend the payment through CY 2010. Section 105 of the MMEA extended the payment through CY 2011. Subsequent to the publication of the CY 2012 PFS final rule with comment period, section 305 of the Temporary Payroll Tax Cut Continuation Act of 2011 extended the payment through February 29, 2012 and section 3006 of the Middle Class Tax Relief and Job Creation Act of 2012 extended the payment through June 30, 2012.

2. Revisions to Payment for TC of Certain Physician Pathology Services

In the CY 2012 PFS final rule with comment period, we finalized our policy that an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished after December 31, 2011, to a hospital inpatient or outpatient (76 FR 73278 through 73279, 73473). As discussed above, subsequent to publication of that final rule with comment period, Congress acted to continue payment to independent laboratories through June 30, 2012. Therefore, the policy that we finalized in the CY 2012 PFS final rule with comment period was superseded by statute for 6 months. To be consistent with the statutory changes and our current policy, we proposed conforming changes to § 415.130(d) such that we continued payment under the PFS to independent laboratories furnishing the TC of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital on or before June 30, 2012 (77 FR 44763). Independent laboratories may not bill the Medicare contractor for the TC of physician pathology services furnished after June 30, 2012, to a hospital inpatient or outpatient. We received no public comments on the proposed conforming changes so we are finalizing the revisions to § 415.130(d) without modification.

G. Therapy Services

1. Outpatient Therapy Caps for CY 2013

Section 1833(g) of the Act applies annual, per beneficiary, limitations (therapy caps) on expenses considered incurred for outpatient therapy services under Medicare Part B. There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined. Although therapy services furnished in an outpatient hospital setting have been exempt from the application of the therapy caps, section 3005(b) of the MCTRJCA amended section 1833(g) of the Act to include therapy services furnished in an outpatient hospital setting in the therapy caps. This provision is in effect from October 1, 2012 through December 31, 2012.

The therapy cap amounts are updated each year based on the Medicare Economic Index (MEI). The annual change in the therapy cap amount for CY 2013 is computed by multiplying the cap amount for CY 2012 by the MEI for CY 2013 and rounding to the nearest $10. This amount is added to the CY 2012 cap, which is $1,880, to obtain the CY 2013 cap amount. The MEI for CY 2013 is 0.8 percent, resulting in a therapy cap amount for CY 2013 of $1,900.

An exceptions process to the therapy caps has been in effect since January 1, 2006. Since originally authorized by section 5107 of the Deficit Reduction Act (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been extended through subsequent legislation (MIEA–TRHCA, MMSEA, MIPPA, the Affordable Care Act, MMEA, and TPTCCA). Last amended by section 3005 of the MCTRJCA, the Agency's authority to provide for an exception process to therapy caps expires on December 31, 2012. To request an exception to the therapy caps, therapy suppliers and providers use the KX modifier on claims for services after the beneficiary's services for the year have exceeded the therapy cap. Use of the KX modifier indicates that the services are reasonable and necessary and that there is documentation of medical necessity in the beneficiary's medical record.

Section 3005 of the MCTRJCA also required two additional changes to Medicare policies for outpatient therapy services. Effective for services furnished from October 1 through December 31, 2012, after a beneficiary's incurred expenses for PT and SLP services combined exceed the threshold of $3,700 during the calendar year, section 1833(g)(5)(C) of the Act, as amended by 3005(a)(5) of the MCTRJCA, requires that we apply a manual medical review process as part of the therapy caps exceptions process. Similar to the therapy caps, there is a separate $3,700 threshold for OT services. All requests for exceptions to the therapy caps for services after the $3,700 threshold is reached are subject to manual medical review. The manual medical review process is being phased in over a 3-month period. Unlike the therapy caps, exceptions are not automatically granted for therapy services above the $3,700 threshold based upon the therapist's determination that they services are reasonable and necessary. To request an exception to the therapy caps for services after the threshold is reached, the provider sends a request for an exception to the Medicare contractor. The contractor then uses the coverage and payment requirements contained within Pub. 100–02, Medicare Benefit Policy Manual, section 220 and applicable medical review guidelines, and any relevant local coverage determinations to make decisions as to whether an exception is approved for the services. For more information on the manual medical review process, go to *www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/TherapyCap.html.*

2. Claims-Based Data Collection Strategy for Therapy Services

a. Introduction

Section 3005(g) of the MCTRJCA requires CMS to implement, beginning on January 1, 2013, ''* * * a claims-based data collection strategy that is designed to assist in reforming the Medicare payment system for outpatient therapy services subject to the limitations of section 1833(g) of the Act. Such strategy shall be designed to provide for the collection of data on patient function during the course of therapy services in order to better understand patient condition and outcomes.''

b. History/Background

In 2011, more than 8 million Medicare beneficiaries received outpatient therapy services, including

physical therapy (PT), occupational therapy (OT), and speech-language-pathology (SLP). Medicare payments for these services exceeded $5.8 billion. Between 1998–2008, Medicare expenditures for outpatient therapy services increased at a rate of 10.1 percent per year while the number of Medicare beneficiaries receiving therapy services only increased by 2.9 percent per year. Although a significant number of Medicare beneficiaries benefit from therapy services, the rapid growth in Medicare expenditures for these services has long been of concern to the Congress and the Agency. To address this concern, efforts have been focused on developing Medicare payment incentives that encourage delivery of reasonable and necessary care while discouraging overutilization of therapy services and the provision of medically unnecessary care. A brief review of these efforts is useful in understanding our policy for CY 2013.

(1) Therapy Caps

Section 4541 of the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA) amended section 1833(g) of the Act to impose financial limitations on outpatient therapy services (the ''therapy caps'' discussed above) in an attempt to limit Medicare expenditures for therapy services. Prior to the BBA amendment, these caps had applied to services furnished by therapists in private practice, but the BBA expanded the caps effective January 1, 1999, to include all outpatient therapy services except those furnished in hospital outpatient departments. Since that time, the Congress has amended the statute several times to impose a moratorium on the application of the caps or has required us to implement an exceptions process for the caps. The therapy caps have only been in effect without a moratorium or an exceptions process for less than 2 years. (See the discussion about the therapy cap exceptions process above.) Almost from the inception of the therapy caps, Congress and the Agency have been exploring potential alternatives to the therapy caps.

(2) Multiple Procedure Payment Reduction (MPPR)

In the CY 2011 PFS final rule with comment period (75 FR 73232–73242), we adopted a MPPR of 25 percent applicable to the practice expense (PE) component of the second and subsequent therapy services furnished to a beneficiary when more than one of these services is furnished in a single session. This reduction applies to nearly 40 therapy service codes. (For a list of therapy service codes to which this policy applies, see Addendum H.) The Physician Payment and Therapy Relief Act of 2010 (PPATRA) subsequently revised the reduction to 20 percent for the second and subsequent therapy services furnished to a beneficiary in an office setting, leaving the 25 percent reduction in place for therapy services furnished to a beneficiary in institutional settings. We adopted this MPPR as part of our directive under section 1848(c)(2)(K) of the statute, as added by section 3134(a) of the Affordable Care Act, to identify and evaluate potentially misvalued codes. By taking into consideration the expected efficiencies in direct PE resources that occur when services are furnished together, this policy results in more appropriate payment for therapy services. Although we did not adopt this MPPR policy specifically as an alternative to the therapy caps, paying more appropriately for combinations of therapy services that are commonly furnished in a single session reduces the number of beneficiaries impacted by the therapy caps in a given year. For more details on the MPPR policy, see section II.B.4. of this final rule with comment period.

(3) Studies Performed

The therapy cap is a uniform dollar amount that sets a limit on the total value of services furnished unrelated to the specific services furnished or the beneficiary's condition or needs. A uniform cap does not deter unnecessary care or encourage efficient practice for low complexity beneficiaries. In fact, it may even encourage the provision of services up to the level of the cap. Conversely, a uniform cap without an exceptions process restricts necessary and appropriate care for certain high complexity beneficiaries. Recognizing these limitations in a uniform dollar value cap, we have been studying therapy practice patterns and exploring ways to refine payment for these services as an alternative to therapy caps.

On November 9, 2004, the Secretary delivered the Report to Congress, as required by the BBA as amended by the BBRA, ''Medicare Financial Limitations on Outpatient Therapy Services.'' This report included two utilization analyses. Although these analyses provided details on utilization, neither specifically identified ways to improve therapy payment. In the report, we indicated that further study was underway to assess alternatives to the therapy caps. The report and the analyses are available on the CMS Web site at *www.cms.gov/TherapyServices/*.

Since 2004, we have periodically updated the utilization analyses and posted other reports on the CMS Web site. These reports highlighted the expected effects of limiting services in various ways and presented plans to collect data about beneficiary condition, including functional limitations, using available tools. Through these efforts, we have made progress in identifying the types of outpatient therapy services that are billed to Medicare, the demographics of the beneficiaries who utilize these services, the HCPCS codes used to bill the services, the allowed and paid amounts of the services, the providers of these services, the therapy utilization patterns among states in which the services are furnished, and the type of practitioner furnishing services.

From these and other analyses in our ongoing research effort, we have concluded that without the ability to define the services that are typically needed to address specific clinical cohorts of beneficiaries (those with similar risk-adjusted conditions), it is not possible to develop payment policies that encourage the delivery of reasonable and necessary services while discouraging the provision of services that do not produce a clinical benefit. Although there is widespread agreement that beneficiary condition and functional limitations are critical to developing and evaluating an alternative payment system for therapy services, a system for collecting such data uniformly does not exist. Currently diagnosis information is available from Medicare claims. However, we believe that the diagnosis on the claim is a poor predictor for the type and duration of therapy services required. Additional work is needed to develop an appropriate system for classifying clinical cohorts to determine therapy needs.

A 5-year CMS project titled ''Development of Outpatient Therapy Payment Alternatives'' (DOTPA) is expected to provide some of this information. The purpose of the DOTPA project is to identify a set of measures that we could collect routinely and reliably to support the development of payment alternatives to the therapy caps. Specifically, the measures being collected are assessed for administrative feasibility and usefulness in identifying beneficiary need for outpatient therapy services and the outcomes of those services. The data collection processes have just been completed and a final DOTPA report is expected in late CY 2013. In addition to developing alternatives to the therapy caps, the DOTPA project reflects our interest in

value-based purchasing by identifying components of value, namely, the beneficiary need and the effectiveness of therapy services. Although we expect DOTPA to provide meaningful data and practical information to assist in developing improved methods of paying for appropriate therapy services, it is unlikely that this one project alone will provide adequate information to implement a new payment system for therapy. This study combined with data from a wider group of Medicare beneficiaries would enhance our ability to develop alternative payment policy for outpatient therapy services.

(c) System Description and Requirements

(1) Overview

Section 3005(g) of MCTRJCA requires CMS to implement a claims-based data collection strategy on January 1, 2013 to gather information on beneficiary function and condition, therapy services furnished, and outcomes achieved. This information will be used in assisting us in reforming the Medicare payment system for outpatient therapy services. By collecting data on beneficiary function over an episode of therapy services, we hope to better understand the Medicare beneficiary population who uses therapy services, how their functional limitations change as a result of therapy services, and the relationship between beneficiary functional limitations and furnished therapy.

The long-term goal is to develop an improved payment system for Medicare therapy services. The desired payment system would pay appropriately and similarly for efficient and effective services furnished to beneficiaries with similar conditions and functional limitations that have potential to benefit from the services furnished. Importantly, such a system would not encourage the furnishing of medically unnecessary or excessive services. At this time, the data on Medicare beneficiaries' use and outcomes from therapy services from which to develop an improved system does not exist. This data collection effort is the first step towards collecting the data needed for this type of payment reform. Once the initial data have been collected and analyzed, we expect to identify gaps in information and determine what additional data would be needed to develop a new payment policy. Without a better understanding of the diversity of beneficiaries receiving therapy services and the variations in type and volume of treatments provided, we lack the information to develop a comprehensive strategy to map the way to an improved payment policy. While this claims-based data collection is only the first step in a long-term effort, it is an essential step.

In the CY 2013 proposed rule, we proposed to implement section 3005(g) of MCTRJCA by requiring that claims for therapy services include nonpayable G-codes and modifiers. Through the use of these codes and modifiers, we proposed to capture data on the beneficiary's functional limitations (a) At the outset of the therapy episode, (b) at specified points during treatment and (c) at discharge from the outpatient therapy episode of care. In addition, the therapist's projected goal for functional status at the end of treatment would be reported on the first claim for services and periodically throughout an episode of care.

Specifically, as proposed, G-codes would be used to identify what type of functional limitation is being reported and whether the report is on the current status, projected goal status or discharge status. Modifiers would indicate the severity/complexity of the functional limitation being tracked. The difference between the reported functional status at the start of therapy and projected goal status represents any progress the therapist anticipates the beneficiary would make during the course of treatment/episode of care. We proposed that these reporting requirements would apply to all therapy claims, including those for services above the therapy caps and those that include the KX modifier (described above).

By tracking any changes in functional limitations throughout the therapy episode of care and at discharge, we would have information about the therapy services furnished and the outcomes of such services. The ICD–9 diagnosis codes reported on the claim form would provide some information on the beneficiary's condition.

We proposed that these claims-based data collection requirements would apply to services furnished under the Medicare Part B outpatient therapy benefit and PT, OT, and SLP services under the Comprehensive Outpatient Rehabilitation Facilities (CORF) benefit. We also proposed to include therapy services furnished personally and ''incident to'' the services of physicians or nonphysician practitioners (NPPs). As we explained in the proposed rule, this broad applicability would include therapy services furnished in hospitals, critical access hospitals (CAHs), skilled nursing facilities (SNFs), CORFs, rehabilitation agencies, home health agencies (when the beneficiary is not under a home health plan of care), and in private offices of therapists, physicians and NPPs.

When used in this section ''therapists'' means all practitioners who furnish outpatient therapy services, including physical therapists, occupational therapists, and speech-language pathologists in private practice and those therapists who furnish services in the institutional settings, physicians and NPPs (including, physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), as applicable.) The term ''functional limitation'' generally encompasses both the terms ''activity limitations'' and ''participation restrictions'' as described by the International Classification of Functioning, Disability and Health (ICF). (For information on ICF, see *www.who.int/classifications/icf/en/* and for specific ICF nomenclature (including activity limitations and participation restrictions), see *http://apps.who.int/classifications/icfbrowser/*.

The CY 2013 proposal was based upon an option for claims-based data collection that was developed as part of the Short Term Alternatives for Therapy Services (STATS) project under a contract with CMS, which provided three options for alternatives to the therapy caps that could be considered in the short-term before completion of the DOTPA project. In developing options, the STATS project drew upon the analytical expertise of CMS contractors and the clinical expertise of various outpatient therapy stakeholders to consider policies and available claims data. The options developed were:

- Capturing additional clinical information regarding the severity and complexity of beneficiary functional impairments on therapy claims in order to facilitate medical review and at the same time gather data that would be useful in the long term to develop a better payment mechanism;
- Introducing additional claims edits regarding medical necessity to reduce overutilization; and
- Adopting a per-session bundled payment, the amount of which would vary based on beneficiary characteristics and the complexity of evaluation and treatment services furnished in a therapy session.

Although we did not propose to adopt any of these alternatives at that time, we discussed and solicited public comments on all aspects of these options during the CY 2011 rulemaking. (See 75 FR 40096 through 40100 and 73284 through 73293.) In developing the CY 2013 claims-based data collection proposal, we used the feedback received from the CY 2011 rulemaking.

We noted in the proposal that the proposed claims-based data collection system using G-codes and severity modifiers builds upon current Medicare requirements for therapy services. Section 410.61 requires that a therapy plan of care (POC) be established for every beneficiary receiving outpatient therapy services. This POC must include: the type, amount, frequency, and duration of services to be furnished to each beneficiary, the diagnosis and the anticipated goals. Section 410.105(c) contains similar requirements for services furnished in the CORF setting. We have long encouraged therapists, through our manual provisions, to express the POC-required goals for each beneficiary in functional terms and require that goals be based on measureable assessments or objective data and relate to identified functional impairments. See Pub 100–02, Chapter 15, Section 220.1.2. We also noted that the evaluation and the goals developed as part of the POC would be the foundation for the initial reporting under the proposed system.

The following is a summary of the comments we received regarding the general approach proposed in the CY 2013 PFS proposed rule to require nonpayable G-codes and modifiers on therapy claims to implement the new statutory requirement.

Comment: Most commenters supported a new payment system for therapy services and recognized that data would be a critical factor in the development of such a system. Others recognized that the statute required CMS to implement a claims-based data collection system and therefore addressed comments to the specific elements rather than the overall requirement. Many commenters expressed concerns that the data we would be collecting under the proposed system would not provide adequate data for us to develop a new payment system. Many commenters also expressed concern that the system would not provide the means for therapists to adequately convey why some beneficiaries needed more treatment. Toward this end, commenters suggested that we include a way to risk adjust the data or collect more beneficiary information. Some commenters suggested that we establish additional G-codes to report the beneficiary's complexity, such as whether their condition is of low, moderate, or high complexity. These G-codes would represent the multiple variables that affect a beneficiary's condition and response to therapy, such as age, comorbidities, prognosis, patient safety considerations, and current clinical presentation. One association indicated that it is working on an alternative payment system that will define and use three levels of complexity. Many commenters pointed out that the data we proposed to collect could only provide information on the progress an individual beneficiary made and was not valid for analyzing payment alternatives.

Response: We agree with commenters that the data collected under this system will not alone provide all the information that CMS needs to develop, analyze and implement an alternative payment system. We agree with the commenters that factors such as the patient's overall condition, including age, comorbidities, etc. are likely to affect the response to therapy; and we further agree that being able to analyze the data collected on such variables would enhance the usefulness of our data. Although we agree with the commenters' that it could be beneficial to include additional data elements to reflect the patient's condition and the complexity of the case, a meaningful system to use in classifying a beneficiary's complexity does not currently exist. As experience is gained with this new system, we expect that through future notice and comment rulemaking we will be able to enhance the system.

Comment: Many commenters commented on the administrative burden that therapists would incur if the proposed system was implemented. Some commented that the administrative burden would be particularly significant for physical therapists in private practice who often submit claims after each therapy visit. Commenters labeled the proposal ''improper,'' ''unreasonable,'' and ''overly burdensome.'' Other commenters indicated that the proposed process would not be burdensome stating that the functional assessment tools they use were ''perfectly suited to comply with CMS rule for data collection points, so we anticipate little or no burden in complying with the collection of function at intake, predicting discharge function at intake, during care and at discharge from care.'' In addition to the many commenters who noted the additional work that would be required to comply with this system, one commenter suggested that we also add a billable G-code to pay therapists for the additional work that this proposal would require.

Response: While we recognize that complying with these new reporting requirements will impose an additional burden on therapists, we believe that having available additional data on the therapy services furnished and the beneficiaries who receive them is critical to development of an alternative payment system for therapy services. Although we acknowledge that there would be work and some additional effort in complying with these reporting requirements, we believe that the additional burden is minimal. We designed our proposal to mesh closely with information that therapists already include in the medical record. The proposal would merely require that the information be translated into the new G-codes and modifiers, and included in additional lines on the same claims that would otherwise be submitted. We do not believe this reporting requirement would significantly increase the resources required to furnish therapy services.

Comment: A couple of commenters suggested that we abandon our G-code/modifier proposal and use diagnosis codes in its place. One recognized that CMS's assertion that diagnosis codes on the claims do not provide the data that we need was valid when only the principal diagnosis is used, but stated that if we relied upon principal and secondary diagnosis we could obtain the additional information regarding the patient's clinical condition and functional limitations. The commenter provided the example of when hemiparesis was coded as the secondary diagnosis. Some suggested that when the ICD–10 system is implemented the diagnosis codes would provide better information.

Response: We continue to believe that diagnosis codes, even when secondary diagnoses are included, do not provide the information on functional limitations that the statute requires us to collect. In the example the commenter provided, use of the diagnosis code ''hemiparesis,'' would only tell us that the beneficiary needs therapy due to a paralysis or weakness on one side of his or her body caused by a stroke or other brain trauma, but not the extent of the beneficiary's functional limitation. With regard to use of ICD–10, the statute requires us to implement a functional reporting system by January 1, 2013 so we cannot wait for ICD–10 system to implement the reporting requirements.

Comment: One commenter requested to be exempted from these reporting requirements because the organization furnishes such a small amount of Part B outpatient therapy services. Another noted that ''Given that this policy may affect HOPDs only for 3 months, CMS should consider ways to impose minimal administrative burden on HOPDs to implement this policy.'' One commenter sought assurance that CAHs

were included in this data collection effort.

Response: As we indicated in the proposed rule, our goal is to have data on the complete range of therapy services for which payment is made based on the PFS for use in assessing and developing potential alternative payment systems for those services. This is important since any new payment system would likely apply to all those therapy services that are currently paid at rates under the PFS. To meet this goal, we proposed that the reporting requirements apply to all providers and suppliers of outpatient therapy services and CORFs. We note that the proposed policy would apply to hospital outpatient department services, even if such services are not subject to the therapy caps after December 31, 2012, and to services furnished in CAHs. We are finalizing without change the proposed policy to apply the reporting requirements to hospitals, SNFs, rehabilitation agencies, CORFs, home health agencies (when the beneficiary is not under a home health plan of care) and private offices.

Comment: Several commenters raised concerns about a new payment system based upon the data collected without a standardized tool, stating that such data would not provide reliable information on which to develop an alternative payment system. Additionally, some commenters believed the invalid data would be used to create a payment system based upon functional limitations.

Response: At this time we are not making any changes in the existing payment methodology for therapy services, except that therapists will have to comply with the reporting requirements to receive payment for furnished therapy services. Therapists will continue to be paid in CY 2013 under the existing payment methodology, which includes the therapy caps. We will closely monitor and implement any enacted legislation that would amend the current statutory provisions, including any amendment to extend the therapy cap exceptions process. At this time we are broadly considering options for a revised payment system for therapy services and do not have any preconceived ideas as to what such a system would like or what it would be based upon. The purpose of the data collection proposal described in the CY 2013 PFS proposed rule is to meet the statutory requirement and begin to gather data that will be used, along with other data and information that we have, to develop and analyze potential alternative payment systems. It is likely that changes will be made in the data collected as we gain experience with this system. Therapists and others concerned with Medicare payment for therapy services should not draw conclusions about any future payment system for therapy services based upon the claims-based data that we proposed to collect. The claims-based data is only one set of information that will be used and it is only a beginning step in gathering the information that we would need to consider in developing a revised payment system for therapy services.

Comment: Some commenters suggested that the ''preamble language implies that improvement is a requirement for ongoing Medicare coverage.'' One commenter suggested that the preamble language ''implies that a measurable improvement in a beneficiary's functional limitation is required during an episode of therapy services.'' Others expressed concern that some beneficiaries, such as those with spinal cord injuries, will be denied coverage because they improve too slowly.

Response: We did not intend for the preamble language to raise concern about changing coverage conditions for beneficiaries who need therapy services. As noted above, the purpose of the claims-based data collection system is simply to gather data, and we did not propose, nor are we implementing, any changes to coverage or payment policy for therapy services other than to require that therapists comply with the reporting requirements to receive payment for therapy services they furnish. Under existing IOM requirements, therapists have to establish a long-term goal for beneficiaries receiving therapy. What is new under this system is that at the outset of treatment, the therapist will need to report on the claim the projected goal for treatment using modifiers that describe the percentage of impairment. For beneficiaries who are not expected to improve, such as those receiving maintenance therapy, the same modifier would be used for current status and for projected goal status. It is possible for some beneficiaries that while improvement is expected, it is expected to be limited, and thus it will also be reported using the same modifiers. To emphasize, the collection of these data elements will not affect a beneficiary's coverage of therapy services.

Comment: Some commenters expressed concerns about how this proposal would affect individuals suffering from lymphedema. Commenters stated that some clients experience both pain and swelling while others seem to have only swelling of a limb. Successful management of a beneficiary with lymphedema involves bandaging, compression and skin care instruction, manual lymph drainage, decongestive therapy, manual lymph drainage instruction, and exercise. These services take lots of valuable practitioner time to perform correctly as does instructing caregivers. While lymphedema impacts function to a point of mild to severe disability, many commenters told us that lymphedema severity/complexity is very difficult to quantify and show significant functional improvements in the lymphatic system when many of these improvements are in skin integrity, cellular health and lymphatic flow. Other commenters stated that the patient's functional limitations due to lymphedema (restricted motion and/or mobility) can range from profound to minimal. But all lymphedema patients, including those proficient in self-care who have minimal functional limitations, are at great risk for developing cellulitis or other major medical complications from sustained tissue congestion of the lymphatic system. With ongoing or periodic management, as appropriate, therapy services can successfully prevent these medical crises. Many commenters expressed concern that coverage for therapy services relating to lymphedema would be denied as a result of this proposal. Others questioned which functional limitation to use for lymphedema patients.

Response: As noted earlier, we did not propose to change coverage policy or to use the claims-based data reporting system to determine which beneficiaries are entitled to therapy services. Instead, our proposal would require those furnishing care to provide certain information about the beneficiary and his or her expected response to therapy. We are reiterating in this final rule with comment period that the proposed claims-based data collection system makes no changes in our therapy coverage policies.

With regard to how those treating beneficiaries should comply with the data collection system, we expect therapists to report the G-code for the functional limitation that most closely relates to the functional limitation being treated. As a result of comments on the proposed rule, we are clarifying in this final rule with comment period that if the therapy services being furnished are not intended to treat a functional limitation, the therapist should use the G-code for ''other'' and the modifier representing zero.

Comment: Several commenters suggested that significant education will

be required for therapists to comply with this required reporting.

Response: We are publishing in this final rule with comment period the claims-based reporting requirements that must be met in order to receive payment for therapy services. We will also use our usual methods for providing additional information, including revising relevant sections of the IOM, publishing Medicare Learning Network (MLN) Matters articles; presentations on Open Door Forums, and conducting National Provider Calls on the new requirements. We urge therapist to use these tools to assure that they have the information they need to comply with these new requirements.

(2) Nonpayable G-Codes on Beneficiary Functional Status

We proposed that therapists would report G-codes and modifiers on Medicare claims for outpatient therapy services. We discussed and sought comment on two types of G-codes in the proposed rule—generic and categorical. Table 19 shows the proposed generic G-codes and Table 20 shows the categorical codes discussed in the proposed rule.

TABLE 19—PROPOSED NONPAYABLE G-CODES FOR REPORTING FUNCTIONAL LIMITATIONS

Functional limitation for primary functional limitation:	
Primary Functional limitation, Current status at initial treatment/episode outset and at reporting intervals	GXXX1
Primary Functional limitation, Projected goal status	GXXX2
Primary Functional limitation, Status at therapy discharge or end of reporting	GXXX3
Functional limitation for a secondary functional limitation if one exists:	
Secondary Functional limitation, Current status at initial treatment/outset of therapy and at reporting intervals	GXXX4
Secondary Functional limitation, Projected goal status	GXXX5
Secondary Functional limitation, Status at therapy discharge or end of reporting	GXXX6
Provider attestation that functional reporting not required:	
Provider confirms functional reporting not required	GXXX7

The proposed G-codes differ from the three separate pairs of G-codes discussed in the CY 2011 PFS rulemaking. The CY 2011 discussion included these three pairs of G-codes, all of which reflect specific ICF terminology:

- Impairments of Body Functions and/or Impairments of Body Structures;
- Activity Limitations and Participation Restrictions; and
- Environmental Factors Barriers.

Each pair contained a G-code to represent the beneficiary's current functional status and another G-code to represent the beneficiary's projected goal status. Each claim would have required all three sets of G-codes. Like the G-codes we proposed for CY 2013, the G-codes discussed in the CY 2011 PFS rulemaking would have been used with modifiers to reflect the severity/complexity of each element.

In the CY 2013 PFS proposed rule, we indicated that we were not proposing to use these specific G-codes because we found them to be potentially redundant and confusing. Instead we chose to use G-codes to define ''functional limitations'' synonymously with the ICF terminology ''activity limitations and participation restrictions.'' We noted that requiring separate reporting on three elements would have imposed a greater burden on therapists without providing a meaningful benefit in the value of the data provided. We added that because environmental barriers as discussed in CY 2011 are contextual, we did not believe collecting information on them would contribute to developing an improved payment system.

To create the select categories of G-codes discussed in the proposed rule (See Table 20) we used the two most frequently reported functional limitations in the DOTPA project by each of the three therapy disciplines. We noted that should we decide to use a system with category-specific reporting, we would expect to develop specific nonpayable G-codes for select categories of functional limitations in the final rule. We explained that if one of the select categories of functional limitations describes the functional limitation being reported, that G-code set would be used to report the current, projected goal, and discharge status of the beneficiary. When reporting a functional limitation not described by one of categorical G-codes, one of the generic G-codes previously described would be used.

TABLE 20—SELECT CATEGORIES OF G-CODES DISCUSSED IN PROPOSED RULE

Walking & Moving Around	
Walking & moving around functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXXX8
Walking & moving around functional limitation, projected goal status, at initial therapy treatment/outset and at discharge from therapy	GXXX9
Walking & moving around functional limitation, discharge status, at discharge from therapy/end of reporting on limitation	GXX10
Changing & Maintaining Body Position	
Changing & maintaining body position functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX11
Changing & maintaining body position functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX12
Changing & maintaining body position functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX13
Carrying, Moving & Handling Objects	
Carrying, moving & handling objects functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX14
Carrying, moving & handling objects functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX15

TABLE 20—SELECT CATEGORIES OF G-CODES DISCUSSED IN PROPOSED RULE—Continued

Carrying, moving & handling objects functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX16
Self Care (washing oneself, toileting, dressing, eating, drinking)	
Self care functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX17
Self care functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX18
Self care functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX19
Communication: Reception (spoken, nonverbal, sign language, written)	
Communication: Reception functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX20
Communication: Reception functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX21
Communication: Reception functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX22
Communication: Expression (speaking, nonverbal, sign language, writing)	
Communication: Expression functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX23
Communication: Expression functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX24
Communication: Expression functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX25

We sought input from therapists on categories of functional limitations, such as those described in this section. We specifically requested comments regarding the following questions: Would data collected on categories of functional limitations provide more meaningful data on therapy services than that collected through use of the generic G-codes in our proposal? Should we choose to implement a system that is based on at least some select categories of functional limitation, which functional limitations should we collect data on in 2013? Is it more, less or the same burden to report on categories of functional limitations or generic ones? The categories of functional limitations described above are based on the ICF categories, but these ICF categories also have subcategories. Should we use subcategories for reporting? Are there specific conditions not covered by these ICF categories? Would we need to have G-codes for the same categories of secondary limitations? We sought public comment on whether these proposed G-codes allow adequate reporting on beneficiary's functional limitations. We also noted that we would particularly appreciate receiving specific suggestions for any missing elements.

The following is a summary of the comments we received on the G-codes, generic and categorical, whether these proposed G-codes allow adequate reporting on beneficiary's functional limitations, and specific suggestions for any missing elements.

Comment: Two commenters disagreed with our proposal to develop new G-codes and instead encouraged us to use the three pairs of G-codes (activities and participation restrictions, impairments to body functions/structures and environmental barriers) from the STATs project to report functional limitations. These commenters agreed that adding these domains might be more burdensome, but one commenter suggested that without these data elements we would likely miss integral beneficiary data in relation to health and wellness benefits, such as increased muscle function, improved quality of life, decreased depression, improved bowel/bladder function, improved respiratory function, improved autonomic function and improved circulation. Another commenter specifically agreed with our decision to use only the one ICF-defined G-code from the STATS for activity impairments and participation restrictions. They noted that it would be potentially redundant and confusing to adopt the two additional G-codes for body functions/structures and environmental barriers and noted that these other two categories would ''provide the agency with little meaningful data.'' One commenter suggested that if we adopted this additional reporting we could minimize the additional burden by eliminating goal reporting.

Response: We appreciate the views of these commenters about which ICF categories to capture in our G-code data collection. We continue to believe that the reporting of functional limitations will be less confusing and more defined with the G-codes as described in our proposal for activity impairments/participation restrictions. As we move forward with functional reporting in following years, we may revisit the addition of other categories.

Comment: Commenters had divergent views on the categorical and generic G-codes. Many found the proposed system complicated, burdensome and stated that it would not provide the data we sought. Some criticized the categorical codes as being too broadly defined and stated that this will lead to confusion as to what areas of impairment are being reported. For example, one commenter stated, ''The suggested categories are very broad and, in our view, will lead to confusion regarding which areas of impairment would be reported for certain therapy activities.'' One commenter opposed the use of generic G-codes saying that data from these codes would be ''useless.'' On the other hand, we received much support for the proposed G-codes. Many commenters supported the use of categorical G-codes codes saying their use will provide more useful information than the generic ones. One commenter stated, ''We believe having therapists report on these categories will provide CMS with more useful information than generic reporting on a functional limitation.'' Many favored use of the categorical G-codes in addition to using ''generic'' or ''other'' codes only for functional limitations that did not fit in one of the categorical ones. Several commenters gave us specific guidance, recommending that instead of the generic G-codes, we add an ''other'' G-code to the categorical codes for functional limitations that don't fit into one of the defined categories.

Response: Based upon the comments we received suggesting that we use the categorical codes, but include an ''other'' category to use when one of the categorical codes does not apply, we are modifying our proposal to adopt categorical G-codes to define functional limitations and including within the categorical G-codes ''other'' G-codes to use when one of the more specific categorical codes does not apply. In addition to this change, as discussed below, we are replacing the two SLP categorical codes with eight new ones to better reflect the diversity of services

furnished. Table 21 provides a complete list of the codes that will be available for reporting functional limitations. With regard to the commenters' concern that the categories are too broad and this will lead to confusion as to what is being reported, we acknowledge that the categories are broad, but disagree that the use of broad categories will result in confusion. Instead, we believe that the result will be the collection of data that includes information on broadly defined functional limitations. Without more specific input and greater support from the commenters, we do not believe we should create these in this final rule with comment period. Moreover, we believe it is important to gain experience with a limited number of codes in this new reporting system before we vastly expand the number of codes that are used. We sought comment on ways to better define the categories and where we received specific suggestions for additional G-codes that were sufficiently developed, such as those for SLP (explained below), we included them in our final set of G-codes. We anticipate that we will continue to refine the categories through future notice and comment rulemaking as we get more information and experience with this system.

Comment: Several commenters pointed out that there were many functional limitations for which there was not a categorical G-code. The American Speech-Language and Hearing Association pointed out the lack of appropriate SLP categories and suggested that we take advantage of the experience that has been gained through the use of its system for collecting data on functional limitations in this area. Specifically, they urged us to assign G-codes to the top seven reported functional communication measures used in National Outcomes Measurement System (NOMS). This commenter stated that, using this system, we would be able to collect ''consistent'' and ''meaningful'' ratings across all settings nationally.

Others told us that there were many conditions and situations that our system did not address and that some of these beneficiaries did not exhibit functional limitations that could be easily measured or reported. They cited, as examples, beneficiaries seen for lymphedema management, wound care, wheelchair assessment/fitting, cognitive impairments, and incontinence training.

Response: We agree with commenters that the G-codes discussed in the proposed rule did not go far enough in addressing SLP functional limitations. After consideration of the comments, we also agree that adoption of the most frequently used NOMS measures would be the best way to address this issue and would significantly improve our system in several ways. By using a system familiar to many speech-language pathologists, the quality of our data collection will be enhanced and the burden on those reporting will be less. We agree that it is reasonable to incorporate categories that are more specific, when appropriate, and note that this is an opportunity to align with existing measurement systems.

Accordingly, we are replacing the two of the categorical codes relating to SLP with seven categorical codes and one ''other'' code for SLP. (See Table 21.) The seven categorical codes mirror the seven most frequently reported NOMS categories and should be used when appropriate. For all other SLP treatments, the ''SLP Other'' category should be used.

For functional limitations not defined by the specific categorical codes and for therapy services that are not addressing a particular functional limitation; the ''other'' G-codes should be used. As we begin collecting data in this initial year, we will continue to assess the need for additional G-codes, refinement of existing ones, and examine ways to address those situations for which beneficiaries do not have functional limitations.

We have addressed in this final rule with comment period those areas for which we have adequate information to do so at this time and for which an additional burden will not be created. We will continue to refine this system through further notice and comment rulemaking in future years.

Comment: We received mixed feedback in response to our request for comment regarding the use of the ICF subcategories. Some commenters noted that adding more subcategories would result in too many codes and only add to the confusion. At least one other commenter supported subcategory reporting, but did not suggest which subcategories we should use.

Response: Given the comments received, we will not be implementing reporting by subcategories at this time. Once the system is operational, we will reassess whether subcategory reporting is necessary to provide the data that we need.

Comment: Some commenters interpreted our proposal to limit each therapy discipline to using only the two codes that represented the top two reported functional limitations for that discipline and suggested that we allow therapists to use any appropriate functional limitation.

Response: We agree with commenters that therapists should be able to use any appropriate functional limitation. In the proposed rule, we indicated that we developed the 6 categorical codes to correspond with the two most commonly reported functional limitations for each of the three therapy disciplines. However, this was only a way of identifying the functional limitations for which we needed codes. To be clear, therapists are to use the most appropriate categorical G-code that describes the functional limitation that is the primary reason for treatment without restriction by discipline.

Comment: A few commenters urged us to clarify that therapists using Patient Inquiry by Focus on Therapeutic Outcomes, Inc (FOTO), or another measurement system that provides a composite functional status score, did not need to report on secondary limitations.

Response: In assessing this comment, we recognized the need to clarify how composite functional scores should be reported. We are clarifying that a composite score should be reported using G8990 (Other physical or occupational primary functional limitation, current status, at therapy episode outset and at reporting intervals), G8991(Other physical or occupational primary functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting) and G8992 (Other physical or occupational primary functional limitation, discharge status, at discharge from therapy or to end reporting). Should there be the occasion to report on a second condition after the reporting on the first had ended, the therapist would use the G-code set for ''other subsequent'' functional limitation, G8993–G8896.

(3) Number of Functional Limitations on Which Reporting Occurs

We proposed that, using a set of G-codes with appropriate modifiers, the therapist would report the beneficiary's primary functional limitation defined as the most clinically relevant functional limitation at the time of the initial therapy evaluation and the establishment of the POC. The projected goal would also be reported at this time. At specified intervals during treatment, claims would also include the current functional status and the goal functional status, which would not typically change during therapy, except as described below. On the final claim for an episode of care, the therapist would report the status at this time for this functional limitation and the goal status.

Early results from the DOTPA project suggest that most beneficiaries have more than one functional limitation at treatment outset. In fact, only 21 percent of the DOTPA assessments reported just one functional limitation. Slightly more than half (54 percent) reported two, three or four functional limitations.

To the extent that the DOTPA finding is typical, the therapist may need to make a determination as to which functional limitation is primary for reporting purposes. In cases where this is unclear, the therapist may choose the functional limitation that is most clinically relevant to a successful outcome for the beneficiary, the one that would yield the quickest and/or greatest mobility, or the one that is the greatest priority for the beneficiary. In all cases, this primary functional limitation should reflect the predominant limitation that the furnished therapy services are intended to address.

We sought comment on specific issues regarding reporting data on a secondary limitation. Specifically, we requested comments regarding whether reporting on secondary functional limitations should be required or optional.

The following is a summary of the comments we received on the percentage of Medicare therapy beneficiaries with more than one functional limitation at the outset of therapy and whether reporting on secondary functional limitations should be required or optional.

Comment: The responses on the number of functional limitations being treated showed a wide variation. One commenter treating beneficiaries with spinal cord injuries indicated that 100 percent had more than one functional limitation, with an average of 10 functional limitations. Another respondent told us that 50 percent of SLP patients have two or more functional limitations. Another respondent indicated that nearly 98 percent of patients seen by therapists using FOTO were surveyed for only one condition. Most commenters recommended that therapists be required to report only one functional limitation, especially as we are just beginning to require functional reporting. The commenters stated that it would be burdensome and would pose clinical challenges to require reporting both a primary and secondary functional limitation. Others suggested that it would be costly, time intensive and burdensome to report numerous secondary functional limitations. Some stated that reporting on only one functional limitation would not capture sufficient information since treatment of multiple functional limitations is interrelated and treatment for these occurs simultaneously, not sequentially. Some commenters suggested allowing the optional reporting of a second or third functional limitation. Some commenters questioned how functional reporting would be handled when the beneficiary was being treated by more than one discipline or when a substitute therapist treats a beneficiary.

Response: In response to comments, we have decided to limit reporting to one functional limitation at this time. Recognizing that therapists treat the patient as a whole and work on more than one functional limitation at a time, we believe that limiting reporting in this way will make it less burdensome in the situations involving more than one functional limitation. Although many commenters favored the option of reporting on additional functional limitations when appropriate, we believe that allowing additional optional reporting would not produce consistent or useful data on beneficiaries who have more than one functional limitation that is being treated, and could potentially complicate the use of the data we collect for the development of future therapy payment policy. As we seek to improve reporting in future years, we may reconsider whether to permit or require reporting on additional functional limitations. We note that this is a new reporting system designed to gather data on the changes in beneficiary function throughout an episode of care. We are not expecting therapists to change the way they treat patients because of our reporting requirements.

We also explained that in situations where treatment continues after the treatment goal is achieved and reporting ended on the primary functional limitation, reporting will be required for another functional limitation. Thus, reporting on more than one functional limitation may be required for some patients, but not simultaneously. Instead, once reporting on the primary functional limitation is complete, the therapist will begin reporting on a subsequent functional limitation using another set of G-codes. If this additional functional limitation is not described by one of the specific categorical codes, one of the three ''other'' codes should be used depending on the circumstances.

In response to the comments, we are making several modifications in the G-codes that we proposed, as noted in the responses to comments above. To summarize, the G-codes, and their long descriptors, that will be used for reporting functional limitations of beneficiaries are listed in Table 21. There are 11 G-codes that describe categorical functional limitation, including seven for SLP services, and three more general G-codes for functional limitations that do not fit within one of the 11 categories. The general categorical codes would be used when none of the specific categories apply or when an assessment tool is used that yields a composite score that combines several or many functional measures, such as is done with the FOTO Patient Inquiry tool, for example. Two of these general G-code sets are to be used for ''other'' PT and OT services and one for ''other'' SLP services. In addition, we deleted the requirement to report a G-code to signal that no reporting was required and thus deleted the G-code that would have been used for this. (For discussion about the comments on this G-code and our decision to remove this reporting requirement, see section II.F.2.(b).(6).) Therapists would use the code that best describes the functional limitation that is primary to the therapy plan of care.

TABLE 21—G-CODES FOR CLAIMS-BASED FUNCTIONAL REPORTING FOR CY 2013

Mobility: Walking & Moving Around	
G8978	Mobility: walking & moving around functional limitation, current status, at therapy episode outset and at reporting intervals.
G8979	Mobility: walking & moving around functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8980	Mobility: walking & moving around functional limitation, discharge status, at discharge from therapy or to end reporting.
Changing & Maintaining Body Position	
G8981	Changing & maintaining body position functional limitation, current status, at therapy episode outset and at reporting intervals.

TABLE 21—G-CODES FOR CLAIMS-BASED FUNCTIONAL REPORTING FOR CY 2013—Continued

G8982	Changing & maintaining body position functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8983	Changing & maintaining body position functional limitation, discharge status, at discharge from therapy or to end reporting.
Carrying, Moving & Handling Objects	
G8984	Carrying, moving & handling objects functional limitation, current status, at therapy episode outset and at reporting intervals.
G8985	Carrying, moving & handling objects functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8986	Carrying, moving & handling objects functional limitation, discharge status, at discharge from therapy or to end reporting.
Self Care	
G8987	Self care functional limitation, current status, at therapy episode outset and at reporting intervals.
G8988	Self care functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8989	Self care functional limitation, discharge status, at discharge from therapy or to end reporting.
Other PT/OT Primary Functional Limitation	
G8990	Other physical or occupational primary functional limitation, current status, at therapy episode outset and at reporting intervals.
G8991	Other physical or occupational primary functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8992	Other physical or occupational primary functional limitation, discharge status, at discharge from therapy or to end reporting.
Other PT/OT Subsequent Functional Limitation	
G8993	Other physical or occupational subsequent functional limitation, current status, at therapy episode outset and at reporting intervals.
G8994	Other physical or occupational subsequent functional limitation, projected goal status, at therapy episode outset, at reporting intervals, and at discharge or to end reporting.
G8995	Other physical or occupational subsequent functional limitation, discharge status, at discharge from therapy or to end reporting.
Swallowing	
G8996	Swallowing functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G8997	Swallowing functional limitation, projected goal status, at initial therapy treatment/outset and at discharge from therapy.
G8998	Swallowing functional limitation, discharge status, at discharge from therapy/end of reporting on limitation.
Motor Speech	
G8999	Motor speech functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9157	Motor speech functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9158	Motor speech functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
Spoken Language Comprehension	
G9159	Spoken language comprehension functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9160	Spoken language comprehension functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9161	Spoken language comprehension functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
Spoken Language Expression	
G9162	Spoken language expression functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9163	Spoken language expression functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9164	Spoken language expression functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
Attention	
G9165	Attention functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9166	Attention functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9167	Attention functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
Memory	
G9168	Memory functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9169	Memory functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9170	Memory functional limitation, discharge status at discharge from therapy/end of reporting on limitation.

TABLE 21—G-CODES FOR CLAIMS-BASED FUNCTIONAL REPORTING FOR CY 2013—Continued

Voice	
G9171	Voice functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9172	Voice functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9173	Voice functional limitation, discharge status at discharge from therapy/end of reporting on limitation.
Other SLP Functional Limitation	
G9174	Other speech language pathology functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals.
G9175	Other speech language pathology functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy.
G9176	Other speech language pathology functional limitation, discharge status at discharge from therapy/end of reporting on limitation.

(4) Severity/Complexity Modifiers

We proposed that for each functional G-code used on a claim, a modifier would be required to report the severity/complexity for that functional limitation. We proposed to adopt a 12-point scale to report the severity or complexity of the functional limitation involved. The proposed modifiers are listed in Table 22.

TABLE 22—PROPOSED MODIFIERS

Modifier	Impairment limitation restriction difficulty
XA	0%.
XB	Between 1–9%.
XC	Between 10–19%.
XD	Between 20–29%.
XE	Between 30–39%.
XF	Between 40–49%.
XG	Between 50–59%.
XH	Between 60–69%.
XI	Between 70–79%.
XJ	Between 80–89%.
XK	Between 90–99%.
XL	100%.

We noted that there are many valid and reliable measurement and assessment tools that therapists use to inform their clinical decision-making and to quantify functional limitations, including the four assessment tools we discussed in CY 2011 PFS rulemaking that produce functional scores—namely, the Activity Measure—Post Acute Care (AM–PAC) tool, the FOTO Patient Inquiry, OPTIMAL, and NOMS. We list these four tools as recommended for use by therapists, though not required, in the outpatient therapy IOM provision of the Benefits Policy Manual, Chapter 15, Section 220.3C ''*Documentation Requirements for Therapy Services.''* We suggested that the scores from these and other measurement tools already in use by therapists that produce numerical or percentage scores be mapped or crosswalked to the proposed 12-point severity modifier scale.

In assessing the ability of therapists to provide the required severity information regardless of what assessment tool or combination of tools they use, if any, we considered the comments received on the CY 2011 PFS proposed rule discussion. These indicated that we needed greater granularity in our severity scale so that the changes in functional limitation over the course of therapy could be more accurately reflected. Specifically, most commenters on the CY 2011 proposed rule favored the 7-point scale over the 5-point ICF-based scale. They indicated that they preferred a scale with more severity levels and equal increments since it would allow the therapist to document smaller changes that many therapy beneficiaries make towards their goals.

Believing that neither the 5- or 7-point scales would be adequate for this reporting system, we developed and proposed a 12-point scale that we believed was an enhancement over the 7-point scale. We thought it addressed concerns that those commenting on the CY 2011 options had raised regarding the 7-point scale. We thought that a more sensitive rating scale (one with more increments) had the advantage of demonstrating the progress of beneficiaries with conditions that improve slowly, such as those recovering from strokes or with spinal cord injuries. In addition, we believed that the proposed scale's 10-percentage point increments would make it easier for therapists to convert composite and overall scores from assessment instruments or other measurement tools to this scale.

The following is a summary of the comments we received regarding our proposal for a 12-point scale to capture the severity/complexity of beneficiaries' functional limitations.

Comment: Several commenters stated that not all tests and measurement tools that therapists use could be easily crosswalked to any single numerical scale, stating that, for example, some tests and measures of functional limitations use ordinal scales. Further, the scores from some tests that are not linear or proportional to each other are not easily translatable to the 12-point scale. Some commenters pointed out the problems of developing a single score when more than one tool is used. Some commenters noted that there are a wide variety of therapy measurement tools that are used to inform clinical decision making and these are not measures that typically produce a functional assessment. Further, these commenters told us that combining the results of multiple measures make it extremely difficult to quantify beneficiary function and, as such, said it will be very difficult to crosswalk this type of information to a severity scale. And, many of these commenters expressed concerns about how therapist will implement the use of our severity/complexity modifier scale; they noted that much education is needed for therapists to understand the selection of a severity modifier. One commenter questioned whether aggregated subjective and objective data would be valid or usable by CMS.

Response: It is essential that the data reported on functional limitations be grouped using the same numeric scale. Moreover, we believe that is easier for those reporting data on functional limitations to use ranges of percentages rather than the absolute values. We acknowledge that therapists will incur some challenges when initially adopting our system as they learn how to translate the information obtained through various tests and measures to a particular modifier scale. However, as therapists gain experience in doing so, we anticipate that these translations will become easier and a normal part of their evaluative and treatment processes. Moreover, we are hopeful that forthcoming modifications from tool sponsors or others will make it easier for therapists to report the functional

limitations measured by these tools, such as modifying the tool so the results match the Medicare severity/complexity scale or issuing instructions or guidance on translating the results to the Medicare severity/complexity scale. We also expect that some translation tools are likely to become available. We are hopeful that forthcoming guidance and translation tools from tool sponsors and others will clarify some of translation questions therapists have regarding the Medicare severity scale. Given that it is essential for our purposes to have a severity/complexity scale, we are adopting one in this final rule. With regard to education, CMS will make information about the severity/complexity scale, as well as other aspects of our new system, widely available to therapists. It will be incumbent upon individual therapists to learn how to translate the score from a singular assessment tool or the combined results from multiple tests/measures along with other information regarding their patient's functional limitation to the Medicare scale. Finally, we acknowledge that a system that combines objective and subjective data is not ideal. However, at this time it appears that there is not an alternative. We will continue to refine and improve this system.

Comment: Some commenters offered alternative suggestions to the use of a severity/complexity scale. Several commenters suggested that we use the secondary diagnoses on claims instead. Others suggested capturing the medical complexity of a beneficiary using other indicators, such as E/M codes or co-morbidities.

Response: We appreciate these suggestions. While we are able to collect secondary diagnosis data from claims, we know from prior studies that diagnoses alone cannot predict the amount of therapy services needed. We do not believe that diagnoses and comorbidities measure functional limitations, which the statute requires us to collect. Nor do we believe using existing or therapy-specific E/M codes would provide the data on functional limitations that we are seeking to collect. We do, however, believe that these elements may provide additional data that could contribute to our analysis of payment alternatives. As we consider refinements to the claims-based data collection system in future years we will consider these additional data elements.

Comment: Commenters had differing views on the use of the proposed 12-point scale to convey the severity of the beneficiary's functional limitations. Those supporting the use of the proposed 12-point scale stated that it was more sensitive and so better reflected change in a beneficiary's functional limitation. For example, commenters using FOTO said that they would not have problems adopting our proposed 12-point scale because they receive a composite score from FOTO, based on the patient's functional survey results, which can be easily mapped as a percentage of overall beneficiary function. Other commenters suggested that the 12-point scale we proposed was too complicated and had too many levels. Some of these commenters also stated that therapists were not familiar with such a scale. Several commenters believed that we should modify the 12-point scale to a 10-point one by eliminating the separate modifiers for zero and 100 percent because they believed it would be more recognizable and easier for therapists to use. Many suggested that we use the 7-point scale discussed in the CY 2011 rulemaking. A couple of these commenters thought that this 7-point scale was a valid and reliable one. Another commenter added that a 7-point scale is used by many outcome tools, such as NOMS, although no other examples of a tool using a 7-point scale were provided. One commenter was opposed to a severity/complexity scale but suggested that if one was used, it should be a 5- or 7-point scale.

Response: After reviewing the comments, it is clear to us that, given the diversity of views among therapy professionals, the range in functional limitations being measured, the variability of beneficiary conditions being treated and the plethora of assessment tools and instruments being used, the translation of functional information to any scale used is likely to require adjustments by some therapists. Although we proposed a 12-point scale as we thought it would be easier to use and provided more sensitivity, a majority of commenters favored the 7-point scale over the 12-point scale. After consideration of the many comments on the use of a 12-point scale, we have determined that a 7-point scale as preferred by commenters will provide appropriate data for our analysis. Accordingly, are finalizing the 7-point scale in Table 23.

Comment: Some commenters read our proposal to require that therapists use one of the IOM-recommended assessment tools, and thought that we should allow therapists to assign a severity/complexity modifier using their clinical judgment when a functional assessment tool is not used. Other commenters noted that physical and occupational therapists typically use multiple measurement tools during the evaluative process to inform clinical decision making; and, that clinical judgment is needed to combine these results to determine a functional limitation percentage. One commenter pointed out that the IOM outpatient coverage guidelines recommend, but do not mandate, the use of standardized measurement instruments and sought guidance as to how the modifier scale would apply to a therapist who satisfies documentation guidelines but does not use a standardized measurement instrument that produces a global functional score.

Response: We appreciate commenters' concerns that our proposed policy would require therapists to use a functional assessment tool to determine the overall degree of functional impairment. This was not our intent. However, when one of the four functional assessment instruments is not utilized, we require as part of our IOM *Documentation Guidelines,* that the therapist documents using objective measures the beneficiary's physical functioning. We are also aware that use of one of the four functional instruments is not widespread; and that physical and occupational therapists typically use multiple objective tests and measures to establish and compare a beneficiary's physical function and progress throughout the therapy episode. As such, we recognize that a therapist's judgment is critical in determining how to best measure their patient's functional impairment and how to assimilate the various necessary objective findings to ascertain a certain percentage of function that can be translated to the Medicare severity scale. Our requirements for documenting the beneficiary's functional status were established prior to this data collection effort, and the primary purpose for measuring functional impairment continues to aid the therapist in furnishing therapy services. Our data collection system is designed to collect data that is developed in the evaluative process and assessed throughout the course of treatment, not to prescribe how or what measures therapists use to assess functional impairment or deliver services. Accordingly, it is acceptable for therapists to use their professional judgment in the selection of the appropriate modifier. Our IOM provisions already assert that when assessing the level of functional impairment, the therapist uses his/her professional judgments in addition to the objective measures and accepted methodologies that are recognized in the

therapy community and in professional practice guidelines.

Because there will be many cases for which one single functional measurement tool is not available or clinically inappropriate, therapists can use their clinical judgment in the assignment of the appropriate modifier. Therapists will need to document in the medical record how they made the modifier selection so that the same process can be followed at succeeding assessment intervals.

Comment: Many commenters evaluated our proposed 12-point scale as if it was itself to be used as an assessment tool, rather than simply a scale to report results of assessments. Some of these commenters also warned us that the 12-point scale could not give us valid and reliable data to use as an alternative payment system for therapy services unless a single assessment tool were used.

Response: We appreciate the views expressed by the many commenters. However, the 12-point scale was not intended to be used as an assessment tool. Rather, it was intended to be used to express the beneficiary's functional limitation in terms of a percentage of 100 total points so that there is a uniform scale for the degree of functional limitation. In other words, the scale that is used to report the degree of impairment would not affect the validity of the data. The reported data are as valid and reliable as the assessment tool or instrument (at times in combination with the therapist's judgment) that was used to develop the score. We also realize that there are limitations to the data that we will collect, in part because it is not all derived from one consistent, assessment tool.

Comment: Commenters noted that pain is a clinical complexity that is factored in when the beneficiary and therapist plan the course of treatment, but is not factored in to the proposed scale.

Response: We believe that the commenter meant that pain is a definite limiter of function and is difficult to measure and hard to quantify. However, we believe that pain and the functional limitations that it engenders can be captured by our severity scale. There are many valid and reliable measures that a therapist can use to quantify the functional limitations of painful conditions.

In response to the comments, we are adopting the following 7-point severity/complexity scale to report the severity of the beneficiary's functional impairment, which is based upon the scale developed as part of the STATs project.

TABLE 23—SEVERITY/COMPLEXITY MODIFIERS FOR CY 2013

Modifier	Impairment limitation restriction
CH	0 percent impaired, limited or restricted.
CI	At least 1 percent but less than 20 percent impaired, limited or restricted.
CJ	At least 20 percent but less than 40 percent impaired, limited or restricted.
CK	At least 40 percent but less than 60 percent impaired, limited or restricted.
CL	At least 60 percent but less than 80 percent impaired, limited or restricted.
CM	At least 80 percent but less than 100 percent impaired, limited or restricted.
CN	100 percent impaired, limited or restricted.

(4) Assessment Tools

In the proposed rule we noted that therapists frequently use assessment tools to quantify beneficiary function. FOTO and NOMS are two such assessment tools in the public domain that can be used to determine a score for an assessment of beneficiary function. Therapists could use the score produced by such instruments to select the appropriate modifier for reporting the beneficiary's functional status. Although we recommend the use of four of these functional assessment instruments to determine beneficiary functional limitation in the IOM, we did not propose to require the use of a particular functional assessment tool to determine the severity/complexity modifier. We explained our reasons for not doing so in the proposed rule saying ''Some tools are proprietary, and others in the public domain cannot be modified to explicitly address this data collection project. Further, this data collection effort spans several therapy disciplines. Requiring a specific instrument could create burdens for therapists that would have to be considered in light of any potential improvement in data accuracy, consistency and appropriateness that such an instrument would generate.'' We noted that we might reconsider this decision once we have more experience with claims-based data collection on beneficiary function associated with furnished therapy services. We sought public comment on the use of assessment tools. In particular, we were interested in feedback regarding the benefits and burdens associated with use of a specific tool to assess beneficiary functional limitations. We requested that those favoring a requirement to use a specific tool provide information on the preferred tool and describe why the tool is preferred.

The following is a summary of the comments we received regarding the use of assessment tools and the benefits and burdens associated with use of a specific tool to assess beneficiary functional limitations.

Comment: Many commenters appreciated that we recognized the need to use consistent and objective measurement tools to quantify beneficiary function. All commenters who addressed assessment tools agreed that there is not currently a single assessment tool that would meet the diverse needs of beneficiaries receiving therapy services, and most did not recommend requiring the use of a single tool. However, many commenters stated we would be ineffective in reaching our data collection goals without prescribing some rules about assessing function; and thus suggested alternatives due to concerns of consistency and validity of the data. MedPAC noted that collecting data without a tool ''would generate large amounts of data, and not provide clear information on the patients' limitations or functional status.'' MedPAC elaborated that variations among the assessment methods used by therapists ''would potentially impede the utility of such data for policymakers.''

Commenters found the following potential drawbacks to our proposal to allow therapists to choose the assessment tool(s) (or use their professional judgment) to determine the complexity/severity modifier. Commenters stated that the current proposal would collect individual level data that is not comparable among groups of beneficiaries or providers. Commenters also stated that gathering data on beneficiary condition, functional limitation, and progression necessitates the use of one standardized collection tool by all therapists. One commenter revealed that the same beneficiary could obtain widely distinct modifier scores depending on the tool used. Further, a commenter acknowledged that there are over 400 different measurement tools used by physical therapists, many of which only measure one domain of function. Additionally, another commenter urged us to provide more instruction on how each tool interfaces with the complexity/severity scale and provide crosswalks and guidance for each tool to promote consistency in the data collected.

Commenters suggested the following alternatives to our proposal to address the potential drawbacks they identified. Commenters supported endorsing a small number of standardized tools with proven validity, reliability, and responsiveness that would be distinct for each therapy discipline. The American Speech-Language and Hearing Association (ASHA) urged we adopt NOMS and a 7-point severity scale specifically for SLP to recognize the distinctiveness of the discipline and record meaningful outcomes for SLP beneficiaries. Many commenters supported the use of FOTO stating that it measures a broad scope of conditions reliably, results in a composite score, and creates little undue burden to report. Those commenters also stated that FOTO is already the tool of choice for their respective providers.

Two commenters suggested developing a list of approved tools for specific beneficiary populations and settings. Another commenter suggested assigning G-codes to specific assessment tools so that the data could be compared. As a future alternative, a few commenters proposed developing core items that could be used in any tool to standardize data collection. MedPAC suggested that ''CMS consider developing an instrument that collects the necessary information that would allow Medicare to categorize beneficiaries by condition and severity in order to pay appropriately'' and pointed to the ''Reason for Therapy'' form used in the DOTPA study as a starting point, noting that it is ''concise, easy to assess and document for clinicians, and collects information on function and limitations across three therapy disciplines.''

Response: We continue to recommend the use of four functional assessment tools to determine beneficiaries' functional limitations. In addition, when these tools are not used, we require the use of objective measures to document the functional status of beneficiaries. We continue to believe that no one tool currently meets the needs of all three therapy disciplines; and, therefore, we are not requiring the use of any one specific assessment tool, or even the use of any assessment tool. We acknowledge that because of the use of the variety and kinds of assessment tools and other measurement instruments, including the use of a therapist's professional judgment, the value of the data we collect under this system will have limitations. However, we believe that the data we gather will assist us in taking a first step towards an improved payment system.

We appreciate the comments providing information on the benefits of using specific tools, such as NOMS and FOTO. However, at this time we do not believe that they are sufficiently widely used to require the use of one of these tools. In this final rule with comment period, we are not requiring the use of a specific assessment tool. We are continuing to encourage, but not require, the use of assessment tools in the IOM.

We did, however, adopt G-codes and a modifier scale for SLP that are consistent with NOMS so it is possible to move to a standardized tool for SLP in the future. We will consider the possibility using coding to identify the specific functional assessment tool used in subsequent refinements. As noted above, therapists can also use their professional judgment in determining the percentage of functional limitations in conjunction with objective data from evaluations and assessments and the subjective reports from beneficiaries.

(5) Reporting Projected Goal Status

We proposed that the therapist's projected goal for the beneficiary's functional status at the end of treatment would be reported on the first claim for services, periodically throughout an episode of care, and at discharge from therapy.

The following is a summary of the comments regarding goal reporting.

Comment: Of those commenting on goal status, most objected to the collection of goal data, particularly during the first year of data collection. Commenters noted that reporting on goals was not specified as part of the claims-based data collection effort required by MCTRJCA. Some stated that it would be a significant practice change to report goal data, involving changes to medical documentation, electronic health records, and billing processes. Commenters stated the identification and reporting of goals raised several clinical issues, such as the variability in goals among therapists, the need to change goals over the course of treatment, and the fact that therapists often set several goals (for example, short and long-term goals) for each beneficiary. Others noted that using goal data to classify a group of beneficiaries would be flawed because therapists create goals specific to the individual. One commenter noted that if goals influence payment, therapists could set the goal low or high to induce ongoing therapy and therefore the data would not be useful. As a result of these factors, many commenters believed data reporting on therapy goals would not provide reliable and useful information. In addition, a number of commenters stated that the proposal did not clearly express the intent of collecting goal data and many commenters expressed concerns about how we would use this data. Some commenters suggested that we clarify that the functional status data would be used only to track a beneficiary's progression rather than for any other purposes, such as making comparisons across beneficiaries, therapists, or settings. Several commenters expressed concern that the reporting of goals implied an improvement standard and that care would be denied to beneficiaries who improved slowly or not at all. Alternatively, one commenter supported our proposal for reporting of a projected goal, as well as periodic updates of the beneficiary status in the context of that goal.

Response: We understand the commenters' concerns about the complexity and intricacies of goal reporting. However, we currently require in the Benefit Policy Manual (Chapter 15, section 220.1.2) that long-term treatment goals be developed for the entire episode of care. Further, we specify that the projected goals should be measurable and pertain to identified functional limitations, and that these goals also need to be documented in the medical record. Since many of these goal requirements already exist, the additional work imposed by this requirement would be for the therapist to establish the percentage of functional limitation for projected for this goal at the end of the therapy episode and translate the goal to the G-code/modifier scale. We understand that the claims-based reporting is a change for therapists; however, these adjustments in operations will yield meaningful information on beneficiary functional status. We appreciate the recommendation to delay goal reporting for a year, but we believe that it is important to include goal data to gather a complete description of a beneficiary's functional status.

At this time, we intend to use the projected goal to have an understanding of therapists' ability to project the likely progress a beneficiary will make. We ultimately may employ these data to help us develop proposals to improve payment for therapy services, but do not anticipate using the goal data for purposes of payment or coverage decisions. In cases where the therapist does not expect improvement, such as for those individuals receiving maintenance therapy, the reported projected goal status will be the same as current status. We appreciate that commenters raised concerns about

potential ambiguity of the description of the proposal on progress and outcomes but, given as we have clarified in this final rule with comment period, goal reporting does not establish an improvement standard. In fact, it allows the therapist to state at the outset the expectations. We understand there will be wide variability in goals. Since these goals are used in beneficiary treatment, as well as for reporting, we do not expect therapists to establish goals purely to make themselves look better. Recognizing the limitations of the collected goal data, we still believe it will be useful to us. Therefore, we are finalizing our requirement for reporting of goal G-codes on the claims form along with the related severity modifier for that goal.

(6) Reporting Frequency

We proposed to require claims-based reporting in conjunction with the initial service at the outset of a therapy episode, at established intervals during treatment, and at discharge. As proposed, the number of G-codes required on a particular claim would have varied from one to four, depending on the circumstances. We provided the following (Table 24) graphic example of which codes would have been used for periodic reporting. This example represents a therapy episode of care occurring over an extended period, such as might be typical for a beneficiary receiving therapy for the late effects of a stroke. We chose to use an example with a much higher than average number of treatment days in order to show a greater variety of reporting scenarios.

TABLE 24: Example of Proposed Reporting

	Evaluation/Treatment Day 1, Begin Reporting Period #1	End Reporting Period #1	Begin Reporting Period #2	Claim for treatment days 5 and 6 in Period #2	End Reporting Period #2	Begin Reporting Period #3	Discharge/End of reporting on Primary Functional Limitation	End Reporting Period #3
Primary Function Status								
GXXX1 – Current	X	X	X		X	X		
GXXX2 – Goal	X		X			X	X	
GXXX3 – Discharge							X	
Secondary Function								
GXXX4 – Current			X		X	X		X
GXXX5 – Goal			X			X		
GXXX6 – Discharge								
No Functional Reporting Required								
GXXXX7				X				

• *Outset.* As proposed, the first reporting of G-codes and modifiers would occur when the outpatient therapy episode of care begins. This would typically be the date of service when the therapist furnishes the evaluation and develops the required plan of care (POC) for the beneficiary. At the outset, the therapist would use the G-codes and modifiers to report a current status and a projected goal for the primary functional limitation. We indicated in the proposal that if a secondary functional limitation would need to be reported, the same information would be reported using G-codes and associated modifiers for the secondary functional limitation.

The following is a summary of comments on the frequency of reporting at the outset.

Comment: All commenters that addressed frequency of reporting agreed that reporting should occur at the outset of the therapy episode of care. Although commenters agreed with reporting at the outset, many recommended removing the requirement to report the projected goal status. (Comments on reporting projected goal status are discussed above.)

Response: We are finalizing the requirement to report current status and projected goal status at the outset of therapy.

• *Every 10 Treatment Days or 30 Calendar Days, Whichever Is Less.* We proposed to require reporting once every 10 treatment days or at least once during each 30 calendar days, whichever time period is shorter. As we explained in the proposed rule, the first treatment day for purposes of reporting would be the day that the initial visit takes place. The date the episode of care begins, typically at the evaluation, even when the therapist does not furnish a separately billable procedure in addition to the evaluation on this day,

would be considered treatment day one, effectively beginning the count of treatment days or calendar days for the first reporting period.

A treatment day is defined as a calendar day in which treatment occurs resulting in a billable service. Often a treatment day and a therapy ''session'' (or ''visit'') may be the same, but the two terms are not interchangeable. For example, a beneficiary might receive certain services twice a day, although this is a rare clinical scenario, these two different sessions (or visits) on the same day by the same discipline are counted as one treatment day.

We explained that the proposal would require that on the claim for service on or before the 10th treatment day or the 30th calendar day after treatment day one, the therapist would only report the G-code and the appropriate modifier to show the beneficiary's current functional status at the end of this reporting period under the proposal. We added that the next reporting period begins on the next treatment day and that the time period between the end of one reporting period and the next treatment day does not count towards the 30-calendar day period. On the claim for services furnished on this date, the therapist would report both the G-code and modifier showing the current functional status at this time along with the G-code and modifier reflecting the projected goal that was identified at the outset of the therapy episode. This process would continue until the beneficiary concludes the course of therapy treatment.

Further, we proposed that on a claim for a service that does not require specific reporting of a G-code with modifier (that is, on a claim for therapy services within the time period for which reporting is not required), GXXX7 would be used. By using this code, the therapist would be confirming that the claim does not require specific functional reporting. This is the only G-code that we proposed to be reported without a severity modifier.

As we noted in the proposed rule, we proposed the 10/30 frequency of reporting to be consistent with our existing timing requirements for progress reports. These timing requirements are included in the *Documentation Requirements for Therapy Services* (see Pub. 100–02, Chapter 15, Section 220.3, Subsection D). By making these reporting timeframes consistent with Medicare's other requirements, therapists who are already furnishing therapy services to Medicare outpatients would have a familiar framework for successfully adopting our new reporting requirement. In addition to reflecting the Medicare required documentation for progress reports, we believe that this simplifies the process and minimizes the new burden on therapists since many therapy episodes would be completed by the 10th treatment day. In 2008, the average number of days in a therapy episode was 9 treatment days for SLP, 11 treatment days for PT, and 12 treatment days for OT. Under the proposal, when reporting on two functional limitations, the therapist would report the G-codes and modifiers for the second condition in the manner described above. In other words, at the end of the reporting period as proposed, two G-codes would be reported to show current functional status—one for the primary (GXXX1) and one for the secondary (GXXX4) limitation. Similarly as proposed, at the beginning of the reporting period four G-codes would be reported. GXXX1 and GXXX4 would be used to report current status for the primary and secondary functional limitations, respectively; and, GXXX2 and GXXX5 would be used to report the goal status for the primary and secondary functional limitations, respectively.

We noted that the proposal required that the same reporting periods be used for both the primary and secondary functional limitation. We added that the therapist can accomplish this by starting them at the same time or if the secondary functional limitation is added at some point in treatment, the primary functional limitation's reporting period must be re-started by reporting GXXX1 and GXXX2 at the same time the new secondary functional limitation is added using GXXX4 and GXXX5.

Further, for those therapy treatment episodes lasting longer periods of time, the periodic reporting of the G-codes and associated modifiers would reflect any progress that the beneficiary made toward the identified goal. In summary, we proposed to require the reporting of G-codes and modifiers at episode outset (evaluation or initial visit), and once every 10th treatment day or at least every 30 calendar days, whichever time period is less, and at discharge.

We noted that we believed it was important that the requirements for this reporting system be consistent with the requirements for documenting any progress in the medical record as specified in our manual. Given the current proposal for claims-based data collection, we believe it is an appropriate time to reassess the manual requirements. We sought comment on whether it would be appropriate to modify the periodicity of the progress report requirement in the IOM to one based solely on the number of treatment days, such as six or ten. We noted that if a timing modification was made for progress reporting, a corresponding change would be made in the functional reporting interval.

The following is a summary of the comments we received on our proposal to require reporting every 10 treatment days or 30 calendar days, whichever is less, and whether it would be appropriate to modify the progress report requirement in the IOM to one based solely on the number of treatment days, such as six or ten, and the clinical impact of such a change.

Comment: Although many commenters appreciated our effort to align the claims-based reporting with existing requirements for a progress report, several commenters requested that we recognize the significant time burden of the new reporting frequency and that we ameliorate some of the burden with a simplification of the existing manual requirement. Commenters in favor of reporting every 10 treatment days explained that using treatment days as compared to calendar days is more easily programmed into software systems and in accord with certain therapist's billing practices. A couple of other commenters supported reporting every 30 calendar days as this accommodates therapists working in settings where claims are required to be submitted on a monthly basis, such as hospitals, rehabilitation agencies and SNFs. Several commenters objected to the periodic reporting and suggested that reporting only at the outset and at discharge of therapy would be sufficient to capture a beneficiary's functional progression. A few of those commenters were okay with the proposed 10 treatment day or 30 calendar day reporting timeframe, if periodic claims reporting is necessary.

A few commenters urged us to eliminate the requirement for functional status reporting at the visit subsequent to the progress report because a beneficiary's status probably would remain the same unless there is a significant gap between visits.

We received many comments concerning the reporting of GXXX7; which we proposed to be used to indicate that the therapist confirms functional reporting not required. These commenters stated that the reporting of GXXX7, which is required for claims with dates of services when a functional status measure is not collected, would be unnecessary and burdensome, especially for daily billers. They urged us to require reporting only when a functional status is required to be reported. Further commenters stated

that there was no purpose for this G-code.

Response: Based on the public comments, we are making several changes. We believe that reporting every 10 treatment days would be less burdensome for therapists than the proposed 10 treatment days/30 calendar days. We believe a 10 treatment day reporting period is straightforward for therapists to track, allows for better monitoring of changes in functional status, and is more easily adopted within our current claims processing systems. Therefore, we are finalizing the requirement that G-codes and associated modifiers are reported at least once every 10 treatment days and we will modify the IOM to establish the same timing requirement for progress reports. By making this change, we no longer need the therapist to report functional status at the visit subsequent to the end of a reporting period to signal the beginning of a new reporting period. So in response to comments, we have eliminated the requirement to report data at the start of a new reporting period.

After assessing the comments, we agree that reporting a G-code (GXXX7) to tell us that no reporting is required would not provide meaningful data and would pose an additional burden for therapists and therapy providers. When proposed, we believed it would be convenient for therapists to use the code to indicate that this was a claim for therapy services that did not require the functional reporting because it would assist them in complying with the reporting requirements and would assist us in enforcing them. When we reassessed the issue based on feedback from commenters, it was clear that the ''no report due'' code would not aid us in enforcing the requirements as we would still have to verify that claims with the proposed GXXX7 were in fact claims that did not require reporting. Since commenters pointed out that not only would it not assist them, but would in fact burden them, we have decided not to include this code. Accordingly, we are also modifying our proposal to remove the requirement to report a ''no report due'' code on claims when functional reporting is not due, such as between the first and the tenth day of service. We expect these changes will significantly reduce the frequency of required reporting during a therapy episode and believe they will appropriately simplify the claims-based reporting system.

• *Discharge.* In addition, we proposed to require reporting of the G-code/modifier functional data for the current status and for the goal at the conclusion of treatment so that we have a complete set of data for the therapy episode of care. Requiring the reporting at discharge mirrors the IOM requirement of a discharge note or summary. This set of data would reveal any functional progress or improvement the beneficiary made toward the projected therapy goal during the entire therapy episode. Specifically, information on the beneficiary's functional status at the time of discharge shows whether the beneficiary made progress towards or met the projected therapy goal. As we noted in the proposed rule, the imposition of this reporting requirement does not justify scheduling an additional and perhaps medically unnecessary final session in order to measure the beneficiary's function for the sole purpose of reporting.

Although collection of discharge data is important in achieving our goals, we recognize that data on functional status at the time therapy concludes is sometimes likely to be incomplete for some beneficiaries receiving outpatient therapy services. The DOTPA project has found this to be true. There are various reasons as to why the therapist would not be able to report functional status using G-codes and modifiers at the time therapy ends. Sometimes, beneficiaries may discontinue therapy without alerting their therapist of their intention to do so; simply because they feel better; they can no longer fit therapy into their life, work, or social schedules; a physician told them further therapy was not necessary; or their transportation is unavailable. Whatever the reason, there would be situations where the therapy ends without the planned discharge visit taking place. In these situations, we said that we would not require the reporting at discharge. However, we encourage therapists to include discharge reporting whenever possible on the final therapy claim for services.

Since the therapist is typically reassessing the beneficiary during the therapy episode, the data critical to the severity/complexity of the functional measure may be available even when the final therapy session does not occur. In these instances, the G-codes and modifiers appropriate to discharge should be reported when the final claim for therapy services has not already been submitted.

We sought feedback on how often the therapy community finds that beneficiaries discontinue therapy without the therapist knowing in advance that it is the last treatment session and other situations in which the discharge data would not be available for reporting.

The following is a summary of the comments we received regarding the proposal to require reporting of the G-code/modifier functional data at the conclusion of treatment so that we have a complete set of data for the therapy episode of care.

Comment: In addition to outset reporting, a majority of commenters supported claims-based reporting at discharge of the therapy episode of care. With regard to the number of beneficiaries who stop therapy services without notice, the responses varied from about 12 percent for beneficiaries being treated for a spinal cord injury to 26 percent of patients with orthopedic conditions in a large system of outpatient therapy clinics. Many commenters who supported discharge reporting recommended that if the beneficiary misses his or her last visit, the therapist should be exempt from reporting the functional status at discharge. Another commenter believed, however, that having a separate G-code in each set to report discharge status is unnecessary; the commenter further stated that the last reported current status and goal status G-codes could be used to represent the end of treatment.

Response: Although we recognize that there may be some challenges with discharge reporting, this information is important for our purposes to complete the data set for each therapy episode; and, thus, we are maintaining the requirement. We do not agree with the commenter who suggested that we could simply use the last reported current status to represent the status at discharge since this may not be an accurate representation of the beneficiary's status at the time of discharge. However, in those cases where this functional status is derived from a patient survey, for example, FOTO, Am-PAC or OPTIMAL, and the survey is routinely sent to the patient who misses his/her final treatment, the therapist should report this data once subsequently gained, on the final bill for services unless the bill for the last treatment day has already been submitted. There are instances where not reporting the discharge status would make it impossible for us to distinguish the start of the reporting for a new or subsequently-reported functional limitation or the treatment for a new therapy episode in the data. We are finalizing our proposal to require discharge reporting (except in cases where therapy services are discontinued by the beneficiary prior to the planned discharge visit) using the discharge G-code, along with the goal status G-code, to indicate the end of a therapy episode or to signal the end of reporting on one

functional limitation, while further therapy is necessary for another one.

• *Significant Change in Beneficiary Condition.* We proposed that, in addition to reporting at the intervals discussed above, the G-code/modifier measures would be required to be reported when a formal and medically necessary re-evaluation of the beneficiary results in an alteration of the goals in the beneficiary's POC. This could result from new clinical findings, an added comorbidity, or a failure to respond to treatment. We noted that this reporting affords the therapist the opportunity to explain a beneficiary's failure to progress toward the initially established goal(s) and permits either the revision of the severity status of the existing goal or the establishment of a new goal or goals. Under the proposal, the therapist would be required to begin a new reporting period when submitting a claim containing a CPT code for an evaluation or a re-evaluation. This functional reporting of G-codes, along with the associated modifiers, could be used to show an increase in the severity of functional limitations; or, they could be used to reflect the severity of newly identified functional limitations as delineated in the revised plan of care.

The following is a summary of the comments we received regarding the proposal that in addition to reporting at the intervals discussed above, the G-code and related modifier would be required to be reported when a formal and medically necessary re-evaluation of the beneficiary results in an alteration of the goals in the beneficiary's POC.

Comment: One commenter recommended that instead of requiring periodic reporting throughout a therapy episode that we require it only at the time of a re-evaluation. This commenter believed that capturing the functional information using G-codes within the treatment episode is burdensome and reporting at the time of the progress report would put unnecessary emphasis on a therapist capturing a change in a beneficiary's assessment.

Response: We did not receive comments objecting to claims-based reporting at the time that a re-evaluation code is billed for PT or OT or a subsequent or second evaluation code is billed for SLP. Therefore, we are finalizing the requirement for functional reporting when a formal and medically necessary re-evaluation, for PT or OT, or a second or repeat SLP evaluation of the beneficiary is furnished. We are requiring claims-based reporting in conjunction with the evaluation at the outset of therapy, on or before each 10th treatment day throughout therapy, and at therapy discharge (except in cases where therapy services are unexpectedly discontinued by the beneficiary prior to the planned discharge visit and the necessary information is not available) or to signal the end of reporting on one functional limitation. On a claim, two G-codes would be required depending on the reporting interval. Table 25 shows a revised example of which codes are used for specified reporting under our final policy. We should note that this example utilizes the mobility functional limitation G-codes, G8978–G8980 for ''walking and moving around'' and the ''Other or Primary'' G-codes, G8990–G8992 and is for illustrative purposes only. This table not only shows how the final reporting works but by comparing it to the table showing the same details for reporting under the proposed policy one can see how much less reporting is required. Any of the other functional limitation G-code sets listed in Table 21 would also be applicable here.

TABLE 25: Example of Required Reporting

	Evaluation/Treatment Day One, Begin Reporting Period #1	End Reporting Period #1	Reporting Period #2 Begins Next Treatment Day	Claim for treatment days 5 and 6 in Period #2	End Reporting Period #2	Reporting Period #3 Begins Next Treatment Day	Discharge /End of reporting on Walking & Moving Around Functional Limitation	Begin Reporting Period #1 for Other Primary
Mobility: Walking & Moving Around								
G8978 – Current	X	X			X			
G 8979– Goal	X	X			X		X	
G8980 – Discharge							X	
Other Primary								
G8990 – Current								X
G8991 – Goal								X
G8992 – Discharge								
No Functional Reporting Required								
No coding exists.								

In summary, we maintain that claims-based reporting should occur at the outset of therapy episode, on or before every 10 treatment days throughout the course of therapy, and at the time of discharge from therapy. Additionally, functional reporting is also required at the time the beneficiary's condition changes significantly enough to clinically warrant a re-evaluation such that a HCPCS/CPT code for a re-evaluation or a repeat evaluation is billed.

(7) Documentation

We proposed to require that documentation of the information used for reporting under this system must be included in the beneficiary's medical record. As proposed, the therapist would need to track in the medical record the G-codes and the corresponding severity modifiers that were used to report the status of the functional limitations at the time reporting was required. Including G-codes and related modifiers in the medical record creates an auditable record, assists in improving the quality of data CMS collects, and allows therapists to track assessment and functional information. In the proposed rule, we provided the example of a situation where the therapist selects the mobility functional limitation of ''walking and moving'' as the primary functional limitation and determines that at therapy outset the beneficiary has a 60 percent limitation and sets the goal to reduce the limitation to 5 percent. We noted that the therapist uses GXXX1–XH to report the current status of the functional impairment and GXXX2–XB to report the goal. Additionally, we said that the therapist should note in the beneficiary's medical record that the functional limitation is ''walking and moving'' and document the G-codes and severity modifiers used to report this functional limitation on the claim for therapy services.

The following is a summary of comments we received concerning our documentation requirements.

Comment: Some commenters suggested that the proposal would impose significant additional documentation and claims reporting requirements. Further, one commenter objected to the requirement to include information in the medical record on the G-codes and modifiers used for billing as it would be highly unusual and time intensive to do so. Another commenter supported our proposal, agreeing that documentation of the information used for reporting under this system must be included in the beneficiary's medical record.

Response: We disagree with the commenters' statements that the required documentation is overly burdensome. In fact, by maintaining the G-code descriptor and related modifier in the medical record, therapists may find it easier to link treatment and reporting. Additionally, to enforce the reporting requirements on the claims, documentation in the medical record is required. In cases where the therapist uses other information in addition to certain measurement tools in order to assess functional impairment, he or she would also want to document the relevant information used to determine the overall percentage of functional limitation to select the severity modifier. In instances where it becomes necessary for a different therapist to furnish the therapy services, the substitute therapist can look in the beneficiary's medical record to note previous G-codes and related modifiers

reported. We are finalizing the proposed requirement that the G-codes and related modifiers must be documented in the beneficiary's medical record.

(8) Claims Requirements

In the proposed rule, we noted that except for the addition of the proposed G-codes and the associated modifiers, nothing in this proposal would modify other existing requirements for submission of therapy claims. We noted in the proposed rule that, in addition to the new G-codes and modifiers used for the claims-based data collection system, the therapy modifiers—GO, GP, and GN, would still be required on claims to indicate that the therapy services are furnished under an OT, PT, or SLP plan of care, respectively; and, therefore, we are designating these nonpayable G-codes as ''always therapy.'' We noted in the proposed rule that institutional claims for therapy services would require that a charge be included on the service line for each one of these G-codes used in the required functional reporting. We also noted that this charge would not be used for payment purposes and would not affect processing. Further, we noted claims for professional services do not require that a charge be included for these nonpayable G-codes, but that reporting a charge for the nonpayable G-codes would not affect claims processing. To illustrate this policy, for each nonpayable G-code on the claim, that line of service would also need to contain one of the severity modifiers, the corresponding GO, GP, or GN therapy modifier to indicate the respective OT, PT, or SLP therapy discipline and related POC; and the date of service it references. For each line on the institutional claim submitted by hospitals, SNFs, rehabilitation agencies, CORFs and HHAs, a charge of one penny, $0.01, can be added. For each line on the professional claim submitted by private practice therapists and physician/NPPs, a charge of $0.00 can be added. We believe that many therapists submitting professional claims are already submitting nonpayable G-code quality measures under the PQRS and will be familiar with the parameters of nonpayable G-codes on claims for Medicare services.

Finally, we noted that Medicare does not process claims that do not include a billable service. As a result, reporting under this claims-based data collection system would need to be included on the same claim as a furnished service that Medicare covers.

We did not receive any comments specifically on the claims requirements so we are finalizing these as proposed.

(9) Implementation Date

In accordance with section 3005(g) of the MCTRJCA, we proposed to implement these data reporting requirements on January 1, 2013. We recognized that with electronic health records and electronic claims submission, therapists might encounter difficulty in including this new data on claims. To accommodate those that may experience operational or other difficulties with moving to this new reporting system and to assure smooth transition, we proposed a testing period from January 1, 2013 until July 1, 2013. We noted that we would expect that all those billing for outpatient therapy services would take advantage of this testing period and would begin attempting to report the new G-codes and modifiers as close to January 1, 2013, as possible, in preparation for required reporting beginning on July 1, 2013. Taking advantage of this testing period would help to minimize potential problems after July 1, 2013, when claims without the appropriate G-codes and modifiers would be returned unpaid.

The following is a summary of comments we received concerning our implementation of the new system on January 1, 2013 with enforcement beginning after July 1, 2013.

Comment: Given the statutory deadline, most commenters acknowledged that the new program needed to be implemented on January 1, 2013. Many commenters supported the proposed testing period. They indicated that a testing period was needed to train therapists, change documentation practices, modify electronic health records systems, educate billing contractors, and adjust billing systems. However, numerous commenters expressed concern that 6 months is an insufficient and unrealistic amount of time to transition to the new data reporting requirements. Commenters requested that we recognize the significant time and financial burden of the new reporting requirement and that we alleviate these concerns with delayed enforcement. Commenters requested a longer period to make software adjustments and educate therapists on the new reporting and frequency of documentation requirements. Further, commenters believed that we, in the limited time period, did not recognize the potential capital changes that would be necessary or allow for the typical process for acquiring funds. Commenters proposed various alternatives, which included extending the testing period to 9 or 12 months. A few suggested that we delay implementation of the mandate until the completion of the DOTPA study. As an alternative to nationwide data reporting, a few commenters suggested we consider testing the requirement under a pilot program in a small sample of the country, allowing us to analyze preliminary data and draw conclusions regarding the effectiveness of reporting through non-payable G-codes and modifiers before it is implemented nationwide.

Response: We are required by law to implement the claims-based data collection strategy on January 1, 2013. Our contractors and systems will be able to accept and process claims for therapy services with functional information at this time. We recognize that therapists may need time to adjust their claims processing to accommodate these additional codes but, we believe the necessary changes can be accomplished well within the 8 months between the time this final rule with comment period is issued and the end of the testing period. We do not believe a small pilot as suggested by some commenters would meet the statutory requirement to implement as of January 1, 2013 a claims-based data collection strategy to assist in reforming outpatient therapy services. Nor would it meet our needs to gather data to assist in developing potential alternative payment systems for therapy services. We are finalizing an implementation date of January 1, 2013 with a 6-month testing period such that claims that do not comply with the data reporting requirements will be returned beginning July 1, 2013.

(10) Compliance Required as a Condition for Payment and Regulatory Changes

To implement the claims-based data collection system required by MCTRJCA and described above, we proposed to amend the regulations establishing the conditions for payment governing outpatient and CORF PT, OT, and SLP services to add a requirement that the claims include information on beneficiary functional limitations. In addition, we proposed to amend the POC requirements set forth in the regulations for outpatient therapy services and CORFs to require that the therapy goals, which must be included in the POC, are consistent with the beneficiary's functional limitations and goals reported on claims for services.

Specifically, we proposed to amend the regulations for outpatient OT, PT, and SLP (§ 410.59, § 410.60, and § 410.62, respectively) by adding a new paragraph (a)(4) to require that claims submitted for services furnished contain

the required information on beneficiary functional limitations.

We also proposed to amend the POC requirements set forth at § 410.61(c) to require that the therapy goals, which must be included in the treatment plan, must be consistent with those reported on claims for services. This requirement is in addition to those already existing conditions for the POC.

To achieve consistency in the provision of PT, OT, and SLP services across therapy benefits, we proposed to amend § 410.105 to include the same requirements for these services furnished in CORFs. These proposed revisions would require that the goals specified in the treatment plan be consistent with the beneficiary functional limitations and goals reported on claims for services and that claims submitted for services furnished contain specified information on beneficiary functional limitations, respectively. The requirements do not apply to respiratory therapy services.

We did not receive any comments on the proposed regulatory changes and are finalizing the changes as proposed.

(11) Consulting With Relevant Stakeholders

Section 3005(g) of the MCTRJCA requires us to consult with relevant stakeholders as we propose and implement this reporting system. In the CY 2013 PFS proposed rule, we indicated that we are meeting this requirement through the publication of this proposal and specifically by soliciting public comment on the various aspects of our proposal. In addition, we noted that we would meet with key stakeholders and discuss this issue in Open Door Forums over the course of the summer.

During the CY 2013 proposed rule comment period, we met with the various therapy professional associations and provider groups in order to solicit their comments on the various aspects of this proposal. At the CMS Physicians, Nurses & Allied Health Professionals Open Door Forum on July 17, 2012, we discussed the provisions of the proposed rule, including these requirements. We also discussed this proposed rule at the CMS Hospital & Hospital Quality Open Door Forum on July 18, 2012. In developing the final rule, we took into consideration many of the critical issues that were raised by the various stakeholders in these meetings and Forums. Accordingly, we believe we have met our obligation to consult with relevant stakeholders in proposing and implementing the required claims-based data collection strategy, and in developing our final policies, we have taken into consideration the various needs of stakeholders affected by this effort.

H. Primary Care and Care Coordination

In recent years, we have recognized primary care and care coordination as critical components in achieving better care for individuals, better health for individuals, and reduced expenditure growth. Accordingly, we have prioritized the development and implementation of a series of initiatives designed to improve payment for, and encourage long-term investment in, primary care and care management services. These initiatives include the following programs and demonstrations:

- The Medicare Shared Savings Program (described in ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule'' which appeared in the **Federal Register** on November 2, 2011 (76 FR 67802)).

++ The testing of the Pioneer ACO model, designed for experienced health care organizations (described on the Center for Medicare and Medicaid Innovation's (Innovation Center's) Web site at *innovations.cms.gov/initiatives/ACO/Pioneer/index.html*).

++ The testing of the Advance Payment ACO model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center's Web site at *innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html*).

- The Primary Care Incentive Payment (PCIP) Program (described on the CMS Web site at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf*).
- The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available (described on the CMS Web site at *www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf*).
- The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS Web site at *www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf* and the Innovation Center's Web site at *innovations.cms.gov/initiatives/FQHCs/index.html*).
- The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's Web site at *innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html*). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in certain markets across the country.

In coordination with these initiatives, we also continue to explore other potential refinements to the PFS that would appropriately value primary care and care coordination within Medicare's statutory structure for fee-for-service physician payment and quality reporting. We believe that improvements in payment for primary care and recognizing care coordination initiatives are particularly important as EHR technology diffuses and improves the ability of physicians and other providers of health care to work together to improve patient care. We view these potential refinements to the PFS as part of a broader strategy that relies on input and information gathered from the initiatives described above, research and demonstrations from other public and private stakeholders, the work of all parties involved in the potentially misvalued code initiative, and from the public at large.

In the CY 2012 PFS proposed rule (76 FR 42793 through 42794), we initiated a discussion to gather information about how primary care services have evolved to focus on preventing and managing chronic conditions. We also proposed to review evaluation and management (E/M) services as potentially misvalued and suggested that the American Medical Association Relative (Value) Update Committee (AMA RUC) might consider changes in the practice of chronic conditions management and care coordination as key reason for undertaking this review. In the CY 2012 PFS final rule with comment period (76 FR 73062 through 73065), we did not finalize our proposal to review E/M codes due to consensus from an overwhelming majority of commenters that a review of E/M services using our current processes could not appropriately value the evolving practice of chronic care coordination at the time, and therefore, would not accomplish the agency's goal of paying appropriately for primary care services. We stated that we would continue to consider ongoing research projects, demonstrations, and the numerous policy alternatives suggested by commenters. In addition, in the CY 2012 PFS proposed rule (76 FR 42917 through 42920), we initiated a public

discussion regarding payments for post-discharge care management services. We sought broad public comment on how to further improve care management for a beneficiary's transition from the hospital to the community setting within the existing statutory structure for physician payment and quality reporting. We specifically discussed how post discharge care management services are coded and valued under the current E/M coding structure, and we requested public comment. The physician community responded that comprehensive care coordination services are not adequately represented in the descriptions of, or payments for, office/outpatient E/M services. The American Medical Association (AMA) and the American Academy of Family Physicians (AAFP) created workgroups to consider new options for coding and payment for primary care services. The AAFP Task Force recommended that CMS create new primary care E/M codes and pay separately for non-face-to-face E/M Current Procedural Terminology (CPT) codes. (A summary of these recommendations is available at *www.aafp.org/online/en/home/publications/news/news-now/inside-aafp/20120314cmsrecommendations.html*.) The AMA workgroup, Chronic Care Coordination Workgroup (C3W), has and continues to develop codes to describe care transition and care coordination activities. (Several workgroup meeting minutes and other related items are available at *www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/care-coordination.page*.) Since the publication of the proposed rule, the C3W has completed development of two new transitional care management (TCM) codes. These new codes are:

- 99495 Transitional Care Management Services with 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.

++ Face-to-face visit, within 14 calendar days of discharge.

- 99496 Transitional Care Management Services with 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.

++ Face-to-face visit, within 7 calendar days of discharge.

We discuss these codes in greater detail below.

Under current PFS policy, care coordination is a component of E/M services which are generally reported using E/M CPT codes. The pre- and post-encounter non-face-to-face care management work is included in calculating the total work for the typical E/M services, and the total work for the typical service is used to develop RVUs for the E/M services. In the CY 2012 PFS proposed rule, we highlighted some of the E/M services that include substantial care coordination work. Specifically, we noted that the vignettes that describe a typical service for mid-level office/outpatient services (CPT codes 99203 and 99213) include furnishing care coordination, communication, and other necessary care management related to the office visit in the post-service work. We also highlighted vignettes that describe a typical service for hospital discharge day management (CPT codes 99238 and 99239), which include furnishing care coordination, communication, and other necessary management related to the hospitalization in the post-service work.

The payment for non-face-to-face care management services is bundled into the payment for face-to-face E/M visits. Moreover, Medicare does not pay for services that are furnished to parties other than the beneficiary and which Medicare does not cover, for example, communication with caregivers. Accordingly, we do not pay separately for CPT codes for telephone calls, medical team conferences, prolonged services without patient contact, or anticoagulation management services.

However, the physician community continues to tell us that the care coordination included in many of the E/M services, such as office visits, does not adequately describe the non-face-to-face care management work involved in primary care. Because the current E/M office/outpatient visit CPT codes were designed to support all office visits and reflect an overall orientation toward episodic treatment, we agree that these E/M codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries such as those who are returning to a community setting following discharge from a hospital or SNF stay. As part of our multi-year strategy to recognize and support primary care and care management, we proposed in the CY 2013 PFS proposed rule (77 FR 44776–44780) to create a HCPCS G code to describe 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 community mental health center (CMHC) partial hospitalization program to care furnished by the beneficiary's primary physician in the community. We also solicited comment on how care furnished in these settings might be incorporated into the current fee-for-service structure of the PFS.

Specifically, this HCPCS G code would describe all non-face-to-face services related to the TCM furnished by the community physician or qualified nonphysician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, long-term care hospital, skilled nursing facility, and inpatient rehabilitation facility; hospital outpatient for observation services or partial hospitalization services; and a partial hospitalization program at a CMHC to community-based care. The post-discharge TCM service includes non-face-to-face care management services furnished by clinical staff member(s) or office-based case manager(s) under the supervision of the community physician or qualified nonphysician practitioner. We based the concept of this proposal, in part, on our policy for care plan oversight services. We currently pay physicians for the non-face-to-face care plan oversight services furnished for beneficiaries under care of home health agencies or hospices. These beneficiaries require complex and multidisciplinary care modalities that involve: Regular physician development and/or revision of care plans, subsequent reports of patient status, review of laboratory and other studies, communication with other health professionals not employed in the same practice who are involved in the patient's care, integration of new information into the care plan, and/or adjustment of medical therapy. Physicians furnishing these services bill HCPCS codes G0181 or G0182 (See the Medicare benefit manual, 100–02, Chapter 15, Section 30 for detailed description of these services.)

For CY 2013, we proposed to create a new code to describe post-discharge TCM services. This service was proposed to include:

- Assuming responsibility for the beneficiary's care without a gap.

++ Obtaining and reviewing the discharge summary.

++ Reviewing diagnostic tests and treatments.

++ Updating of the patient's medical record based on a discharge summary to incorporate changes in health conditions and on-going treatments related to the hospital or nursing home stay within 14 business days of the discharge.

• Establishing or adjusting a plan of care to reflect required and indicated elements, particularly in light of the services furnished during the stay at the specified facility and to reflect result of communication with beneficiary.

++ An assessment of the patient's health status, medical needs, functional status, pain control, and psychosocial needs following the discharge.

• Communication (direct contact, telephone, electronic) with the beneficiary and/or caregiver, including education of patient and/or caregiver within 2 business days of discharge based on a review of the discharge summary and other available information such as diagnostic test results, including each of the following tasks:

++ An assessment of the patient's or caregiver's understanding of the medication regimen as well as education to reconcile the medication regimen differences between the pre- and post-hospital, CMHC, or SNF stay.

++ Education of the patient or caregiver regarding the on-going care plan and the potential complications that should be anticipated and how they should be addressed if they arise.

++ Assessment of the need for and assistance in establishing or re-establishing necessary home and community based resources.

++ Addressing the patient's medical and psychosocial issues, and medication reconciliation and management.

When indicated for a specific patient, the post-discharge transitional care service was also proposed to include:

• Communication with other health care professionals who will (re)assume care of the beneficiary, education of patient, family, guardian, and/or caregiver.

• Assessment of the need for and assistance in coordinating follow up visits with health care providers and other necessary services in the community.

• Establishment or reestablishment of needed community resources.

• Assistance in scheduling any required follow-up with community providers and services.

The proposed post-discharge transitional care HCPCS G code was described as follows:

GXXX1 Post-discharge transitional care management with the following required elements:

• Communication (direct contact, telephone, electronic) with the patient or caregiver within 2 business days of discharge.

• Medical decision making of moderate or high complexity during the service period.

• To be eligible to bill the service, physicians or qualified nonphysician practitioners must have had a face-to-face E/M visit with the patient in the 30 days prior to the transition in care or within 14 business days following the transition in care.

The post-discharge transitional care services HCPCS G code we proposed would be used by the community physician or qualified nonphysician practitioner to report the services furnished in the community to ensure the coordination and continuity of care for patients discharged from a hospital (inpatient stay, outpatient observation, or outpatient partial hospitalization), SNF stay, or CMHC. The post-discharge transitional care service would parallel the discharge day management service for the community physician or qualified nonphysician practitioner and complement the E/M office/outpatient visit CPT codes.

We proposed that the post-discharge transitional care service HCPCS G code would be used to report physician or qualifying nonphysician practitioner services for a patient whose medical and/or psychosocial problems requires moderate or high complexity medical decision-making during transitions in care from hospital (inpatient stay, outpatient observation, and partial hospitalization), SNF stay, or CMHC settings to community-based care. The Evaluation and Management Guidelines define decision-making of moderate and high medical complexity. In general, moderate complexity medical decision-making includes multiple diagnoses or management options, moderate complexity and amount of data to be reviewed, a moderate amount and/or complexity of data to be reviewed; and a moderate risk of significant complications, morbidity, and/or mortality. High complexity decision-making includes an extensive number of diagnoses or management options, an extensive amount and/or complexity of data to be reviewed, and high risk of significant complications, morbidity, and/or mortality (See Evaluation and Management Services Guide, Centers for Medicare & Medicaid Services, December 2010.) We proposed that the post-discharge transitional care HCPCS code (GXXX1) would be payable only once in the 30 days following a discharge, per patient per discharge, to a single community physician or qualified nonphysician practitioner (or group practice) who assumes responsibility for the patient's post-discharge TCM services. The service would be billable only at 30 days post discharge or thereafter. The post-discharge TCM service would be distinct from services furnished by the discharging physician or qualified nonphysician practitioner reporting CPT codes 99238 (Hospital discharge day management, 30 minutes or less); 99239 (Hospital discharge day management, more than 30 minutes); 99217 (Observation care discharge day management); or Observation or Inpatient Care services, CPT codes 99234 -99236; as appropriate.

We proposed to pay only one claim for the post-discharge transitional care GXXX1 billed per beneficiary at the conclusion of the 30 day post-discharge period Given the elements of the service and the short window of time following a discharge during which a physician or qualifying nonphysician practitioner will need to perform several tasks on behalf of a beneficiary, we stated our belief that it would be unlikely that two or more physicians or practitioners would have had a face-to-face E/M contact with the beneficiary in the specified window of 30 days prior or 14 days post discharge and have furnished the proposed post-discharge TCM services listed above. Therefore, we did not believe it necessary to take further steps to identify a beneficiary's community physician or qualified nonphysician practitioner who furnished the post-discharge TCM services. We proposed to pay only one claim for the post-discharge transitional care GXXX1 billed per beneficiary at the conclusion of the 30 day post-discharge period. Post-discharge TCM services relating to any subsequent discharges for a beneficiary in the same 30-day period would be included in the single payment. Practitioners billing this post-discharge transitional care code accept responsibility for managing and coordinating the beneficiary's care over the first 30 days after discharge.

Comment: We received many comments on the proposed new code. The vast majority supported the concept in whole or in part. Only a handful of comments were generally opposed to the proposal to recognize and pay for TCM services. One commenter, while acknowledging that our proposal was ''well intentioned,'' expressed concern about adopting such an important proposal without explicit statutory direction. In particular, the commenter

recommended that we should be more judicious in using the PFS rulemaking process to adopt far-reaching new policies requiring sizable BN adjustments. The commenter suggested that, if the proposed policies had been mandated by the Congress, the BN adjustment would presumably not be required. Another commenter suggested that the proposed new code was duplicative, because pre- and post-encounter non-face-to-face care management work is included in the total work for the typical E/M services, and the total work for subsequent post-operative visits that accompany surgical procedures.

Response: We thank the commenters who wrote in support of this proposal. For the reasons that we stated in the proposed rule, we do not believe that all the pre- and post- encounter non-face-to-face care management work that typically occurs when a beneficiary is discharged from a hospital, SNF or CMHC stay is included in the total work for the typical E/M services. This is because the E/M codes represent the typical outpatient visit and do not capture or reflect the significant care coordination that needs to occur when a beneficiary transitions from institutional to community-based care. (77 FR 44776) Therefore, we continue to believe that separate payment for TCM services does not duplicate payment for typical E/M services. We also believe that adoption of new codes such as our proposed TCM code is consistent with our statutory directive to maintain the physician fee schedule by recognizing changes in practice patterns and by adjusting codes, relative values, and payment accordingly. We have routinely added new codes created by AMA CPT to the fee schedule. As we indicated in the proposed rule, our proposal was, in part, a response to work by the AMAs C3W to develop new codes for TCM services. Below we discuss the AMA's recommendation that we adopt the TCM codes developed by that workgroup in place of our proposed TCM G-code.

Comment: Most comments were generally supportive of the proposal to recognize and pay for TCM services. A few commenters merely expressed general support for the proposal. However, the great majority of these generally positive comments also recommended adopting the proposed TCM G code with revisions to the code description, or adopting the AMA's new CPT TCM codes in place of our proposed TCM G-code.

Response: We appreciate the widespread support for our initiative to recognize and pay for TCM services. As we discuss below, we are proceeding with our proposal in a modified form, adopting some of the commenters' specific recommendations for revision. Most importantly, we are accepting the recommendation of many commenters that we adopt the AMA's CPT TCM codes in place of our proposed TCM G-code. As discussed below, we will therefore pay for new CPT TCM codes 99495 and 99496 with some small modifications to the code descriptions developed by the AMA's C3W. The new TCM codes developed by the AMA C3W are:

- 99495 Transitional Care Management Services with 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.
  - ++ Face-to-face visit, within 14 calendar days of discharge.
- 99496 Transitional Care Management Services with 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.
  - ++ Face-to-face visit, within 7 calendar days of discharge.

We discuss these codes in greater detail and respond to these specific recommendations below.

Comment: Many commenters, including the AMA and other specialty societies, expressed appreciation for our initiative to propose a new G-code and language to describe TCM, but urged us instead to implement the new CPT TCM codes. Commenters emphasized that these codes represented the consensus of the physician community as represented by the AMA's C3W. Commenters also emphasized that the CPT TCM codes are very similar to our proposal, with a few key differences. We summarize the key differences between our proposed TCM G-code and the CPT TCM codes in Table 26.

TABLE 26—KEY DIFFERENCES BETWEEN PROPOSED TRANSITIONAL CARE MANAGEMENT (TCM) G-CODE AND THE CPT CODES

	CMS Proposed TCM G-code	CPT TCM codes
Code(s)	GXXX1—Post-discharge transitional care management (medical decision making of moderate to high complexity).	99490X—Transitional care management services (medical decision making of moderate complexity), *and* 99491X—Transitional care management services (decision making of high complexity).
Face-to-face visit	Separately billed face-to-face E/M visit within 30 days prior to the hospital discharge or within the first 14 days of the 30-day period of TCM services.	Face-to-face visit within 14 calendar days of discharge (99490X), or within 7 calendar days (99491X). The first face-to-face visit is part of the TCM service and not reported separately. E/M services after the first face-to-face visit may be reported separately.
Relationship with patient	The patient may be new to the physician's practice (provided the face-to-face visit requirements above are met).	The reporting physician or NPP must have an established relationship with the patient. Established patient means a visit in the past 3 years.
Discharge management	The physician or NPP who bills for discharge management services during the time period covered by TCM services may not also bill for GXXX1.	A physician or NPP may report both the discharge code and appropriate TCM code.

TABLE 26—KEY DIFFERENCES BETWEEN PROPOSED TRANSITIONAL CARE MANAGEMENT (TCM) G-CODE AND THE CPT CODES—Continued

	CMS Proposed TCM G-code	CPT TCM codes
Global services	The physician who reports a service with a global period of 010 or 090 days may not also report the TCM service.	The physician who reports a service with a global period of 010 or 090 days may not also report the TCM service. However, the AMA recommends that specialties work on a CPT proposal for a new code to describe extensive post-discharge TCM services.

A few commenters from the medical community did not specifically recommend adopting the CPT TCM codes. For example, one major medical society supported our proposal on the grounds, among other considerations, that it was consistent with the ''general direction of organized medicine, as evidenced by the fact that the AMA's CPT Editorial Panel has created two new codes for transitional care management.'' This commenter then expressed support for several of the several elements in our proposed G code which differ from the CPT TCM codes, such as our ''proposal to keep the required post-discharge face-to-face E/M separately reportable.'' (We discuss this issue in further detail later in this section.)

Response: We agree with those commenters who recommended that we should acknowledge the physician community's work on primary care by adopting the CPT TCM codes in place of our proposed G-code. With regard to the differences noted above, we agree with the AMA's CPT construction that uses two separate codes to distinguish moderate and high complexity services in place of our single proposed G-code, which allowed for reporting services of either moderate or high complexity. We discuss the issues connected with the other differences between our proposed TCM G-code and the AMA's CPT TCM codes in responses to more specific comments of the AMA and others below.

We explicitly constructed this proposal as a payment for non-face-to-face post-discharge TCM services separate from payment for E/M or other medical visits. However, we believe that it is important to ensure that the community physician or qualified nonphysician practitioner furnishing post-discharge TCM services either already have or establish, soon after discharge, a relationship with the beneficiary. As such, we proposed that the community physician or qualified nonphysician practitioner reporting post-discharge TCM GXXX1 should already have a relationship with the beneficiary, or establish one soon after discharge, prior to furnishing TCM and billing this code. Therefore, we specifically proposed that the community physician or qualified nonphysician practitioner reporting a TCM G-code must have billed an E/M visit for that beneficiary within 30 days prior to the hospital discharge (the start of post-discharge TCM period), or must conduct an E/M office/outpatient visit (99201 to 99215) within the first 14 days of the 30-day post-discharge period of TCM services. In either case, the E/M visit would be separately billed under our G-code proposal. While we proposed that the post-discharge TCM code would not include a face-to-face visit, and that physicians or qualified nonphysician practitioners would bill and be paid for this care management service separately from a medical visit, we sought comments about whether we should require a face-to-face visit when billing for the post-discharge TCM service: That is, whether we should bundle a required visit into the reporting and payment for the TCM codes. We were also concerned about whether beneficiaries would understand their coinsurance liability for the post-discharge transitional care service when they did not visit the physician's or qualified nonphysician practitioner's office.

Comment: The AMA and many other commenters recommended that we should require a face-to-face visit within 7 to 14 days after discharge when billing for the post-discharge TCM service. Under the CPT TCM codes, the first face-to-face visit is part of the TCM service and not reported separately. Additional E/M services required for managing the beneficiary's clinical issues in addition to the required face-to-face visit may be reported separately. These commenters emphasized that requiring a face-to-face visit within 7 to 14 days of discharge will provide for a more successful transition from facility to community. Other commenters maintained that we should retain the requirement for a separately billable face-to-face E/M either within 30 days before or 14 days after discharge. These commenters emphasized that such a requirement acknowledges that an established relationship with the patient is needed to bill the new code, and the level of E/M service will not be the same for every patient. A few commenters specifically recommended that it was not necessary to adopt any such requirement for a face-to-face visit (whether separately billable or not) in the context of a service that is essentially non-face-to-face. Some emphasized that it could be inefficient to require a visit that may not always be clinically necessary, and that the clinical decision about whether a visit is necessary should be left to the physician or qualified nonphysician practitioner. Other commenters emphasized that an office visit could be impractical in cases where patients may have limited mobility or otherwise have difficulty travelling to a physician office. Some of these commenters urged that we not adopt such a requirement, while others recommended that we expand the list of acceptable face-to-face visits to include other outpatient visit codes, such as home visits (99341–99350) and domiciliary/rest home visits (99324–99337). Still others stated that the window in which the post discharge visit must occur should be extended to 30 days post-discharge, not 14 days.

Response: The primary driver in creating these new CPT TCM codes has been to improve care coordination and to provide better incentives to ensure that these patients are seen in a physician's office, rather than be at risk for readmission. Therefore, we agree that care coordination beginning immediately upon discharge and the face-to-face visit within 7 or 14 days of discharge (as appropriate) will provide for a more successful transition from a facility to the community. However, as we indicated in the proposed rule, our adoption of codes for TCM services is part of the broader HHS and CMS multi-year strategy to recognize and support primary care and care management, and we are committed to considering new options and developing future proposals for payment of primary care services under the MPFS. Therefore, we consider the requirement for a face-to-face visit in

association with the non-face-to-face tasks of TCM to be a short-term, transitional strategy while we continue to explore our interest in further improvements to advanced primary care payment.

We also share the commenters' concerns about beneficiaries who may have limited mobility or otherwise have difficulty travelling to a physician office in the period following a discharge. We note that the final CPT TCM codes, 99495 and 99496, which we are adopting in this final rule with comment period, requires a face-to-face visit, but does not specify the location/setting for that portion of the service. The AMA RUC states in its recommendation that, ''each code includes a timely face-to-face visit which typically occurs in the office, but can also occur at home or other location where the patient resides.'' Finally, we agree with those commenters who stated that beneficiaries would understand their coinsurance liability better if the TCM services included a required E/M visit as part of the service.

We also sought comments regarding whether we should incorporate such a required visit on the same day into the payment for the proposed code. We considered several reasons for requiring a face-to-face visit on the same day as the date of discharge. We wondered whether, with a face-to-face visit immediately after discharge, the plan of care would be more accurate given that the patient's medical or psychosocial condition may have changed from the time the practitioner last met with the patient and the practitioner could better develop a plan of care through an in-person visit and discussion. On the other hand, we contemplated several scenarios where it is not possible for a beneficiary to get to the physician's or qualified nonphysician practitioner's office and welcomed comment on whether an exception process would be appropriate if we were to finalize a same day face-to-face visit as a requirement for billing the post-discharge TCM code.

Comment: Commenters were almost uniformly opposed to a requirement for a same day visit. The commenters believed that a same day visit is unrealistic and should not be required because hospital discharge records are not always immediately available to the physician who would be assuming responsibility for transitional care. Some commenters, including several who favor a face-to-face requirement other than a same day requirement, also favored an exception for beneficiaries too feeble to travel to an office. Other commenters maintained that a requirement for a face-to-face encounter with an exception process could prove confusing and administratively challenging as it would require communication of exceptions criteria and audit/appeals processes.

Response: In conjunction with adopting the AMA's recommendation to require a face-to-face visit within 7 or 14 days of discharge for reporting the CPT TCM codes, we have also decided not to proceed with a requirement for a same day face-to-face visit. We agree with commenters who stated that such a requirement would be unrealistic in many situations, and would require the adoption of an exceptions process that could, unto itself, prove administratively difficult and confusing. At the same time, we emphasize that we believe physicians should seek to make an assessment and conduct the face-to-face visit as quickly as medically necessary after discharge in order to address patient care needs.

Comment: As we noted above, we proposed to require communication (direct contact, telephone, electronic) with the patient or caregiver within 2 business days of discharge. Some commenters stated that the specific requirement for the physician to communicate with the patient within 2 business days of discharge to begin the coordination of care is unrealistic. Some contended that hospital discharge records are not always available that quickly. Several other commenters expressed concern about the references to ''business days'' in this requirement. (Other requirements, for length of TCM service and the timing of the required E/M visit are established in terms of calendar days for purposes of the TCM codes.) The commenters noted that, traditionally, business days are Monday through Friday, except for holidays. However, many primary care practices are also open on weekends, making those ''business days'' for those practices. Most importantly, beneficiaries' need for medical care and care coordination is not limited to ''business days,'' nor are their discharges. Thus, the commenters recommended that CMS change ''business days'' to ''calendar days'' in this context, which, they asserted, would be consistent with CMS's proposal to define the code as a 30 calendar day service. The AMA CPT TCM codes incorporate a requirement for an interactive contact with the patient or caregiver, as appropriate, within 2 business days of discharge. This contact may be direct (face-to-face), telephonic, or by electronic means. The AMA CPT TCM codes also specify that, for purposes of this requirement, business days are Monday through Friday, except holidays, without respect to normal practice hours or date of notification of discharge. If two or more separate attempts are made in a timely manner, but are unsuccessful and other TCM criteria are met, the service may be reported. We emphasize, however, that we expect attempts to communicate to continue until they are successful.

Response: Our proposed TCM G-code contained a requirement for communication with the patient or caretaker within 2 business days of discharge. We also agree with the AMA's assessment concerning the importance of such a requirement to meeting the goals of successful TCM. We also agree with the AMA's provision to allow for billing of the TCM service if two or more separate, unsuccessful attempts at communication are made within a timely fashion. We believe that this provision should substantially reduce the concerns of some commenters about the tight timeline for making this initial contact. We also believe that concerns about the availability of hospital discharge records should decline dramatically as both hospitals and physicians respond to the current incentive payments (and the payment reductions beginning in 2015) to encourage adoption of electronic health records systems. We cannot agree with those commenters who suggested that we should substitute ''calendar days'' for ''business days'' in this requirement. We do not believe that the timeframe for this requirement needs to be expressed in calendar days to be consistent with the 30 calendar day timeframe for the service. More importantly, establishing a timeframe of 2 calendar days for this initial contact would severely disadvantage those practices which do not have regular business hours on the weekends.

Comment: In our proposed G-code, we required that physicians or qualified nonphysician practitioners must have had a face-to-face E/M visit with the beneficiary in the 30 days prior to the transition in care or within 14 business days following the transition in care. However, we allowed that, if the physician or qualified nonphysician practitioner met this requirement, the patient could otherwise be new to the practice. The AMA recommended that the physician reporting the CPT TCM codes must have an established relationship with the patient, as required for the those codes, rather than allowing physicians to bill for TCM services furnished to patients who are new to their practices. Under CPT TCM definitions, an established relationship with a patient exists when a physician has billed a visit with the patient within

the last three years. Many commenters maintained that a visit within 30 days prior to the discharge was largely irrelevant to the actual provision of TCM services. Other commenters maintained that defining a pre-existing relationship as a visit within 30 days prior to the discharge is far too restrictive. A patient with established disease may only be seen by a physician every 3 to 6 months. We should therefore allow an E/M service to be furnished any time in the 12 months prior to the discharge to be considered evidence of an established relationship.

Response: We agree with commenters that a visit within 30 days before the hospital discharge might be too restrictive for purposes of establishing an existing relationship with a patient. We are therefore accepting the AMA's recommendation not to include such a requirement in the CPT TCM codes and note that the CPT TCM codes also do not require a visit within 30 days before discharge. Rather, as the AMA has recommended, we will include a requirement for a face-to-face visit with the beneficiary within 14 days (in the case of CPT code 99495) or 7 days (in the case of CPT code 99495. This required visit is bundled into the payment for the codes and is not separately payable. We do not entirely agree with the AMA's recommendation that the physician must have an established relationship prior to the discharge with the patient to report the CPT TCM codes. We are concerned that such a requirement would make it impossible for an especially vulnerable group of patients, specifically, those who do not have an established a relationship with a primary care or other community physician, to receive the benefit of post-discharge TCM services. These patients may well be among those who would benefit most from these services, particularly because receiving TCM services could provide the opportunity for them to establish a continuing relationship with a physician who is able to assume overall management of their care. Therefore,, in conjunction with our adoption of the CPT TCM codes, we will develop additional Medicare-specific guidance for the use of these codes that modifies this element of the CPT TCM prefatory instructions, to allow a physician to bill these codes for new patients (provided that the physician meets visit requirement and all other requirements for the CPT TCM codes). It is important to note, however, that the payment amount for the CPT TCM codes will be the same whether the codes are billed under Medicare for treating new or established patients under the TCM codes. For Medicare purposes we are modifying the prefatory instructions for the CPT TCM codes because we wish to encourage the provision of TCM services to those beneficiaries who can benefit from the services—whether the beneficiary is a new or established patient. However, we believe that the typical case will involve provision of TCM services to an established patient, and relative values for codes are established on the basis of the typical case. Physicians may choose to bill other appropriate codes (for example, new patient E/M codes) that better describe the services furnished.

Comment: We proposed that a physician or qualified nonphysician practitioner who bills for discharge day management during the time period covered by the TCM services code may not also bill for HCPCS code GXXX1. The CPT discharge day management codes are 99217, 99234–99236, 99238–99239, 99281–99285, or 99315–99316. The AMA/RUC and many other commenters recommended that a physician reporting the discharge management should also be able to report the new TCM service. The AMA/RUC and other commenters noted an AMA data analysis that nearly 25 percent of those visits reported within 14 days of discharge were from the physician who also furnished the discharge services. The commenters emphasized that discharge management services reflect the work done at the time of discharge. The TCM service describes the work following discharge. Therefore, the commenters contended that there should be minimal or no overlap in the actual work performed in providing these two services. Other commenters emphasized that the physician or group practice billing for discharge day management could also be the physician or group practice regularly responsible for the patient's primary care and would therefore be the appropriate physician to take responsibility for the patient's transition to the community.

Response: We accept the AMA/RUC's recommendation (as supported by a number of commenters) to allow a physician to report both the discharge management code and a CPT TCM code. We agree with those commenters who emphasized that the physician billing discharge day management could also be the physician who is regularly responsible for the beneficiary's primary care (this may be especially the case in rural communities), and who would therefore be the appropriate physician to take responsibility for the patient's transition to the community. However, we continue to be concerned that there could be some overlap in the actual work involved in providing these two services and, that payment to one physician for both of these services might be excessive as a result. Therefore, we will monitor claims data to ascertain the extent to which the same physician bills for both the discharge day management and TCM services and analyze whether it may be appropriate to develop a payment adjustment that recognizes overlap in resources in the future.

In addition, we note that the CPT TCM code prefatory language provides that the TCM service period ''commences upon the date of discharge and continues for the next 29 days.'' Subsequent CPT TCM language indicates that the first visit must occur within 7 or 14 calendar days of the date of discharge depending on the level of decision-making. We are unclear as to whether the CPT TCM prefatory language intends to allow the first visit to occur on the same date as discharge. We note that there is a distinction between the discharge day management and TCM services, and we wish to avoid any implication that the E/M services furnished on the day of discharge as part of the discharge management service could be considered to meet the requirement for the TCM service that the physician or nonphysician practitioner must conduct an E/M service within 7 or 14 days of discharge. Therefore, we will specify that the E/M service required for the CPT TCM codes cannot be furnished by the same physician or nonphysician practitioner on the same day as the discharge management service.

Comment: A number of commenters suggested that payment for the E/M hospital discharge management codes (CPT 99238 or 99239) is inadequate to reflect the discharging duties of the physician. While most of these commenters supported enhanced payment for community physicians to furnish care coordination services on the receiving end, they stated that a corresponding increase in payment to those physicians who are discharging patients is also warranted.

Response: We continue to believe that the current hospital discharge management codes (CPT codes 99238 and 99239) and nursing facility discharge services (CPT codes 99315 and 99316) adequately capture the care coordination services required to discharge a beneficiary from hospital or skilled nursing facility care. The work relative values for those discharge management services include a number of pre-, post-, and intra-care

coordination activities. For example, the hospital discharge management codes include the following pre-, intra-, and post- service activities relating to care coordination:

Pre-service care coordination activities include:

- Communicate with other professionals and with patient or patient's family.

Intra-service care coordination activities include:

- Discuss aftercare treatment with the patient, family and other healthcare professionals;
- Provide care coordination for the transition including instructions for aftercare to caregivers;
- Order/arrange for post discharge follow-up professional services and testing; and
- Inform the primary care or referring physician or qualified nonphysician practitioner of discharge plans.

Post-service care coordination activities include:

- Provide necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this hospitalization; and
- Revise treatment plan(s) and communicate with patient and/or caregiver, as necessary.

The hospital and nursing facility discharge management codes also include a number of other pre-, intra and post-service activities.

We certainly recognize that the services of physicians and other practitioners providing discharge management services are crucial to the overall success of TCM services. These codes have been valued by the AMA/RUC in the past, and these valuations have been reviewed and accepted by us. At this time, we are not aware of any substantive evidence that these codes are systematically undervalued.

Comment: We proposed that a physician or qualified nonphysician practitioner who bills for emergency department visits (99281–99285), home health care plan oversight services (HCPCS code G0181), or hospice care plan oversight services (HCPCS code G0182) during the time period covered by the TCM services code may not also bill for HCPCS code GXXX1. We indicated that we believed these codes describe care management services for which Medicare makes separate payment and should not be billed in conjunction with GXXX1, which is a comprehensive post-discharge TCM service. The AMA noted that for the proposed TCM G-code we would not allow TCM services to be reported with emergency department visits, home health care oversight (G0181), hospice care plan oversight (G0182). The AMA CPT TCM codes allow for reporting of emergency department visits. The AMA also indicated that a physician or other qualified health care professional who reports a TCM code may not report the CPT codes for care plan oversight services (99339, 99340, 99374–99380). At the same time, the CPT TCM codes also specify that many other codes may not be reported with TCM (for example, non-face-to-face services such as telephone calls).

Response: In conjunction with adopting the AMA CPT TCM, we accept the recommendation to allow reporting of emergency department visits when also billing the CPT TCM codes. We also agree with the recommendation not to allow reporting of care plan oversight services when also billing the CPT TCM codes. We had proposed to prohibit billing of the G-codes that we employ for home health care oversight (G0181), and hospice care plan oversight (G0182) with our proposed TCM G-code, on the grounds that such care management services duplicate the services provide in TCM. We are including these G-codes in the list of codes for such services that are precluded from billing with the CPT TCM codes, because we continue to believe that they are duplicative of the CPT care plan management aspects of the CPT TCM codes. We will also accept the AMA recommendation specifying many additional codes that may not be reported with CPT TCM codes (for example, non-face-to-face services such as telephone calls), as specified in the descriptions of CPT TCM codes 99495 or 99496 below. We are accepting these recommendations because they similarly avoid duplicate payment for the same services.

Further, we proposed that a physician or qualified nonphysician practitioner billing for a procedure with a 10- or 90-day global period would not also be permitted to bill HCPCS code GXXX1 in conjunction with that procedure because any follow-up care management would be included in the post-operative portion of the global period.

Comment: Many commenters expressed concerns with prohibiting physicians who bill services with a global period from billing the TCM code as well. One commenter stated that ''permitting a surgeon to receive payment under these circumstances would not result in duplicate payment for the same service * * * [I]f follow-up care management included in the post-operative portion of a global period can be reimbursed separately from the proposed transitional care management code when performed by two different physicians, they should remain separately reimbursable when these functions are all performed by the same physician.'' One commenter specifically agreed with our proposal to prohibit the billing of TCM by a physician providing the original care within a 010 or 090 day global period code. The AMA CPT TCM codes do not allow physicians billing services with global periods of 010 and 090 days to bill for TCM services. However, the AMA RUC recommends that specialties work with the CPT Editorial Panel to develop a new code for those cases in which comprehensive TCM services are furnished along with the services already bundled into the global codes. However, the AMA RUC also indicates that it would not be typical for a surgeon to furnish TCM services.

Response: We agree with the commenters that the physician who reports a global procedure should not be permitted to also report the TCM service, and we are adopting that policy in this final rule. The AMA RUC specifically states in its comment letter that it would not be typical for surgeons billing global procedures to also provide TCM services. Our goal is that the physician billing for TCM services should have an ongoing relationship with the beneficiary. We do not believe surgeons typically would be in a position to coordinate all aspects of a patient's care, because their relationship with a beneficiary frequently ends after the end of the global period (unless or until additional surgery is required).

We proposed that the TCM code would be payable only once in the 30 days following a discharge, per patient per discharge, to a single community physician or qualified nonphysician practitioner (or group practice) who assumes responsibility for the patient's post-discharge TCM. We expressed our belief that, given the elements of the TCM service and the short time period during which they must be furnished, it would be unlikely that two or more physicians would meet the requirements for billing the TCM code.

Comment: Many commenters requested clarification concerning whether the TCM codes could be billed again if another hospital admission and discharge occur within the initial 30 day period following a discharge. The commenters recommended that we allow the clock to start over with each admission, that is, allow for payment of TCM even when readmission occurs within the original 30 day period after a discharge. A few commenters recommended that CMS develop a mechanism to monitor readmissions for patients receiving TCM services to

determine if this effort positively impacts beneficiary outcomes and decreases the burden on the healthcare system. The mechanism would require physician reporting at the beginning and end of the care period, and may require a ''start'' and a ''stop'' modifier to the new G-code. A few commenters specifically supported the ''only once within 30 days of discharge'' policy. The AMA's C3W stipulated that the CPT TCM codes may be reported ''* * * only once per patient within 30 days of discharge. Another CPT TCM code may not be reported by the same individual or group for any subsequent discharge(s) within the 30 days.''

Response: In adopting the CPT TCM codes, we believe it is appropriate to maintain the limitation that the codes can be billed only once per patient within 30 days of discharge, which is consistent with the policy we proposed for our TCM G-code. Preventing unnecessary hospital readmissions in the period shortly after a discharge is an important goal and part of the reason we proposed improved recognition and payment of TCM services (as well as other initiatives within the Medicare program). We believe that it would be at least inconsistent with this goal, and perhaps even counterproductive to it, to allow for another TCM code to be billed when a hospital discharge occurs within 30 days after the original discharge for which a TCM code has been billed. We appreciate the comments recommending that we monitor readmissions for patients receiving TCM services to determine if this effort positively impacts beneficiary outcomes and decreases the burden on the healthcare system. We will consider how to incorporate this into our existing initiatives that address these issues.

Comment: We proposed that the TCM G-code would be payable to a single community physician or nonphysician practitioner (or group practice) who assumes responsibility for the patient's post-discharge TCM. Many commenters recommended allowing more than one physician to bill a TCM code during the same 30-day period on the grounds that: ''Complex patients often have to follow-up with more than one provider after a discharge. Each of these providers could be performing care coordination and should be compensated accordingly.'' The CPT TCM codes allow for only one individual to report these services and only once per patient within 30 days of discharge.

Response: We disagree that more than one physician should be allowed to bill the TCM codes during a single 30 day period after a discharge. Coordination of care intrinsically involves developing and implementing a single plan of care for a patient. Allowing multiple physicians to furnish this service simultaneously would introduce the danger that an individual patient might be subjected to inconsistent or even contradictory plans of care. In other words, allowing more than one physician to bill TCM codes simultaneously could lead to uncoordinated rather than coordinated post-discharge care. We will therefore follow the CPT TCM code rule that these services may be billed by only one individual during the 30 day period after discharge.

Comment: Other commenters recommended further restricting and/or raising the bar for billing TCM codes. Many objected to our proposal to pay the first physician or qualified nonphysician practitioner who submitted a claim because, they asserted, it would lead to an uncoordinated, sub-optimal ''race to bill.'' One of these commenters expressed concern that practitioners' offices would have to compete with each other to submit the bill first. In addition, this commenter was concerned that practitioners' offices would not be able to track whether or not they are the first to submit a claim and could get paid for the service. MedPAC noted that the first physician or nonphysician practitioner to submit a claim may not be providing the bulk of the TCM services, and recommended raising the bar to ensure payment goes to physicians actually providing comprehensive primary care to the beneficiary by requiring that the billing provider must have billed for an E&M visit (that is, a face-to-face visit) that took place within the 30 days prior to admission and within the 14 days following discharge. Another commenter recommended that we adopt a multi-stage process of screening claims to identify the beneficiary's primary care physician, who then would be the only physician permitted to bill a TCM code. The commenter noted that we referred to the community-based physician as the one who would manage and coordinate a beneficiary's care in the post-discharge period, and we anticipated that most community physicians will be primary care physicians and practitioners. The commenter also stated: ''It is thus perplexing that CMS did not propose to restrict the use of this code to actual primary care physicians.'' Others recommended employing a ''plurality of services'' determination in case more than one physician and/or nonphysician practitioner bills TCM after the same discharge. One commenter recommended that we should require beneficiaries to prospectively identify their primary care provider.

Response Any physician who is appropriately enrolled in Medicare and furnishes the service may bill for that service. We continue to expect that most community physicians who are furnishing TCM services will be primary care physicians and practitioners. However, we also believe that there will be circumstances in which cardiologists, oncologists, or other specialists will be in the best position to furnish transitional care coordination after a hospital discharge. Furthermore, we believe that the requirements for physicians or qualified nonphysician practitioners to furnish multiple specific services for the beneficiary within a restricted period of time will limit the circumstances under which more than one practitioner might be able to bill the TCM codes. We appreciate MedPAC's suggestion that we require that the billing provider must have billed for an E/M visit (that is, a face-to-face visit) that took place within the 30 days prior to admission and within the 14 days following discharge. However we are concerned that adopting such a policy would actually have the unintended consequence of prohibiting many physicians with well-established relationships and a history of providing comprehensive care for their beneficiaries from reporting the TCM service for these same patients, simply because an office visit may not have occurred within 30 days prior to a, possibly even unanticipated, hospitalization. After considering all these comments, we continue to believe that it is not necessary to develop any further restrictions or complex operational mechanisms to identify one and only one physician or nonphysician practitioner who may bill the codes for a specific beneficiary. We have used such a ''first claim'' policy in other areas, such as a radiology interpretation and the Annual Wellness Visit. However, we would expect the discharging physician to support TCM services by discussing post-discharge services with the beneficiary (which is an element in the discharge day management vignette), and to identify a community physician for follow-up whenever possible. Specifically, we expect discharging physicians and other physicians seeing beneficiaries in a facility to inform the beneficiaries that they should receive TCM services from their doctor or other practitioner after their discharge, and that Medicare will pay for those services. As a part of this

disclosure to patients, we also expect that the discharging physician would ask the beneficiary to identify the physician or nonphysician practitioner whom he or she wishes to furnish these transitional care management services. If the beneficiary does not have a preference for the physician who would furnish these services, the discharging physician may suggest a specific physician who might be in the best position to furnish the TCM services. The recording of this information could also help in the transitional care coordination activities. We believe that it could be helpful for the physician providing discharge day management services to record the community physician who would be providing TCM services in the discharge medical record and the discharge instructions for patients. We note that recent literature highlights the importance of these patient-centered communication activities for effective transitional care management.[1] As we further consider how Advanced Primary Care practices can fit with a fee-for-service model, we also will actively consider methodologies that could allow Medicare to identify the beneficiary's community/primary care physician.

Comment: Many commenters endorsed our proposal not to restrict billing of this proposed TCM code to primary care physicians. Other commenters requested that we confirm that specialists can bill the new code if they meet the service requirements of comprehensive TCM services. Other commenters similarly requested confirmation that they can bill the TCM code if they meet the requirements. Some commenters from health care professions other than physicians, NPs, PAs, CNSs, and CNMs similarly requested that they be permitted to bill the CPT TCM codes and receive payment for these services.

Response: We appreciate these comments and take this opportunity to confirm that, while we expect the TCM codes to be billed most frequently by primary care physicians, specialists who furnish the requisite services in the code descriptions may also bill the new TCM codes. As for nonphysician qualified health care professionals, we believe only NPs, PAs, CNSs, and certified nurse midwives (CNMs) can furnish the full range of E/M services and complete medical management of a patient under their Medicare benefit to the limit of their state scope of practice. Other nonphysician practitioners (such as registered dieticians, nutrition professionals or clinical social workers) or limited-license practitioners, (such as optometrists, podiatrists, doctors of dental surgery or dental medicine), are limited by the scope of their state licensing or their statutory Medicare benefit to furnish comprehensive medical evaluation and management services, and there is no Medicare benefit category that allows explicit payment to some of the other health professionals (such as pharmacists and care coordinators) seeking to bill TCM services. Accordingly, we will not adopt the requests of other health care professionals to bill the CPT TCM codes because these services go beyond the statutory benefit and state scope of practice for the requesting practitioners. As already discussed, we consider the separate coding and payment for these TCM services to be a short-term initiative as we further consider alternatives to ensure that any payment for primary care services would constitute a minimum level of care coordination, such as payments in a FFS setting.

Comment: Several commenters requested that we extend recognition of care coordination to RHC physicians and providers as well or at least clarify whether providers practicing in rural health clinics may utilize the new HCPCS G-code.

Response: While we recognize that RHCs have an important role in furnishing care in their communities, RHCs are paid an all-inclusive rate per visit. Since RHCs are not paid under the PFS, physicians and other RHC providers whose services are paid within the RHC all-inclusive rate cannot bill using the CPT TCM codes for services furnished in the RHC. However, an RHC physician or other qualified provider who has a separate fee-for-service practice when not working at the RHC may bill the CPT TCM codes, subject to the other existing requirements for billing under the MPFS.

Comment: We also proposed that the TCM G-code would be ''billable only at 30 days post discharge or thereafter.'' Although we proposed that the billing for TCM services would occur, as it does for most services, after the conclusion of the service that is, only at 30 days post discharge or thereafter), we welcomed comment on whether, in this case, there would be merit to allowing billing for the code to occur at the time the plan of care is established. Many commenters recommended that billing of TCM services should occur (as proposed) at the end of the 30-day TCM period. A smaller number of commenters recommended that it should be allowed to occur at the time the plan of care is established. One commenter observed that billing for the post-transitional service at the time the plan of care is established may help prevent a ''race to the billing office'' by various providers, as the appropriate provider coordinating the post-transitional care would be well-established among the various medical providers involved in the patient's care. The CPT TCM code prefatory language provides: ''Only one individual may report these services and only once per patient *within* 30 days of discharge.'' (Emphasis supplied.)

Response: We continue to believe that the billing for TCM services under the PFS should occur, as it does for most fee schedule services, after the conclusion of the service (that is, only at 30 days post discharge or thereafter). Allowing for billing at the time the plan of care is established, or at any other time prior to the end of the 30-day period, would pose serious administrative problems. For example, adopting any policy other than billing at the end of the 30-day service period would make it difficult to monitor the CPT TCM requirement that the code be billed only once in the 30-day period beginning with the discharge. It would also be very challenging to monitor our policy that subsequent hospital admissions during that period will not begin a new 30-day period and allow reporting of another TCM service. We will provide guidance to physicians and qualified NPPs regarding the billing of the CPT TCM codes, which will occur at the conclusion of the period for providing TCM services, 30 days post discharge. We appreciate the concern about preventing a situation where two physicians may rush to bill for TCM services. However, as we have previously discussed, we believe it would be quite unlikely that more than one physician or nonphysician practitioner will be able simultaneously to satisfy the numerous and complex requirements for billing the CPT TCM codes.

Comment: Some commenters were concerned about the large number of activities that are required to furnish the TCM service. The commenters emphasized that many of the activities listed could require a lengthy discussion or actions that need to be undertaken with the patient that would far exceed that allowable time. Some commenters stated that the specific requirement that the physician communicate with the patient within 2 business days of discharge to begin the coordination of care is unrealistic because hospital

[1] Hesselink MA, Schoonhoven L, Barach P et al. Improving patient handovers from hospital to primary care. *Annals of Internal Medicine* 2012; 157: 417–428.

discharge records are not always available that quickly. Other commenters pointed to the requirement for an assessment of the patient's psychosocial needs as potentially an excessively burdensome requirement. One commenter asked us to reconsider the requirement that these codes only cover patients of moderate to high complexity on the grounds that most admissions are relatively straightforward and patients do not require moderate to complex decision making but that these less complex patients still require TCM services. On the other hand, some commenters recommended additions to the services already listed, such as the addition of communication between the accepting primary care/community physician and the discharging inpatient physician.

Response: We agree with the commenters that a large number of activities are required to report the TCM codes. However, we believe that these requirements are entirely appropriate. As we have noted before, TCM services require management and coordination of all relevant aspects of a beneficiary's health status in the post-discharge period. And as a number of commenters maintained, physicians should not undertake TCM services unless they are capable and willing to assume comprehensive responsibility for a patient's care during the period of the service. In the light of these considerations, we believe the lengthy list of services required by our proposed G-code, and largely paralleled in the AMA's CPT TCM codes that we are adopting in this final rule, is quite appropriate to the nature of the service. With regard to the specific requirement for assessment of psychosocial needs, we note again for example that depression in older adults occurs in a complex psychosocial and medical context and opportunities are often missed to improve behavioral health and general medical outcomes when mental disorders are under-recognized and undertreated in primary care settings. We believe that it is therefore important to emphasize the equal importance of the beneficiary's mental health and his or her physical condition to successful discharge into the community. We believe that AMA has confirmed our assessment by requiring those reporting the CPT TCM codes to oversee the ''management and coordination of services, as needed, for all medical conditions, psychosocial needs and activity of daily living supports * * *'' The AMA has also confirmed our assessment that patients typically require complex and multidisciplinary care modalities in the post-discharge period by establishing a requirement of moderate to high complexity for reporting the CPT TCM codes. We do not believe that it is necessary to add a formal requirement for communication between the accepting primary care/community physician and the discharging inpatient physician. The accepting community physician is responsible for reviewing the discharge summary, and the community physician can decide whether standard clinical practice indicates the need for further communication with the discharging physician. However, as indicated above, we note our expectation that the discharging physician will communicate with the community physician as necessary as part of billing for discharge day management services.

Comment: Some commenters recommended that we create disease specific TCM codes for major chronic conditions (for example, Alzheimer's, diabetes, HIV, cancer survivors planning services, etc.) or for special services (for example, comprehensive medication management services). The commenters were concerned that, otherwise, many cognitive specialists and other practitioners would not be able to bill the proposed TCM G-code.

Response: With regard to treatment of the chronic conditions mentioned by commenters, both our proposed TCM G-code and the CPT TCM codes we are adopting in this final rule are defined broadly enough to incorporate the TCM activities involved in the treatment of patients with such diseases in the period after discharge. In addition, as we discuss below, we will be considering adoption of the complex care coordination codes developed by the AMA as we continue to explore payment for primary care services in future rulemaking. With regard to the TCM codes, we indicated in the proposed rule that we proposed the TCM G-code to recognize the services related to TCM by a community physician or qualified nonphysician practitioner. We used the term community physician and practitioner to refer to the community-based physician managing and coordinating a beneficiary's care in the post-discharge period. We also indicated that we anticipated that most community physicians would be primary care physicians and practitioners. This is because the nature of the services involved in TCM (for example, communication with patient and family education to support self-management, independent living, and activities of daily living, assessment and support for treatment regimen adherence and medication management, etc.) are characteristic of primary care services as such services are usually understood. At the same time, neither the TCM G-code we proposed, nor the CPT TCM codes we are adopting in this final rule, preclude cognitive or other specialists from reporting these codes when they are appropriately furnishing the required primary care services of TCM. We certainly want to encourage cognitive and other specialists to assume responsibility for the comprehensive care of patients contemplated in the requirements of the CPT TCM codes when they are in the position to do so during the post-discharge period.

Comment: A few commenters recommended that there should be special TCM G-codes for psychologists and others who are not permitted to bill E/M codes.

Response: The TCM service includes ''the management and/or coordination of services, as needed, for all medical conditions, psychosocial needs and activities of daily living.'' For reasons we have discussed at length above, the services described in the CPT E/M codes are intrinsic to furnishing the TCM service. It was for this reason that the AMA decided to include a post-discharge, face to face E/M service as a requirement for reporting the CPT TCM codes. We have had a longstanding restriction on the use of E/M codes by clinical psychologists. As we have explained in previous rulemaking (62 FR 59057), the evaluation and management services included in the codes that psychologists cannot bill are services involving *medical* evaluation and management. Psychologists are not licensed to perform these types of services. Therefore, we do not believe it would be appropriate to provide a special TCM G-code for these practitioners. However, we would expect the community physicians and qualified nonphysician practitioners to refer patients to psychologists and other mental health professionals as part of the TCM service when doing so is warranted by evaluation of patients' psychosocial needs in the period after discharge. As indicated above, we believe the only nonphysician practitioners who may furnish the full range of E/M services and complete medical management of a patient under their Medicare benefit are NPs, PAs, CNSs, and CNMs, unless they are otherwise limited by their state scope of practice. Other nonphysician practitioners or limited-license practitioners, (such as optometrists, podiatrists, doctors of dental surgery or

dental medicine), are limited by the scope of their state licensing or their Medicare benefit from furnishing comprehensive medical evaluation and management services. As already discussed, we consider these TCM services to be a short-term initiative as we further consider alternatives to target payment for primary care services.

Comment: Some commenters cited our statement that the proposed TCM G-code may be used ''[d]uring transitions in care from hospital (inpatient stay, outpatient observation, and partial hospitalization), SNF stay, or CMHC settings to community-based care.'' The commenters stated that this statement seems to avoid the reality that in many instances the transition from a hospital to a facility such as a SNF is, for all intents and purposes, the transition back to the community for many patients.

Response: Individuals in SNFs are considered inpatients, and therefore the TCM codes may not be billed when patients are discharged to a SNF. For patients in SNFs there are E/M codes for initial, subsequent, discharge care, and the visit for the annual facility assessment, specifically CPT codes 99304–99318. These codes may be billed for SNF beneficiaries for the care management services they receive in the period after discharge from an acute care hospital. And then when SNF patients are discharged from the SNF to the community or to a nursing facility (even when the SNF and nursing facility are part of the same entity or located in the same building), the physician or practitioner who furnishes transitional care management services can use the CPT TCM codes to bill for those services. As such, we believe there will be appropriate payment for transitional care management services furnished following each transition of care from acute inpatient, to SNF, to the community or nursing facility setting.

After considering all these comments, and for the reasons stated above we are adopting the CPT TCM codes subject to the modifications described in our responses to comments on the issues discussed above. In summary, these specific modifications are: Our decision not to restrict the billing of the CPT TCM codes to established patients, our clarification of the post-discharge service period, and our prohibition against billing a discharge day management service on the same day that a required E/M visit is furnished under the CPT TCM codes for the same patient. We will provide guidance to contractors and revise the relevant manual provisions in order to implement these policies.

Below are the requirements of the CPT TCM codes as modified for Medicare purposes in this final rule.

- 99495 Transitional Care Management Services with 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.

++ Face-to-face visit, within 14 calendar days of discharge.

- 99496 Transitional Care Management Services with 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.

++ Face-to-face visit, within 7 calendar days of discharge.

CPT codes 99495 and 99496 are used to report transitional care management services. These services are for a 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 skilled nursing facility/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 time frames, 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. It is our expectation that the services in the two lists of non-face-to-face services below will be routinely provided as part of transitional care management service unless the practitioner's reasonable assessment of the patient indicates that a particular service is not medically indicated or needed.

Non-face-to-face services provided by clinical staff, under the direction of the physician or other qualified health care professional, may include:

- Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge.
- Communication with home health agencies and other community services utilized by the patient.
- Patient and/or family/caretaker education to support self-management, independent living, and activities of daily living.
- Assessment and support for treatment regimen adherence and medication management.
- Identification of available community and health resources.
- Facilitating access to care and services needed by the patient and/or family.

Non-face-to-face services provided by the physician or other qualified health care provider may include:

- Obtaining and reviewing the discharge information (for example, discharge summary, as available, or continuity of care documents).
- Reviewing need for or follow-up on pending diagnostic tests and treatments.
- Interaction with other qualified health care professionals who will assume or reassume care of the patient's system-specific problems.
- Education of patient, family, guardian, and/or caregiver.
- Establishment or reestablishment of referrals and arranging for needed community resources.
- Assistance in scheduling any required follow-up with community providers and services.

Transitional care management requires a face-to-face visit, initial patient contact, and medication reconciliation within specified time frames. The first face-to-face visit is part of the transitional care management service and not reported separately. Additional E/M services after the first face-to-face visit may be reported separately. Transitional care management requires an interactive contact with the patient or caregiver, as appropriate, within 2 business days of discharge. The contact may be direct (face-to-face), telephonic, or by electronic means. telephonic, or by electronic means. Medication reconciliation and management must occur no later than the date of the face-to-face visit.

Medical decision making and the date of the first face-to-face visit are used to select and report the appropriate transitional care management code. For 99496, the face-to-face visit must occur within 7 calendar days of the date discharge and medical decision making must be of high complexity. For 99495, the face-to-face visit must occur within 14 calendar days of the date of discharge and medical decision making must be of at least moderate complexity.

Medical decision making is defined by the E/M Services Guidelines. The medical decision making over the service period reported is used to define the medical decision making of transitional care management. Documentation includes the timing of the initial post discharge communication with the patient or caregivers, date of the face-to-face visit, and the complexity of medical decision making.

(The E/M Services Guidelines define levels of medical decision making on the basis of the following factors:

- The number of possible diagnoses and/or the number of management options that must be considered;
- The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed, and analyzed; and
- The risk of significant complications, morbidity, and/or mortality as well as comorbidities associated with the patient's presenting problem(s), the diagnostic procedure(s), and/or the possible management options.

Medical decision making of moderate complexity requires multiple possible diagnoses and/or the management options, moderate complexity of the medical data (tests, etc.) to be reviewed, and moderate risk of significant complications, morbidity, and/or mortality as well as comorbidities. Medical decision making of high complexity requires an extensive number of possible diagnoses and/or the management options, extensive complexity of the medical data (tests, etc.) to be reviewed, and a high risk of significant complications, morbidity, and/or mortality as well as comorbidities)

Only one individual may report these services and only once per patient within 30 days of discharge. Another transitional care management service may not be reported by the same individual or group for any subsequent discharge(s) within the 30 days. The same individual may report hospital or observation discharge services and transitional care management. The same individual should not report transitional care management services provided in the post-operative period for a service with a global period.

A physician or other qualified health care professional who reports codes 99495, 99496 may not report care plan oversight services (99339, 99340, 99374–99380), prolonged services without direct patient contact (99358, 99359), anticoagulant management (99363, 99364), medical team conferences (99366–99368), education and training (98960–98962, 99071, 99078), telephone services (98966–98968, 99441–99443), end stage renal disease services (90951–90970), online medical evaluation services (98969, 99444), preparation of special reports (99080), analysis of data (99090, 99091), complex chronic care coordination services (99481X–99483X), medication therapy management services (99605–99607), during the time period covered by the transitional care management services codes.

It is very important to emphasize that we consider the non-face-to-face services to be furnished by physicians, qualified health care professionals, and clinical staff to be intrinsic, indeed essential, components of the TCM codes. To support the non-face-to-face services, the TCM service requires a face-to-face visit, initial patient contact, and medication reconciliation within specified time frames. The first face-to-face visit is part of the TCM service and may not be reported separately. Additional reasonable and necessary E/M services required for managing the beneficiary's clinical issues in addition to the face-to-face visit may be reported separately.

Despite the importance of the face-to-face service that is a required element of the CPT TCM codes, the non-face-to-face services such as communication, referrals, education, identification of community resources, and medication management constitute the truly essential features that distinguish TCM from those services that are predominantly or exclusively face-to-face in nature.

We are adopting these new CPT TCM codes to provide a separate reporting mechanism for 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. Therefore, we plan to monitor the use of the transitional care management billing codes. We wish to emphasize again that the policies we are finalizing in this final rule 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. Because CPT TCM codes 99495 and 99496 are new codes, they will be valued and designated as interim final in this final rule with comment period and subject to public comment.

We would also note that this proposal coincides with our discussion under section III.J. of this final rule with comment period on the Value-based Payment Modifier and Physician Feedback Reporting Program which discusses hospital admission measures and a readmission measure as outcome measures for the proposed value-based payment modifier adjustment beginning in CY 2015.

c. Proposed Payment for Post-Discharge Transitional Care Management Service

To establish a physician work relative value unit (RVU) for the proposed post-discharge TCM, HCPCS code GXXX1, we compared GXXX1 with CPT code 99238 (Hospital discharge day management; 30 minutes or less) (work RVU = 1.28). We recognized that, unlike CPT code 99238, HCPCS code GXXX1 is not a face-to-face visit. However, we believed that the physician time and intensity involved in post-discharge community care management is most equivalent to CPT code 99238 which, like the proposed new G code, involves a significant number of care management services. Therefore, we proposed a work RVU of 1.28 for HCPCS code GXXX1 for CY 2013. We also proposed the following physician times: 8 minutes pre-evaluation; 20 minutes intra-service; and 10 minutes immediate post-service. In addition, we proposed to crosswalk the clinical labor inputs from CPT code 99214 (Level 4 established patient office or other outpatient visit) to proposed HCPCS code GXXX1. For malpractice expense, we proposed a malpractice crosswalk of CPT code 99214 for HCPCS code GXXX1 for CY 2013. We believe the malpractice risk factor for CPT code 99214 appropriately reflects the relative malpractice risk associated with furnishing HCPCS code GXXX1. In our proposal, we noted that, as with other services paid under the PFS, the 20 percent beneficiary coinsurance would apply to the post-discharge TCM service as would the Part B deductible.

Comment: Several commenters recommended that we await the recommendations of the RUC and accept the RUC RVU values, so that we can fully take into account feedback from practicing physicians of all specialties before finalizing values for these non-face-to-face, care management services. With regard to the proposed RVU for physician work, a few commenters noted that our source code for GXXX1 included only 30 minutes of work for the discharging physician for whom most of the information is more readily available and that that time understates the effort required of the receiving physician. The commenters urged us to consider the significant potential variability in time and effort for the receiving physician. Another commenter urged CMS to utilize the

work RVUs used for care plan oversight HCPCS codes G0181 and G0182 in valuing the new code.

With regard to PE, another commenter recommended that we assign clinical staff type RN/LPN only for the clinical staff work for the TCM codes because those are the only two clinical staff types who furnish clinical staff TCM activities. A commenter noted that this proposal largely ignores equipment costs (for example, computer, electronic health record, and telephone) that are essential to furnishing this service, and urged us to reconsider whether 1.41 is an appropriate practice expense RVU amount. Another commenter noted that our source code for practice expense, CPT code 99214, is for moderate complexity decision-making and that we should consider the greater costs associated with a patient of high complexity. One commenter agreed with our proposed malpractice value.

Response: We agree with commenters that any valuation under the PFS should benefit from as much public review and input as possible, including review by the AMA RUC. The AMA RUC conducted a multi-specialty survey of 110 physicians and recommended an RVU for each of the new CPT TCM codes. For CPT code 99495, the AMA RUC recommended the median survey work RVU of 2.11 with 40 minutes of intra-service time, and for CPT code 99496, the AMA RUC recommended the median work RVU of 3.05 with 60 minutes of intra-service time. For CPT code 99496, we disagree with the observed median intra-service time of 60 minutes. We believe that 50 minutes of intra-service time is a more appropriate intra-service time for CPT code 99496. We observe that the primary reference code for CPT code 99495, CPT code 99214, has 25 minutes of intra-service time. We conclude that the typical physician time engaging in additional non-face-to-face activities and overseeing clinical staff care management activities is the difference between the intra-service time for CPT code 99214 and median intra-service time for CPT code 99495, 15 minutes. We believe that 50 minutes of intra-service time is more appropriate for CPT codes 99496 because it adds the additional non-face-to-face care management time of 15 minutes, to the intra-service time for the primary reference CPT code 99496, which is CPT code 99215 with an intra-service time of 35 minutes.

We appreciate comments suggesting that we value our proposed G-code, GXXX1, comparable to CPT codes G0180 and G0181. However, because we not finalizing the proposed G-codes and instead are adopting the CPT TCM codes on an interim final basis in this final rule with comment period, we believe that the AMA RUC recommendation, which reflects the services we included in the proposed G-code as well as a face-to-face visit, is a more basis for appropriate valuation. In response to comments noting that the discharge day management source code, CPT code 99238, for GXXX1, does not contain sufficient time for the receiving physician and that the time does not reflect differences in the complexity of decision-making, we note that we are adopting AMA RUC recommended times as modified in the preceding paragraph on an interim final basis, with refinement, which include a longer time than the proposed time of 30 minutes, and those times are specific to the level of complexity. We also note that there is a significant amount of clinical labor time incorporated in the practice expense calculation for these codes. In summary, we are assigning a work RVU of 2.11 to CPT TCM code 99495 with intra-service time of 40 minutes, and a work RVU of 3.05 with intra-service time of 50 minutes. The work RVUs included in Addendum B to this final rule with comment period reflect these interim final values. The physician time file associated with this PFS final rule with comment period is available on the CMS Web site in the Downloads section for the CY 2013 PFS final rule with comment period at *www.cms.gov/PhysicianFeeSched/*.

Consistent with our policy discussed in section II.C.1. of this final rule with comment period for assigning malpractice RVUs, we developed malpractice RVUs for the new CPT TCM codes. For CPT code 99495, the AMA RUC recommended a malpractice risk factor crosswalk to CPT code 99214, resulting in a malpractice RVU of 0.14 for CPT code 99495. For CPT code 99496, the AMA RUC recommended a malpractice risk factor crosswalk to CPT code 99215, resulting in a malpractice RVU of 0.20 for CPT code 99496. We are accepting the AMA RUC's recommended malpractice crosswalks for CPT codes 99495 and 99496 on an interim final basis. We appreciate comments in support of our proposed malpractice value for our non-face-to-face G-code, GXXX1, of 0.09. We believe that the interim final malpractice crosswalks recommended by the AMA RUC provide appropriate malpractice values for the CPT TCM codes, which include a face-to-face visit.

For practice expense, we are accepting the AMA RUC-recommended practice expense inputs for these codes with one refinement to clinical labor time for CPT code 99496. We are refining the 60 minutes of recommended clinical labor time for a RN/LPN nurse blend dedicated to non-face-to-face care management activities from 60 minutes to 70 minutes. We believe that the total clinical labor staff time and physician intra-service work time that the AMA RUC-recommended for non-face-to-face care management activities was accurate, but that the proportionality between physician work and clinical staff time should be refined to reflect greater clinical staff time. In response to the comment on appropriate clinical staff type for non-face-to-face care management services, we note that we are accepting the AMA RUC recommended clinical labor staff type of an RN/LPN for conducting non-face-to-face care coordination activities. The AMA RUC did not include additional costs for computer, EHR, and telephone in their recommendations. We believe accounting for the infrastructure required to furnish advanced primary care services is an issue we will consider as we pursue the broader HHS and CMS multi-year strategy to recognize and support primary care and care management under the MPFS.

The CY 2013 final rule with comment period direct PE input database reflects these inputs and is available on the CMS Web site under the supporting data files for the CY 2013 PFS final rule with comment period at *www.cms.gov/PhysicianFeeSched/*. The PE RVUs included in Addendum B to this final rule with comment period reflect the RVUs that resulted from adopting these interim final values.

For BN calculations, we estimated that physicians or qualified nonphysician practitioners would furnish post-discharge TCM services for 10 million discharges in CY 2013. We estimated that this number roughly considers the total number of hospital inpatient and SNF discharges, hospital outpatient observation services and partial hospitalization patients that may require moderate to high complexity decision-making following discharge.

Comment: Some commenters indicated that our estimate of the number of claims we would receive for the transitional care services was overstated. Using a different set of assumptions, the AMA RUC commented that the number of billings would be closer to 2 million per year. The AMA RUC provided us with detailed utilization assumptions for the CPT TCM codes. These detailed utilization assumptions indicated physicians would bill 2,166,719 claims in CY 2013 for the CPT TCM codes, with 60 percent of those claims for CPT TCM code99495

and 40 percent for CPT TCM code99496. Commenters also indicated that we should offset the cost of the TCM codes in our BN calculation with savings from reduced readmissions to hospitals and other facilities.

Response: The estimate of the number of billings we will receive in CY 2013 for TCM services is sensitive to the utilization assumptions used and cannot be easily derived from existing codes. The number of discharge day management visits that are billed to Medicare is approximately 10 million. As reflected in the RUC recommendations, we agree with commenters that this is a reasonable starting point in the development of the estimate for the number of billings for the TCM services.

The next step is to determine how many of these discharges will be readmissions in CY 2013. Since the patient would only be eligible for one TCM service associated with a hospital discharge and the later readmission, we are not counting the readmission in our utilization estimate. The AMA RUC used an estimate of 19.6 percent. We disagree with this estimate. More recent work by MedPAC indicates that the all cause readmission rate was closer to 15 percent in CY 2011.[2] Accordingly, we adopted a 15 percent readmission rate.

The AMA RUC also cited a variety of factors that it believes will reduce the number of billings from the universe of discharges, including the number of patients requiring moderate or high complexity decision-making based on the percentage of high cost Medicare patients in the Medicare population, the number of patients currently seen within 14 days of discharge, discharges where the primary care physician didn't know patient was in the hospital, cases where the patient couldn't be contacted or seen, cases where the patient died, cases where the patient changed doctors or didn't see the primary care doctor, and cases for which physicians will not furnish the TCM service as rapidly as we have assumed. The AMA RUC provided assumptions about the number of discharges it believes will not result in the billing of a TCM service. We have posted the AMA RUC calculation on our Web site at *www.cms.gov/PhysicianFeeSched/*. While we generally agree that some of these factors will impact the billings for the TCM code, we believe that the construct of the RUC estimate with assumed exact values for each and every one of these factors understates the likely TCM billings.

In considering this and similar comments, we examined the current distribution of the inpatient, observation, and nursing facility evaluation and management codes. Within each of these families, we also examined the severity of the presenting problems and the level of complexity of the medical decision-making to help differentiate the codes. We found that 85 percent of Hospital Observation and Initial and Subsequent Hospital Care services (CPT codes 99218–99233) were at Level 2 or Level 3, generally indicating moderate to high severity and complexity. We note that over 90 percent of place of service designations for the discharge codes are inpatient or outpatient hospital. We found that 43 percent of Nursing Facility Care services (CPT codes 99304–99310) were at Level 2 or Level 3, generally indicating moderate to high severity and complexity. Although less relevant for the TCM policy, we also examined the Office or Other Outpatient visits (CPT codes 99201–99213) as a point of comparison and found that 41 percent of services were at Level 4 or Level 5, generally indicating moderate to high severity and complexity.

In light of the data on the current severity and complexity levels of the evaluation and management services, and after consideration of the factors included in the AMA RUC estimate and removing 15 percent for readmissions, we believe that two-thirds of the discharges reflected in the discharge day management codes, are likely to result in TCM claims. This represents approximately 5.7 million claims [=10 million discharges * (1 − .15) for readmissions * (⅔) for severity and other factors)].

We disagree with the RUC that 60 percent of those claims will be for 99495 and 40 percent for 99496. In looking at the relationship between the moderate and high Hospital Observation and Initial and Subsequent Hospital Care services (CPT codes 99218–99233) and the relationship between the moderate and high Nursing Facility Care services (99304–99310), we believe a more reasonable estimate is that 75 percent of the TCM claims will be for 99495 and 25 percent for 99496.

Because the practice expense RVUs for the transitional care codes will vary depending on whether or not the service is billed in a facility or non-facility setting, we also need to further refine the estimate to determine the proportion of TCM services that will be paid at the facility rate versus the non-facility rate. After examining the facility and non-facility distribution of the 99214 and 99215 visit codes billed by primary care specialties, we believe that 92 percent of the TCM services will be billed in the non-facility setting.

Lastly, we agree with the RUC that 26 percent of patients had at least one visit within 7 calendar days of discharge and 44 percent had one within 14 days of discharge. Because these are existing visits that will potentially now be billed as part of the TCM service, we partially offset the cost of the TCM services with the cost of the existing visits assumed to be billed as part of the CPT TCM code.

For the comments requesting that we also offset the cost of the CPT TCM codes in our BN calculation with savings from reduced readmissions, there are currently many efforts underway to reduce hospital readmissions. We do not believe that it would be possible to isolate the effect of payment for TCM services on the readmission rate. Furthermore, the statute does not permit costs or savings from outside of the physician fee schedule to be used in the physician fee schedule BN calculation.

For purposes of the Primary Care Incentive Payment Program (PCIP), we proposed to exclude the post discharge TCM services from the total allowed charges used in the denominator calculation to determine whether a physician is a primary care practitioner. Under section 1833(x) of the Act, the PCIP provides a 10 percent incentive payment for primary care services within a specific range of E/M services when furnished by a primary care practitioner. Specific physician specialties and qualified nonphysician practitioners can qualify as primary care practitioners if 60 percent of their PFS allowed charges are primary care services. As we explained in the CY 2011 PFS final rule (75 FR 73435–73436), we do not believe the statute authorizes us to add codes (additional services) to the definition of primary care services. However, to avoid inadvertently disqualifying community primary care physicians who follow their patients into the hospital setting, we finalized a policy to remove allowed charges for certain E/M services furnished to hospital inpatients and outpatients from the total allowed charges in the PCIP primary care percentage calculation.

In the proposed rule, we also proposed that the TCM code should be treated in the same manner as those services for the purposes of PCIP because post-discharge TCM services are a complement in the community setting to the hospital-based discharge day management services already

[2] MedPAC September 7, 2012 Public Meeting Transcript, page 94, at *http://medpac.gov/transcripts/092012_transcript.pdf*, or slide 4 at *http://www.medpac.gov/transcripts/readmissions%20Sept%2012%20presentation.pdf*.

excluded from the PCIP denominator. Similar to the codes already excluded from the PCIP denominator, we expressed concern that inclusion of the TCM code in the denominator of the primary care percentage calculation could produce unwarranted bias against ''true primary care practitioners'' who are involved in furnishing post-discharge care to their patients. Therefore, while physicians and qualified nonphysician practitioners who furnish TCM services would not receive an additional incentive payment under the PCIP for the service itself (because it is not considered a ''primary care service'' for purposes of the PCIP), the allowed charges for TCM services would not be included in the denominator when calculating a physician's or practitioner's percent of allowed charges that were primary care services for purposes of the PCIP.

Comment: Some commenters recommended that the proposed TCM G-codes should be eligible for the PCIP. The commenters acknowledged that, to add our proposed G-code to the codes eligible for PCIP, we would have to revise our previous interpretation concerning the extent of the Secretary's discretion to modify the list of primary care E/M services eligible for PCIP. However, the commenters stated that our previous interpretation of the statutory language was incorrect, or at least not the only reasonable interpretation of the statutory language. A few commenters opposed excluding the allowed charges for TCM services from the denominator of the ratio used to determine qualification for the PCIP.

Response: We continue to believe that the statute does not permit us to add codes (additional services) to the statutory definition of primary care services, which is a range of E/M services including office visits. The new CPT TCM codes fall outside the designated range of codes that qualify for the PCIP. Therefore, we cannot agree with those commenters who contended that it is permissible to add the new TCM codes to the list of codes eligible for PCIP. However, to avoid disadvantaging physicians who furnish post-discharge TCM services to their patients, we are finalizing our proposal to exclude the allowed charges for TCM services from the denominator when calculating a physician's or practitioner's percent of allowed charges that were primary care services for purposes of the PCIP.

Comment: Many commenters urged us not to apply the 20 percent beneficiary coinsurance to TCM services. Some commenters stated a belief that we should categorize TCM as a preventive service and that we should therefore waive the coinsurance for the service. Other commenters expressed concern that beneficiaries will not understand their coinsurance liability for this service, since our proposed new post-discharge TCM G-code would not include a face-to-face visit. Some commenters were also concerned that this confusion would lead to increased bad debt for physicians and qualified NPPs billing the CPT TCM codes. Others urged us to work with the Congress to enact legislation to waive the beneficiary coinsurance for post-discharge care management services. On the other hand, some commenters noted that requiring a face-to-face E/M visit when billing the TCM code would reduce potential beneficiary confusion about the coinsurance for the TCM service.

Response: We appreciate the reasons commenters have offered for waiving the beneficiary coinsurance for TCM as a preventive service. However, we do not believe we have authority to do so through the rulemaking process. This is because section 1861(ddd)(1)(B) of the Act requires, among other criteria, that ''additional preventive services'' can be added only if such services are recommended with a grade of A or B by the United States Preventive Services Task Force. We lack such a recommendation regarding the services described by the new CPT TCM codes. As we have discussed above, we agree with those commenters who observed that requiring a face-to-face E/M visit when billing the TCM code would reduce potential beneficiary confusion about the coinsurance for the TCM service. Now that we have modified our proposal for a TCM service to include a face-to-face service, beneficiaries will experience a face-to-face encounter to which they can relate their copayments for the service. We therefore believe that our adoption of the CPT TCM codes that include a required face-to-face visit as a component of the service will greatly reduce the potential for beneficiary confusion over the coinsurance for the service and the possibility of increased bad debt for physicians.

2. Primary Care Services Furnished in Advanced Primary Care Practices

a. Background

As we discussed above, we are committed to considering new options and developing future proposals for payment of primary care services under the MPFS. Such options would promote comprehensive and continuous assessment, care management, and attention to preventive services that constitute effective primary care by establishing appropriate payment when physicians furnish such services. One potential method for ensuring that any targeted payment for primary care services would constitute a minimum level of care coordination and continuous assessment under the MPFS would be to pay physicians for services furnished in an ''advanced primary care practice'' that has implemented a medical home model supporting patient-specific care. The medical home model has been the subject of extensive study in medical literature. Since 2007, the AMA, American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Physicians (ACP), and the American Osteopathic Association (AOA), and many other physician organizations have also endorsed ''Joint Principles of the Patient-Centered Medical Home.'' In February 2011, the AAFP, the AAP, the ACP, and AOA also published formal ''Guidelines for Patient-Centered Medical Home (PCMH) Recognition and Accreditation Programs'' to develop and promote the concept and practice of the PCMH. (These guidelines are available at *www.aafp.org/online/etc/medialib/aafp_org/documents/membership/pcmh/pcmhtools/pcmhguidelines.Par.0001.File.dat/GuidelinesPCMHRecognition AccreditationPrograms.pdf.*) As we have discussed above, the Innovation Center has been conducting several initiatives based on the medical home concept.

The medical home concept emphasizes establishing an extensive infrastructure requiring both capital investments and new staffing, along with sophisticated processes, to support continuous and coordinated care with an emphasis on prevention and early diagnosis and treatment. The literature, reports, and guidelines dealing with the medical home concept define the requisite elements or functions that constitute this infrastructure and processes in various ways. For example, the Innovation Center's CPC initiative identified a set of five ''comprehensive primary care functions,'' which form the service delivery model being tested and the required framework for practice transformation under the CPC initiative. In the proposed rule (77 FR 44780), we discussed these five ''comprehensive primary care functions'' as an appropriate starting point for discussing the incorporation of the comprehensive primary care services delivered in advanced primary care practices (practices implementing a medical home model) into the MPFS. These five

functions are: Risk-stratified care management, access and continuity, planned care for chronic conditions and preventive care, patient and caregiver engagement, and coordination of care across the medical neighborhood. (See our detailed discussion of these functions at the citation noted above.)

In the proposed rule, we also discussed the need to establish a set of parameters to determine whether or not a clinical practice could be considered an advanced primary care practice (medical home) in the event that we were to establish an enhanced payment for primary care services furnished to Medicare beneficiaries in an advanced primary care practice environment. (77 FR 44781–44782) Specifically, we discussed two possible approaches to determining whether a practice has implemented all the necessary functions to be considered an advanced primary care practice or medical home. One approach would be to recognize one or more of the nationally available accreditation programs currently in use by major organizations that provide accreditation for advanced primary care practices, frequently credentialed as ''PCMHs.'' We identified four national models that provide accreditation for organizations wishing to become an advanced primary care practice; the Accreditation Association for Ambulatory Health, The Joint Commission, the NCQA, and the Utilization Review Accreditation Commission (URAC). Alternatively, we could develop our own criteria using, for example, the five functions of comprehensive primary care used in the CPC initiative and described above, to determine what constitutes advanced primary care for purposes of Medicare payment. We would then need to develop a process for determining whether specific physician practices meet the criteria for advanced primary care. This could include creating our own processes for review or could include using existing accrediting bodies to measure compliance against advanced primary care criteria determined by CMS.

We also discussed another potential issue surrounding comprehensive primary care services delivered in an advanced primary care practice, specifically attribution of a beneficiary to an advanced primary care practice. (77 FR 44782) In a fee-for-service environment we would need to determine which practice is currently serving as the advanced primary care practice for the beneficiary to ensure appropriate payment. One method of attribution could be that each beneficiary prospectively chooses an advanced primary care practice. Other attribution methodologies might examine the quantity and type of E/M or other designated services furnished to that beneficiary by the practice. We welcomed input on the most appropriate approach to the issue of how to best determine the practice that is functioning as the advanced primary care practice for each beneficiary. We emphasized that we would not consider proposals that would restrict a beneficiary's free choice of practitioners.

In summary, we stated our belief that targeting primary care management payments to advanced primary care practices could have many merits, including ensuring a basic level of care coordination and care management. We recognize that the advanced primary care model has demonstrated efficacy in improving the value of health care in several contexts, and we are exploring whether we can achieve these outcomes for the Medicare population through several demonstration projects. Careful analysis of the outcomes of these demonstration projects will inform our understanding of how this model of care affects the Medicare population and of potential PFS payment mechanisms for these services. At the same time, we also believe that there are many policy and operational issues to be considered when nationally implementing such a program within the PFS. Therefore, we generally invited broad public comment on the accreditation and attribution issues discussed above and any other aspect, including payment, of integrating an advanced primary care model into the PFS.

We received many helpful and informative comments on the issues we discussed in relation to recognizing advanced primary care practices, especially on the criteria and processes that should be used to identify such practices. We welcome these comments because we are actively considering such an advanced primary care practice model in the near future after a complete assessment of the results of ongoing demonstrations and policy and operational considerations.

We also received many comments recommending that we adopt the complex care coordination codes developed by the AMA's C3W for CY 2013. As discussed in section III.M.3.a. of this final rule with comment period, on an interim final basis for CY 2013, we are assigning CPT codes 99487, 99488, and 99489 a PFS procedure status indicator of B (Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled (for example, a telephone call from a hospital nurse regarding care of a patient). We will consider these codes, as well as other payment approaches as we continue our multi-year strategy to recognize and support primary care and care management.

I. Payment for Molecular Pathology Services

The AMA CPT Editorial Panel has created new CPT codes to replace the codes used to bill for molecular pathology services that will be deleted at the end of CY 2012. The new codes describe distinct molecular pathology tests and test methods. CPT divided these molecular pathology codes into Tiers. Tier 1 codes describe common gene-specific and genomic procedures. Tier 2 codes capture reporting for less common tests. Each Tier 2 code represents a group of tests that the CPT Editorial Panel believes involve similar technical resources and interpretive work. The CPT Editorial Panel created 101 new molecular pathology CPT codes for CY 2012 and another 14 new molecular pathology codes for CY 2013.

We stated in our notice for the Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting held on July 16, 2012 (77 FR 31620) that we were following our regular process to determine the appropriate basis and payment amounts for new clinical diagnostic laboratory tests, including molecular pathology tests, under the CLFS for CY 2013. However, we also stated that we understand stakeholders in the molecular pathology community continue to debate whether Medicare should pay for molecular pathology tests under the CLFS or the PFS. Medicare pays for clinical diagnostic laboratory tests through the CLFS and for services that ordinarily require physician work through the PFS. We stated that we believed we would benefit from additional public comments on whether these tests are clinical diagnostic laboratory tests that should be paid under the CLFS or whether they are physicians' services that should be paid under the PFS. Therefore, we solicited public comment on this issue in the CY 2013 PFS proposed rule (77 FR 44782 and 44783), as well as public comment on pricing policies for these tests under the CLFS during the CLFS Annual Public Meeting process.

In the PFS proposed rule, we first discussed and requested public comment on whether these molecular pathology CPT codes describe services

that ordinarily require physician work, and then we discussed our proposal to address payment for these CPT codes on the PFS, pending public comment and resolution of the first question. The PFS proposal paralleled the CLFS Annual Public Meeting process during which we receive comments and recommendations on the appropriate basis for establishing a payment amount for the molecular pathology CPT codes as clinical diagnostic laboratory tests under the CLFS.

As detailed in section II.B.1. of this final rule with comment period, Medicare establishes payment under the PFS by setting RVUs for work, practice expense (PE), and malpractice expense for services that ordinarily require physician work. To establish RVUs for physician work, we conduct a clinical review of the relative physician work (time by intensity) required for each PFS service. This clinical review includes the review of RVUs recommended by the American Medical Association/ Specialty Society Relative Value Scale Update Committee (AMA RUC) and others. The AMA RUC-recommended work RVUs for a service typically are based in part on results of a survey conducted by the relevant specialty society. CMS establishes PE RVUs under a resource-based PE methodology that considers the cost of direct inputs, as well as indirect PE costs. The AMA RUC, through the Practice Expense Subcommittee, recommends direct PE inputs to CMS, and the relevant specialty societies provide pricing information for those direct inputs to CMS. After we determine the appropriate direct PE inputs, the PE methodology is used to develop PE RVUs. Physician work and PE RVUs for each CPT code are constructed to reflect the typical case; that is, they reflect the service as it is most commonly furnished (71 FR 69629). CMS establishes resource-based malpractice expense RVUs using weighted specialty-specific malpractice insurance premium data collected from commercial and physician-owned insurers, last updated for the CY 2010 final rule (74 FR 61758). For most services paid under the PFS, beneficiary cost-sharing is 20 percent of the fee schedule payment amount.

CMS establishes a payment rate for new clinical diagnostic laboratory tests under the CLFS by either crosswalking or gap-filling. Crosswalking is used when a new test code is comparable to an existing test code, multiple existing test codes, or a portion of an existing test code on the CLFS. Under this methodology, the new test code is assigned the local fee schedule amounts and the national limitation amount (NLA) of the existing test, with payment made at the lesser of the local fee schedule amount or the NLA. Gap-filling is used when no comparable test exists on the CLFS. In the first year a test is gap-filled, contractor-specific amounts are established for the new test code using the following sources of information: Charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. For the second year, the NLA is calculated, which is the median of the carrier-specific amounts. See § 414.508. Services paid under the CLFS do not account for any physician work, although tests paid under the CLFS can involve assessment by a laboratory technician/technologist, a chemist, molecular biologist, or a geneticist—none of which are health care professional occupations that meet the statutory definition of a physician. Although payments can vary geographically due to contractor discretion across locality areas (which are the same localities used for the GPCIs under the PFS), payments cannot exceed a NLA, nor are they adjusted once rates are determined (apart from inflation updates as required by statute). In the CY 2008 PFS final rule with comment period, we adopted a prospective reconsideration process for new tests paid under the CLFS, allowing a single year for Medicare and stakeholders to review pricing for new tests after a payment is initially established through crosswalking, and in certain circumstances, up to 2 years for Medicare and stakeholders to review pricing for new tests after a payment is initially established through gap-filling (72 FR 66275 through 66279, 66401 through 66402). Finally, in almost all circumstances, there is no beneficiary cost-sharing for clinical laboratory diagnostic tests paid on the CLFS.

For a handful of clinical laboratory services paid under the CLFS, we allow an additional payment under the PFS for the professional services of a pathologist when they meet the requirements for a clinical consultation service as defined in § 415.130(c). The PFS pays for services that ordinarily require the work of a physician and, with regard to pathology services, explicitly pays for both the professional and technical component of the services of a pathologist as defined in § 415.130(b), including surgical pathology, cytopathology, hematology, certain blood banking services, clinical consultations, and interpretive clinical laboratory services.

Molecular pathology tests are currently 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 through the CLFS; and one stacking code, CPT code 83912 (molecular diagnostics; interpretation and report), is paid on both the CLFS and the PFS. Payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician is made under the PFS 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 professional is bundled into payment made under the CLFS using CPT code 83912.

As we stated in the CY 2013 PFS proposed rule (77 FR 44783), since the creation of new molecular pathology CPT codes, there has been significant debate in the stakeholder community regarding whether these new molecular pathology CPT codes describe physicians' services that ordinarily require physician work and would be paid under the PFS, or whether they describe clinical diagnostic laboratory tests that would be paid on the CLFS. In the CY 2013 PFS proposed rule (77 FR 44783), we stated that there is little agreement on whether the technical component and/or professional component (interpretation and report) of these services are ordinarily furnished by a physician or a nonphysician laboratory professional. Additionally, we stated that some stakeholders have suggested that interpretation and report by any health care professional is generally not necessary for these services, as the laboratory result reporting is becoming more automated.

In the CY 2012 PFS final rule with comment period (76 FR 73190), we stated that for CY 2012, Medicare would continue to use the existing stacking codes for the reporting and payment of these molecular pathology tests, and that the new molecular pathology CPT codes would not be valid for payment for CY 2012. We did this because we were concerned that we did not have sufficient information to know whether the new molecular pathology CPT codes describe clinical diagnostic laboratory tests or services that ordinarily require physician work. In the PFS proposed

rule, we stated that, for CY 2013, we continue to have many of the same concerns that led us not to recognize the 101 molecular pathology CPT codes for payment for CY 2012. We requested comment on whether the new molecular pathology CPT codes describe physicians' services that should be paid under the PFS, or whether they describe clinical diagnostic laboratory tests that should be paid under the CLFS. We also requested comment on the following more specific questions:

- Do each of the 101 molecular pathology CPT codes describe services that are ordinarily furnished by a physician?
- Do each of these molecular pathology CPT codes ordinarily require interpretation and written report?
- What is the nature of that interpretation and does it typically require physician work?
- Who furnishes interpretation services and how frequently?

In the CY 2013 PFS proposed rule, we also proposed to price all of the new molecular pathology CPT codes through a single fee schedule, either the CLFS or the PFS. We stated that after meeting with stakeholders and reviewing each CPT code, we believed that there are a discrete number of laboratory methods used to generate results across molecular pathology tests. For example, two different tests (represented by different CPT codes) may be run using the same testing methodologies, but using different genes. However, there are very different processes for establishing payment rates under the PFS and the CLFS. As discussed above, Medicare sets payment under the CLFS by either crosswalking or gap-filling and, after the prospective reconsideration process we do not adjust the payment amount further (apart from inflation updates as required by statute). In contrast, Medicare sets payment under the PFS through a set of resource-based methodologies for physician work, PE, and malpractice expense, and payment can be reviewed and adjusted as the resources required to furnish a service change. We stated that we were concerned that establishing different prices for comparable laboratory services across two different payment systems would create a financial incentive to choose one test over another simply because of its fee schedule placement. We stated that we were also concerned that the differences in prices would become more pronounced over time, as we continue to review the values for physician work and PE inputs on the PFS relative to established CLFS prices. Therefore, largely because of the homogeneity of the laboratory methodologies behind these procedure test codes, we stated that we believe that it is appropriate for all new molecular pathology CPT codes to be priced on the same fee schedule using the same methodology. We invited public comment on that proposal.

As we considered public comment on whether these molecular pathology CPT codes describe services that ordinarily require physician work, we wanted to ensure that there was a payment mechanism in place to pay for these CPT codes for CY 2013, either on the PFS or the CLFS. We stated that, because we believe that these molecular pathology CPT codes may be clinical diagnostic laboratory tests payable on the CLFS, comments and recommendations from the public on the appropriate basis for establishing payment amounts on the CLFS would be discussed and received through the CY 2013 CLFS Annual Public Meeting process. More information on these tests is available on the CMS Web site at *www.cms.hhs.gov/ClinicalLabFeeSched*.

As a parallel to determining the appropriate basis and payment amounts for the molecular pathology CPT codes as clinical diagnostic laboratory tests through the CLFS Annual Public Meeting process, we also proposed payment for these codes under the PFS for CY 2013. In the CY 2013 PFS proposed rule, we stated that the AMA RUC and the College of American Pathologists (CAP) provided CMS with recommendations for physician work RVUs and PE inputs for most of the molecular pathology CPT codes. We did not have recommendations on physician work RVUs or direct PE inputs for a small number of codes, which represent tests that are patented, and therefore the methodology used to furnish the test is proprietary and was unavailable to the AMA RUC or CMS to support developing appropriate work and direct PE inputs. As we stated in the PFS proposed rule, the AMA RUC-recommended physician work RVUs range from 0.13 to 2.35, with a median work RVU of 0.45. The AMA RUC-recommended physician intra-service times (which, for these codes, equals the total times) range from 7 minutes to 80 minutes, with a median intra-service time of 18 minutes. We noted that the physician work RVU for CPT code 83912–26 and all but one of the other clinical diagnostic laboratory services for which CMS recognizes payment for clinical interpretation is 0.37. Table 27 lists AMA RUC-recommended physician work RVUs and times, as well as the AMA RUC-estimated CY 2013 utilization for these codes. This table contains the AMA RUC's estimated CY 2013 utilization for all 115 molecular pathology codes effective for CY 2013 and recommended physician work RVUs and times only for those codes that CAP believes are ordinarily performed by a physician. These values are listed for reference only and were not used for PFS rate-setting.

As we stated in the PFS proposed rule, molecular pathology tests can be furnished in laboratories of different types and sizes (for example, a large commercial laboratory, academic or research laboratory, typically hospital-based, or potentially, a pathology group practice), and tests may be furnished in small or large batches. Also, although there are largely homogenous methods across the different tests considered here, we recognize that for a specific test, the combination of methods may vary across different laboratories. When developing direct PE input recommendations for CMS, CAP and the AMA RUC made assumptions about the typical laboratory setting and batch size to determine the typical direct PE inputs for each service. Given that many of these services are furnished by private laboratories, it was challenging for CAP and the AMA RUC to provide recommendations on the typical inputs for many services, and not possible for other services. We posted the AMA RUC- and CAP-recommended direct PE inputs on the CMS Web site in the files supporting the CY 2013 PFS proposed rule at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. We stated in the CY 2013 PFS proposed rule (77 FR 44784) that we appreciate all of the effort CAP has made to develop national pricing inputs; however, we agree with its view that, in many cases, there is no established approach for the specific number and combination of methods involved in executing many of these tests and that the potential pathways for a laboratory or pathology group practice to execute these tests can vary considerably.

As we discussed in the CY 2013 PFS proposed rule, in addition to recommendations on physician work and direct PE inputs, the AMA RUC provided CMS with recommended utilization crosswalks for most of the molecular pathology tests. When there are coding changes, the utilization crosswalk tracks Medicare utilization from an existing code to a new code. The existing code utilization figures are drawn from Medicare Part B claims data. We use utilization crosswalk assumptions to ensure PFS budget neutrality and to create PE RVUs

through the PE methodology. The AMA RUC's recommended crosswalk utilization is presented in Table 27 for reference, however, we note that because these services are not payable under the PFS, these values were not used for rate-setting. In the CY 2013 PFS proposed rule, we stated that we believe that the utilization assumptions for the technical component of the new CPT codes should be based on the utilization of the corresponding CPT codes currently billed on the CLFS, and not on the utilization of CPT code 83912–26. As we discussed in the CY 2013 PFS proposed rule, several laboratories provided us with a list of the molecular pathology tests that they perform, and identified the stacking codes that are currently used to bill for each test and the new CPT code that would be billed for each test. However, because the same molecular pathology test may be billed using different stacks, and the same stack may be billed for different tests, it is not possible to determine which stacks match which new CPT codes unless the billing entity billed both the new molecular pathology CPT code and the stacking codes. Additionally, if a beneficiary has more than one test on the same date of service and both stacks are billed on the same Medicare claim, it is not possible to determine which stacking codes on the claim relate to each test. Furthermore, some tests described by the new CPT codes are currently billed using general ''not otherwise classified'' (NOC) pathology CPT codes that capture a range of services and not just the specific molecular pathology tests described by the new CPT codes. We stated that, given these factors, it is difficult to estimate the utilization of the new molecular pathology CPT codes based on the Medicare billing of the current stacking and NOC codes.

We stated that if we were to finalize payment for molecular pathology tests under the PFS, we did not believe that we could propose national payment rates, because the following questions remained:

- If these services are furnished by a physician, what are the appropriate physician work RVUs and times relative to other similar services?
- Where and how are each of these services typically furnished—for example, what is the typical laboratory setting and batch size?
- What is the correct projected utilization for each of these services?

In the CY 2013 PFS proposed rule, we stated that, given these major areas of uncertainty, if CMS determined that new molecular pathology CPT codes should be paid under the PFS for CY 2013, we would propose to allow the Medicare contractors to price these codes because we do not believe that we have sufficient information to engage in accurate national pricing and because the price of tests can vary locally. As previously discussed, this proposal was parallel to the CLFS Annual Public Meeting process through which we received comments and recommendations on the appropriate basis for establishing a payment amount for these molecular pathology tests as clinical diagnostic laboratory tests under the CLFS. We stated that if we decided to finalize payment for these new codes under the PFS, we would consider modifying § 415.130 as appropriate to provide for payment to a pathologist for molecular pathology tests.

Finally, we stated that, after reviewing comments received on the proposals contained within the CY 2013 PFS proposed rule (77 FR 44782 through 44787), and after hearing the discussion at the CLFS Annual Public Meeting and reviewing comments and recommendations during the public meeting process, we would determine the appropriate basis for establishing payment amounts for the new molecular pathology CPT codes. We stated that we would publish our final decision in the CY 2013 PFS final rule with comment period and, at the same time the final rule is published, post final payment determinations for any molecular pathology tests that will be paid under the CLFS.

A summary of the comments received on the questions and proposals discussed in the CY 2013 PFS proposed rule, followed by our responses and conclusions are below.

We received the following comments in response to our questions on whether these molecular pathology CPT codes describe services that are ordinarily furnished by a physician; whether the services require interpretation and written report and, if so, who ordinarily furnishes that interpretation and how frequently; what is the nature of that interpretation and does it typically require physician work; and the broader question of whether these codes describe physicians' services that should be paid under the PFS or if they describe clinical diagnostic laboratory tests that should be paid under the CLFS; as well as our proposal to price all molecular pathology CPT codes through a single fee schedule:

Comment: Many commenters stated that these molecular pathology tests are not ordinarily furnished by a physician. These commenters stated that the services described by the new molecular pathology CPT codes do not require physician involvement, and that the vast majority of tests are performed (both the technical component and the interpretation) without a physician. The American Clinical Laboratory Association (ACLA) commented that a survey of its members showed that in most cases, the tests are performed, supervised, and interpreted by nonphysicians, most often doctoral-level scientists with expertise in medical genetics. ACLA noted that both Ph.D. geneticists and pathologists can be certified in genetics by an American Board of Medical Specialties. Comments indicated that some laboratories performing these tests do not employ physicians.

In contrast, other commenters noted that the molecular pathology CPT codes were developed as global services, including both professional (physician work) and technical components together, and so the CPT codes inherently include physician work. They noted that many of the clinical vignettes developed as a part of the CPT and AMA RUC processes demonstrate the incorporation of the technical steps and the professional services by a pathologist associated with each code.

There was little agreement among commenters on whether molecular pathology tests require any interpretation and whether that interpretation is ordinarily furnished by a physician. Several commenters noted that molecular pathology tests can be divided into three groups based on interpretation requirements. The first group includes tests that require interpretation by a physician to generate a beneficiary-specific result, which, they stated, includes tests that utilize fluorescence in situ hybridization or immunohistochemistry technology. The second group includes tests that require interpretation by a nonphysician qualified healthcare professional to produce a beneficiary-specific result, which, they stated, includes many of the genetic tests assigned to Tier 1 and Tier 2 CPT codes. The third group includes tests that do not require interpretation by either a physician or health care professional because the test system produces the beneficiary-specific result, which, they stated, includes multi-analyte assays with algorithmic analyses (MAAAs) and in vitro diagnostic kits for genetic tests that have been assigned Tier 1 and Tier 2 CPT codes.

Other commenters noted that each of the tests represented by the new molecular pathology CPT codes ordinarily requires interpretation and report. Several commenters explained that even clearly negative results, in

most instances, require an expenditure of resources for interpretation. One commenter explained that the results of these technical procedures require interpretation of the raw data generated, and that a pathologist assumes the responsibility for the generation of these results and performs the work associated with interpreting them, irrespective of whether the beneficiary has a positive or negative result. Additionally, one commenter noted that as molecular pathology tests become more and more automated as the field and science evolve, the interpretation and reporting of these tests is concurrently becoming more and more complex.

There was also little agreement among commenters as to whether the interpretation and report associated with these molecular pathology tests is ordinarily performed by a physician. Many commenters stated that clinical molecular diagnostics is a rapidly evolving diagnostic subspecialty that requires both technical and medical knowledge to interpret test results for use in beneficiary care. They explained that these molecular pathology tests require review by an expert who is well-versed in the interpretation of molecular pathology test results, who has the medical knowledge to place the results in a clinical context, and who can guide decisions about beneficiary treatment options and care management. They contended that selecting the best treatment path for an individual beneficiary's disease state is a key facet of molecular pathology and depends upon the pathologist's clinical expertise in the disease area. Commenters stated that, with molecular pathology, it is medically necessary for the pathologist to provide the referring physician with clinical insight about how the result should be interpreted based on the technique used and on the beneficiary's history and medical condition. They contended that this differs from other laboratory subspecialties where the ordering physician typically has the expertise to interpret test results. These commenters stated that interpretation and report of a molecular pathology test is ordinarily furnished by a physician.

In contrast, other commenters noted that, regardless of the nature of the interpretation for a molecular pathology test, doctoral-level geneticists are qualified and credentialed to perform the interpretation. The commenters stated that physician interpretation is not typical. They stated that in some laboratories, physicians may interpret test results when circumstances require a broader clinical review. They went on to note that among 367,370 molecular pathology allowed services with interpretation and report paid by Medicare in 2010, approximately 80 percent of the services did not require a physician interpretation.

Commenters who stated that molecular pathology tests ordinarily require the interpretation of a physician also stated that the molecular pathology tests should be paid under the PFS. Generally, these commenters contended that it is medically necessary for a physician to interpret the molecular pathology test results, guide the beneficiary's treatment, assess the beneficiary's progress, and prepare the final report for the beneficiary's record. As such, the commenter stated molecular pathology, as a field, is fundamentally different from laboratory medicine. They reasoned that complex tests that require physician interpretation to be clinically meaningful belong on the PFS. Additionally, some commenters stated that these services should be paid under the PFS because the resources involved in furnishing molecular pathology tests are changing rapidly. They pointed out that only the PFS currently allows the valuation of the codes to be continuously reviewed and scrutinized, taking into account changing technology and increased efficiencies as technology is adopted and becomes more widespread. They noted that placing the CPT codes for these molecular pathology tests on the PFS will enable the healthcare system to capture those savings. Finally, some commenters who stated that the molecular pathology tests should be paid under the PFS also thought that CMS should establish CLFS payment for laboratory interpretation and report of a molecular pathology test.

Commenters who stated that molecular pathology tests do not ordinarily require the interpretation of a physician also stated that the molecular pathology tests should be paid under the CLFS. Generally, these commenters contended that if a service is not ordinarily furnished by a physician, then CMS is precluded from paying for the service under the PFS. They explained that, as stated by the regulation at § 415.130(b), allowable physician pathology tests can only be paid if they first meet the threshold criteria of § 415.102(a)(1) (''The services are personally furnished for an individual beneficiary by a physician'') and § 415.102(a)(3) (''The services ordinarily require performance by a physician.'') Additionally, some commenters stated that the tests described by the new molecular pathology CPT codes will continue to be performed exactly as they were prior to the coding change and that there is no reason why the tests should not continue to be paid under the CLFS. Finally, some commenters who stated that the molecular pathology tests should be paid under the CLFS also suggested that CMS should establish PFS payment for physician interpretation and report of a molecular pathology test.

Finally, in response to our proposal to price all molecular pathology CPT codes through a single fee schedule, most commenters stated that CMS should assess each CPT code independently and include the molecular pathology tests that require physician work on the PFS, and the molecular pathology tests that do not require physician work on the CLFS. However, as stated above, some commenters stated that all the molecular pathology CPT codes include physician work, and should all be placed together on the PFS, while others stated that none of the molecular pathology CPT codes require physician work, and all should be placed together on the CLFS. Finally, as stated above, some commenters suggested that the tests should be paid under the CLFS with a PFS payment for physician interpretation and report of a molecular pathology test whereas others stated that the tests should be paid under the PFS with a CLFS payment for laboratory interpretation and report of a molecular pathology test.

Response: We thank the commenters for their thorough responses to our questions and proposals. After reviewing the comments, we believe that the molecular pathology CPT codes describe clinical diagnostic laboratory tests that should be paid under the CLFS because these services do not ordinarily require interpretation by a physician to produce a meaningful result. While we recognize that these tests may be furnished by a physician, after reviewing the public comments and listening to numerous presentations by stakeholders throughout the comment period, we are not convinced that all these tests ordinarily require interpretation by a physician. Many commenters stated that geneticists can provide any necessary interpretation for a meaningful test result of a molecular pathology test if some interpretation is required. ACLA noted that both Ph.D. geneticists and pathologists can be certified in genetics by an American Board of Medical Specialties, evidence that the medical community recognizes geneticists as qualified to interpret molecular pathology test results. Commenters described automated laboratory processes and organizational structures that rely on geneticist

interpretation when needed, and they presented a claims analysis demonstrating that physician interpretation currently is not typical across molecular pathology services in CY 2010. Further, commenters stated that these molecular pathology tests are currently payable on the CLFS.

We do not agree with some commenters that these codes inherently include physician work because they were developed as global services. We have a long-standing policy of dividing a global diagnostic service into a professional and technical component to separately capture the resources involved in the professional work and technical component of the test. We are not convinced that a physician must be involved in performing portions of the technical component. We believe that some molecular pathology tests are automated and do not require interpretation. Where the laboratory processes are not automated, laboratory personnel, including doctoral-level geneticists, can produce accurate molecular pathology test results. Although there might be occasions when a physician furnishes some of the technical component of a clinical laboratory test paid under the CLFS, we do not believe that performance by a physician changes the nature of the work. Rather, we believe it would still be appropriate to make payment for the technical work as part of the CLFS payment for the test. One commenter provided a claims analysis demonstrating that physicians are the most common entity to bill CPT code 89312 in the 2009 claims data; that there are more individual pathologists submitting claims for molecular pathology services than there are independent laboratories submitting claims for molecular pathology services. We believe this speaks to the different business structures in the pathology and laboratory communities. We would expect numerous different pathologists working in a hospital-based academic or research laboratory to bill for their professional services interpreting and reporting on a molecular pathology test independently under their NPI or group NPI using CPT code 83912–26. We would expect commercial laboratories to bill CPT code 83912 for interpretation and report by a nonphysician laboratory professional, like a doctoral-level geneticist, for a great volume of tests under a single laboratory NPI. We do not believe this analysis of the typical provider supports an assessment of whether interpretation is ordinarily required for furnishing molecular pathology services.

Finally, while we considered the differences in methodology for pricing under the CLFS versus the PFS, including the ability to apply a budget neutrality adjustment under the PFS, we do not believe that the differences in payment methodologies should be a definitive basis for deciding to choose a specific fee schedule. Rather, the statute requires Medicare to pay using separate methodologies for physicians' services and for clinical diagnostic laboratory tests. Ultimately, we believe the primary criterion for determining the appropriate payment methodology is the identification of a service as one or the other.

Therefore, for CY 2013, we are assigning a PFS procedure status indicator of X (Statutory exclusion. These codes represent an item or service that is not within the statutory definition of ''physicians' services'' for PFS payment purposes (for example, ambulance services). No RVUs are shown for these codes and no payment may be made under the PFS to the molecular pathology CPT codes listed in Table 27, because payment will be made for these tests under the CLFS. More information on the CLFS determination of the appropriate basis for payment (crosswalk or gap-filling) for these tests is available on the CMS Web site at *www.cms.hhs.gov/ClinicalLabFeeSched*.

While we do not believe the molecular pathology tests are ordinarily performed by physicians, we do believe that, in some cases, a physician interpretation of a molecular pathology test may be medically necessary to provide a clinically meaningful, beneficiary-specific result. In order to make PFS payment for that physician interpretation, on an interim basis for CY 2013, we have created HCPCS G-code G0452 (molecular pathology procedure; physician interpretation and report) to describe medically necessary interpretation and written report of a molecular pathology test, above and beyond the report of laboratory results. This professional component-only HCPCS G-code will be considered a ''clinical laboratory interpretation service,'' which is one of the current categories of PFS pathology services under the definition of physician pathology services at § 415.130(b)(4). Section § 415.130(b)(4) of the regulations and section 60 of the Claims Processing Manual (IOM 100–04, Ch. 12, section 60.E.) specify certain requirements for billing the professional component of certain clinical laboratory services including that the interpretation (1) must be requested by the patient's attending physician, (2) must result in a written narrative report included in the patient's medical record, and (3) requires the exercise of medical judgment by the consultant physician. We note that a hospital's standing order policy can be used as a substitute for the individual request by a patient's attending physician. The current CPT code for interpretation and report, 83912–26, is included on the current list of clinical laboratory interpretation services but will be deleted at the end of CY 2012.

We will monitor the utilization of this service and collect data on billing patterns to ensure that G0452 is only being used when interpretation and report by a physician is medically necessary and is not duplicative of laboratory reporting paid under the CLFS. In the near future, we intend to reassess whether this HCPCS code is necessary, and if so, in conjunction with which molecular pathology tests. A discussion of the work and direct PE inputs for HCPCS G-code G0452 can be found later in this section. We note that physicians can continue to receive payment for the current clinical pathology consultation CPT codes 80500 (Clinical pathology consultation; limited, without review of a patient's history and medical records) and 80502 (Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records) if the pathology consultation services relating to a molecular pathology test meet the definition of those codes.

We do not believe it is appropriate to establish a HCPCS G-code on the CLFS for the interpretation and report of a molecular pathology test by a doctoral-level scientist or other appropriately trained nonphysician health care professional. The new molecular pathology CPT codes consolidate the services previously reported using the CLFS stacking codes, including the CLFS stacking code for laboratory interpretation and report of a molecular pathology test (CPT code 83912). As such, we believe that payment for the interpretation and report service would be considered part of the overall CLFS payment for the molecular pathology CPT codes. In addition, geneticists and other nonphysician laboratory personnel do not have a Medicare benefit category that allows them to bill and be paid for their interpretation services; therefore, they cannot bill or receive PFS payment for HCPCS code G0452.

In response to our questions about the appropriate physician work RVUs and times, utilization crosswalks, and direct PE inputs for the molecular pathology services described by the CPT codes, as

well as our proposal to contractor price the codes for CY 2013 if we determined that the codes should be paid under the PFS for CY 2013, we received the following comments:

Comment: Commenters were not in favor of our proposal to contractor price these CPT codes if we determined that the codes should be paid under the PFS. Commenters urged CMS to establish national payment rates for the new molecular pathology CPT codes. Several commenters recommended that we use the AMA RUC- and CAP-recommended RVUs and inputs for these tests. One commenter suggested that contractor pricing is unnecessary to set payment rates for the technical component, since CMS has hospital cost data that can be used to develop payment rates. This commenter went on to strongly urge CMS to provide clear and specific guidance that contractors must work with cost data from constituents in their areas to set appropriate rates for physician services.

Commenters stated that they are concerned that contractor pricing would lack the breadth of input, external scrutiny, and relativity utilized in the development of the AMA RUC recommendations. Commenters also believe that contractor pricing would add administrative complexities and costs, and that variations in contractor pricing would be disruptive. Also, commenters stated that contractor pricing could result in movement of sites of testing to the highest paying regions in order to maximize Medicare payment for individual services. Furthermore, commenters suggested that the variation in the costs of these tests is related to differences in laboratory facilities, equipment, and/or test methodologies, and that the variation is not geographically based; therefore, contractor pricing is not appropriate.

Regarding the utilization estimates for the new molecular pathology CPT codes, the AMA RUC noted that its utilization projections were based on the utilization of CPT code 83912 (molecular diagnostics; interpretation and report), which includes interpretation on both the physician fee schedule (83912–26) and the clinical laboratory fee schedule (83912), when interpretation by technical laboratory personnel, such as a geneticist, accompanies performance of the molecular pathology test represented by other ''stacking'' codes on a claim. The AMA RUC noted that utilization of this service has been growing rapidly and provided updated utilization assumptions based on 2011 Medicare allowed charges for CPT code 83912. These utilization assumptions, and the AMA RUC-recommended physician work RVUs and times, for all 115 codes are included in Table 27 for reference. However, we note that because these services are not payable under the PFS, these values were not used for rate-setting.

Response: We thank the commenters for their detailed responses to our questions and proposals. Beginning in CY 2013, the molecular pathology CPT codes will be paid under the CLFS, and HCPCS code G0452 (Molecular diagnostics; interpretation and report) will be paid under the PFS. Because payment for the molecular pathology CPT codes will be made under the CLFS rather than the PFS, it is not necessary to consider further whether contractor pricing would be appropriate for the molecular pathology CPT codes under the PFS. We will add a new HCPCS code, G0452, to replace the current CPT code that is used to bill under the PFS for interpretation and report of a molecular pathology test (CPT code 83912–26), which is being deleted at the end of CY 2012. After reviewing the public comments, the AMA RUC and CAP recommendations, and the values of the current and similar services, we believe we have enough information to nationally price HCPCS code G0452 for CY 2013. We believe it is appropriate to directly crosswalk the work RVUs, time, utilization, and malpractice risk factor of CPT code 83912–26 to HCPCS code G0452, because we do not believe this coding change reflects a change in the service or in the resources involved in furnishing the service. The current work RVU of 0.37 for CPT code 83912–26 is the same as nearly all the clinical laboratory interpretation service codes. This value is also within the range of AMA RUC- recommended values for the molecular pathology CPT codes—the utilization-weighted average AMA RUC-recommended work RVU was 0.33, and the median AMA RUC-recommended work RVU was 0.45 for the molecular pathology CPT codes. Based on this information, we believe a work RVU of 0.37 appropriately reflects the work of HCPCS code G0452. Therefore, we are assigning a work RVU of 0.37 and 5 minutes of pre-service time, 10 minutes of intra-service time, and 5 minutes of post-service time to HCPCS code G0452 on an interim final basis for CY 2013. We request public comment on the interim final values for HCPCS code G0452.

TABLE 27—AMA RUC-RECOMMENDED PHYSICIAN WORK RVUS, TIMES, AND ESTIMATED CY 2013 UTILIZATION FOR MOLECULAR PATHOLOGY CPT CODES

[Please note, these values are displayed for reference only and were not used for PFS rate-setting.]

CPT code	Short descriptor	AMA RUC recommended work RVU	AMA RUC recommended physician time	AMA RUC estimated CY 2013 utilization
81200	Aspa gene			450
81201	Apc gene full sequence	1.40	60	450
81202	Apc gene known fam variants	0.77	28	90
81203	Apc gene dup/delet variants	0.80	30	400
81205*	Bckdhb gene			450
81206	Bcr/abl1 gene major bp	0.37	15	45,729
81207	Bcr/abl1 gene minor bp	0.15	11	3,500
81208	Bcr/abl1 gene other bp	0.46	18	1,000
81209*	Blm gene			450
81210	Braf gene	0.37	15	7,000
81211*	Brca1&2 seq & com dup/del			4,000
81212*	Brca1&2 185&5385&6174 var			2,000
81213*	Brca1&2 uncom dup/del var			4,000
81214*	Brca1 full seq & com dup/del			4,000
81215*	Brca1 gene known fam variant			1,000
81216*	Brca2 gene full sequence			4,000
81217*	Brca2 gene known fam variant			600

TABLE 27—AMA RUC-RECOMMENDED PHYSICIAN WORK RVUS, TIMES, AND ESTIMATED CY 2013 UTILIZATION FOR MOLECULAR PATHOLOGY CPT CODES—Continued

[Please note, these values are displayed for reference only and were not used for PFS rate-setting.]

CPT code	Short descriptor	AMA RUC recommended work RVU	AMA RUC recommended physician time	AMA RUC estimated CY 2013 utilization
81220	Cftr gene com variants	0.15	10	7,000
81221	Cftr gene known fam variants	0.40	20	1,000
81222	Cftr gene dup/delet variants	0.22	13	1,300
81223	Cftr gene full sequence	0.40	20	1,000
81224	Cftr gene intron poly t	0.15	10	1,300
81225	Cyp2c19 gene com variants	0.37	13	2,000
81226	Cyp2d6 gene com variants	0.43	15	2,000
81227	Cyp2c9 gene com variants	0.38	14	4,000
81228*	Cytogen micrarray copy nmbr			900
81229*	Cytogen m array copy no&snp			900
81235	Egfr gene com variants	0.51	20	9,000
81240	F2 gene	0.13	7	31,000
81241	F5 gene	0.13	8	43,000
81242*	Fancc gene			450
81243	Fmr1 gene detection	0.37	15	4,000
81244	Fmr1 gene characterization	0.51	20	100
81245	Flt3 gene	0.37	15	6,000
81250*	G6pc gene			450
81251*	Gba gene			450
81252	Gjb2 gene full sequence	0.65	30	400
81253	Gjb2 gene known fam variants	0.52	28	150
81254	Gjb6 gene com variants	0.40	15	500
81255*	Hexa gene			450
81256	Hfe gene	0.13	7	25,000
81257	Hba1/hba2 gene	0.50	20	4,500
81260*	Ikbkap gene			450
81261	Igh gene rearrange amp meth	0.52	21	4,500
81262	Igh gene rearrang dir probe	0.61	20	700
81263	Igh vari regional mutation	0.52	23	400
81264	Igk rearrangeabn clonal pop	0.58	22	4,000
81265	Str markers specimen anal	0.40	17	14,000
81266	Str markers spec anal addl	0.41	15	300
81267	Chimerism anal no cell selec	0.45	18	2,000
81268	Chimerism anal w/cell select	0.51	20	300
81270	Jak2 gene	0.15	10	19,000
81275	Kras gene	0.50	20	14,000
81280*	Long qt synd gene full seq			450
81281*	Long qt synd known fam var			450
81282*	Long qt syn gene dup/dlt var			450
81290*	Mcoln1 gene			450
81291	Mthfr gene	0.15	10	9,000
81292	Mlh1 gene full seq	1.40	60	1,000
81293	Mlh1 gene known variants	0.52	28	500
81294	Mlh1 gene dup/delete variant	0.80	30	800
81295	Msh2 gene full seq	1.40	60	1,000
81296	Msh2 gene known variants	0.52	28	500
81297	Msh2 gene dup/delete variant	0.80	30	800
81298	Msh6 gene full seq	0.80	30	450
81299	Msh6 gene known variants	0.52	28	600
81300	Msh6 gene dup/delete variant	0.65	30	500
81301	Microsatellite instability	0.50	20	1,000
81302	Mecp2 gene full seq	0.65	30	200
81303	Mecp2 gene known variant	0.52	28	50
81304	Mecp2 gene dup/delet variant	0.52	28	150
81310	Npm1 gene	0.39	19	4,500
81315	Pml/raralpha com breakpoints	0.37	15	1,000
81316	Pml/raralpha 1 breakpoint	0.22	12	5,000
81317	Pms2 gene full seq analysis	1.40	60	600
81318	Pms2 known familial variants	0.52	28	200
81319	Pms2 gene dup/delet variants	0.80	30	375
81321	Pten gene full sequence	0.80	30	950
81322	Pten gene known fam variant	0.52	28	150
81323	Pten gene dup/delet variant	0.65	30	200
81324*	Pmp22 gene dup/delet			450
81325*	Pmp22 gene full sequence			450
81326*	Pmp22 gene known fam variant			450
81330*	Smpd1 gene common variants			450
81331	Snrpn/ube3a gene	0.39	15	250

TABLE 27—AMA RUC-RECOMMENDED PHYSICIAN WORK RVUS, TIMES, AND ESTIMATED CY 2013 UTILIZATION FOR MOLECULAR PATHOLOGY CPT CODES—Continued

[Please note, these values are displayed for reference only and were not used for PFS rate-setting.]

CPT code	Short descriptor	AMA RUC recommended work RVU	AMA RUC recommended physician time	AMA RUC estimated CY 2013 utilization
81332	Serpina1 gene	0.40	15	1,000
81340	Trb@ gene rearrange amplify	0.63	25	4,000
81341	Trb@ gene rearrange dirprobe	0.45	19	1,000
81342	Trg gene rearrangement anal	0.57	25	5,000
81350	Ugt1a1 gene	0.37	15	850
81355	Vkorc1 gene	0.38	15	4,000
81370	Hla i & ii typing lr	0.54	15	14,000
81371	Hla i & ii type verify lr	0.60	30	9,000
81372	Hla i typing complete lr	0.52	15	4,000
81373	Hla i typing 1 locus lr	0.37	15	4,000
81374	Hla i typing 1 antigen lr	0.34	13	13,000
81375	Hla ii typing ag equiv lr	0.60	15	2,000
81376	Hla ii typing 1 locus lr	0.50	15	2,000
81377	Hla ii type 1 ag equiv lr	0.43	15	2,000
81378	Hla i & ii typing hr	0.45	20	2,000
81379	Hla i typing complete hr	0.45	15	1,000
81380	Hla i typing 1 locus hr	0.45	15	1,000
81381	Hla i typing 1 allele hr	0.45	12	1,000
81382	Hla ii typing 1 loc hr	0.45	15	1,000
81383	Hla ii typing 1 allele hr	0.45	15	1,000
81400	Mopath procedure level 1	0.32	10	2,500
81401	Mopath procedure level 2	0.40	15	2,000
81402	Mopath procedure level 3	0.50	20	2,000
81403	Mopath procedure level 4	0.52	28	2,000
81404	Mopath procedure level 5	0.65	30	2,000
81405	Mopath procedure level 6	0.80	30	1,850
81406	Mopath procedure level 7	1.40	60	1,000
81407	Mopath procedure level 8	1.85	60	1,000
81408	Mopath procedure level 9	2.35	80	1,000
81479*	Unlisted molecular pathology	.....	.....	0

* The AMA RUC concluded that these services are not typically performed by a physician at this time. Therefore, they have not been reviewed for physician work or time by the AMA RUC.

J. Payment for New Preventive Service HCPCS G-Codes

Under section 1861(ddd) of the Act, as amended by section 4105 of the Affordable Care Act, CMS is authorized to add coverage of ''additional preventive services'' if certain statutory criteria are met as determined through the national coverage determination (NCD) process, including that the service meets all of the following criteria: (1) They must be reasonable and necessary for the prevention or early detection of illness or disability, (2) they must be recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and (3) they must be appropriate for individuals entitled to benefits under Part A or enrolled under Part B. After reviewing the USPSTF recommendations for the preventive services, conducting evidence reviews, and considering public comments under the NCD process, we determined that the above criteria were met for the services listed in Table 28. Medicare now covers each of the following preventive services:

- Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse, effective October 14, 2011;
- Screening for Depression in Adults, effective October 14, 2011;
- Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs, effective November 8, 2011;
- Intensive Behavioral Therapy for Cardiovascular Disease, effective November 8, 2011; and
- Intensive Behavioral Therapy for Obesity, effective November 29, 2011.

Table 28 lists the HCPCS G-codes created for reporting and payment of these services. The Medicare PFS payment rates for these services are discussed below. The NCD process establishing coverage of these preventive services was not complete at the time of publication of the CY 2012 PFS final rule with comment period, so we could not include interim RVUs for these preventive services in the addenda to our CY 2012 final rule with comment period. However, we were able to include these HCPCS G-codes with national payment amounts for these services in the CY 2012 PFS national relative value files, which were effective January 1, 2012. From the effective date of each service to December 31, 2011, the payment amount for these codes was established by the Medicare Administrative Contractors.

TABLE 28—NEW PREVENTIVE SERVICE HCPCS G-CODES

HCPCS code	HCPCS code long descriptor	CMS national coverage determination (NCD)	CMS change request (CR)
G0442	Annual alcohol misuse screening, 15 minutes	Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (NCD 210.8).	CR7633
G0443	Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes.	Screening Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (NCD 210.8).	CR7633
G0444	Annual Depression Screening, 15 minutes	Screening for Depression in Adults (NCD 210.9)	CR7637
G0445	High-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior; performed semi-annually, 30 minutes.	Screening for Sexually Transmitted infections(STIs) and High-Intensity Behavioral Counseling (HIBC) to prevent STIs (NCD 210.10).	CR7610
G0446	Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes.	Intensive Behavioral Therapy for Cardiovascular Disease (NCD 210.11).	CR7636
G0447	Face-to-face behavioral counseling for obesity, 15 minutes.	Intensive Behavioral Therapy for Obesity (NCD 210.12).	CR7641

Two new HCPCS codes, G0442 (Annual alcohol misuse screening, 15 minutes), and G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes), were created for the reporting and payment of screening and behavioral counseling interventions in primary care to reduce alcohol misuse.

As we explained in the proposed rule, we believe that the screening service described by HCPCS code G0442 requires similar physician work as CPT code 99211 (Level 1 office or other outpatient visit, established patient). Accordingly, we proposed a work RVU of 0.18 for HCPCS code G0442 for CY 2013, the same work RVU as CPT code 99211. For physician time, we proposed 15 minutes, which is the amount of time specified in the HCPCS code descriptor for G0442. We proposed a malpractice expense crosswalk to CPT code 99211. The proposed direct PE inputs were reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *www.cms.gov/PhysicianFeeSched/*. We requested public comment on this CY 2013 proposed value for HCPCS code G0442.

Comment: Commenters supported the proposed payment for HCPCS code GO442 although a commenter suggested that in the future CMS should use the AMA RUC to assist us in valuing new codes.

Response: In response to the suggestion that we rely upon AMA RUC input in valuing new codes, we agree with the commenter that the input of the AMA RUC is extremely useful in valuing new codes and in general, we obtain its recommendations in establishing the original values for new codes. However, because this new code was added through an NCD effective as of October 14, 2011, public commenters, including the AMA RUC, were not able to comment for consideration for CY 2012. We note that since this code was valued in CY 2012 based upon CPT code 99211 and the AMA RUC had provided a recommendation on this code previously, the AMA RUC was involved, albeit indirectly, in setting this rate. In addition, there was opportunity for the AMA RUC to provide comment on this code in response to the solicitation for comment on the CY 2013 proposed rule.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal to establish a work RVU of 0.18 and a time of 15 minutes for HCPCS code G0442. For malpractice expense, we are finalizing our proposed crosswalk for HCPCS code G0442 to CPT code 99211. We are also finalizing the direct PE inputs as proposed. The direct PE inputs associated with this code are included in the CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *www.cms.gov/PhysicianFeeSched/*. Additionally, we note that the PE RVUs included in Addendum B reflect the values that result from the finalization of this policy.

As we explained in the proposed rule, we believe that the behavioral counseling service described by HCPCS code G0443 requires similar work as CPT code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes). Accordingly, we proposed a work RVU of 0.45 for HCPCS code G0443 for CY 2013, the same work RVU as CPT code 97803. For physician time, we proposed 15 minutes, which is the amount of time specified in the HCPCS code descriptor for G0443. For malpractice expense, we proposed a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *www.cms.gov/PhysicianFeeSched/*. We requested public comment on this CY 2013 proposed value for HCPCS code G0443.

Comment: Commenters supported the proposed payment for HCPCS code G0443. A commenter inquired why HCPCS code G0443 was crosswalked to CPT code 99212 and CPT code 97803 rather than to CPT code 99407 (Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes). We also received a comment that in the future CMS should use the AMA RUC to assist us in valuing new codes.

Response: The commenter was mistaken in stating that HCPCS code G0443 was crosswalked to CPT code 99212; it was crosswalked only to CPT code 97803. In response to the comment about crosswalking this code to CPT 99407, we had considered CPT code 99407 when we initially set the payment rate for HCPCS code G0443 and after consideration of this comment we continue to believe that the value based upon CPT code 97803, which is a 15-minute counseling code is appropriate. In response to the suggestion that we rely upon AMA RUC input in valuing new codes, we agree with the commenter that the input of the AMA RUC is extremely useful in valuing new codes and in general, we obtain its recommendations in establishing the original values for new codes. However, because this new code

was added through an NCD effective as of October 14, 2011, public commenters, including the AMA RUC, were not able to comment for consideration for CY 2012. We note that since this code was valued in CY 2012 based upon CPT code 97803 and the AMA RUC had provided recommendation on this code previously, the AMA RUC was involved, albeit indirectly, in setting this rate. In addition, there was opportunity for the AMA RUC to provide comment on this code in the solicitation for comment on the CY 2013 proposed rule.

After consideration of the public comments that we received, we are finalizing the proposed work RVU of 0.45 and a time of 15 minutes for HCPCS code G0443. For malpractice expense, we are finalizing our proposed crosswalk to for HCPCS code G0443 to CPT code 97803. We are also finalizing the direct PE inputs as proposed. The direct PE inputs associated with this code are included in the CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *www.cms.gov/PhysicianFeeSched/*. Additionally, we note that the PE RVUs included in Addendum B reflect the values that result from the finalization of this policy. HCPCS code G0444 (Annual Depression Screening, 15 minutes) was created for the reporting and payment of screening for depression in adults. As we explained in the proposed rule, we believe that the screening service described by HCPCS code G0444 requires similar physician work as CPT code 99211. Accordingly, we proposed a work RVU of 0.18 for HCPCS code G0444 for CY 2013, the same work RVU as CPT code 99211. For physician time, we proposed 15 minutes, which is the amount of time specified in the HCPCS code descriptor for G0444. For malpractice expense, we proposed a malpractice expense crosswalk to CPT code 99211. The proposed direct PE inputs were reflected in the CY 2013 proposed PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *www.cms.gov/PhysicianFeeSched/*. We requested public comment on this CY 2013 proposed value for HCPCS code G0444.

Comment: Commenters supported the proposed payment for HCPCS code GO444 although a commenter suggested that in the future CMS should use the AMA RUC to assist us in valuing new codes.

Response: In response to the suggestion that we rely upon AMA RUC input in valuing new codes, we agree with the commenter that the input of the AMA RUC is extremely useful in valuing new codes and in general , we obtain its recommendations in establishing the original values for new codes. However, because this new code was added through an NCD effective as of October 14, 2011, public commenters, including the AMA RUC, were not able to comment for consideration for CY 2012. We note that since this code was valued in 2012 based upon CPT code 99211 and the AMA RUC had provided recommendation on this code previously, the AMA RUC was involved, albeit indirectly, in setting this rate. In addition, there was opportunity for the AMA RUC to provide comment on this code in response to the solicitation for comment on the CY 2013 proposed rule.

After consideration of the public comments we received, we are finalizing the proposed a work RVU of 0.18, and a time of 15 minutes for HCPCS G0444 code. For malpractice expense, we are finalizing our proposed crosswalk for HCPCS G0444 code. For malpractice expense, we are finalizing our proposed crosswalk for HCPCS code G0444 to CPT code 99211. We are also finalizing the direct PE inputs as proposed. The direct PE inputs associated with this code are included in the CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *www.cms.gov/PhysicianFee Sched/*. Additionally, we note that the PE RVUs included in Addendum B reflect the values that result from the finalization of this policy. HCPCS code G0445 (high-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: Education, skills training, and guidance on how to change sexual behavioral, performed semi-annually, 30 minutes) was created for the reporting and payment of HIBC to prevent STIs. As we explained in the proposed rule, we believe that the behavioral counseling service describe by HCPCS code G0445 requires similar physician work as CPT code 97803. Accordingly, we proposed a work RVU of 0.45 for HCPCS code G0445 for CY 2013, the same work RVU as CPT code 97803. For physician time, we proposed 30 minutes, which is the amount of time specified in the HCPCS code descriptor for G0445. For malpractice expense, we proposed a malpractice expense, we proposed a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs were reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS CY 2013 proposed rule at *www.cms.gov/PhysicianFeeSched/*. We requested public comment on this CY 2013 proposed value for HCPCS code G0445.

Comment: Commenters supported the proposed payment for HCPCS code G0445 although a commenter suggested that in the future we should use the AMA RUC to assist us in valuing new codes.

Response: In response to the suggestion that we rely upon AMA RUC input in valuing new codes, we agree with the commenter that the input of the AMA RUC is extremely useful in valuing new codes and in general, we obtain its recommendations in establishing the original values for new codes. However, because this new code was added through an NCD effective as of October 14, 2011, public commenters, including the AMA RUC, were not able to comment for consideration for CY 2012. We note that since this code was valued in CY 2012 based upon CPT code 97803 and the AMA RUC had provided recommendation on this code previously, the AMA RUC was involved, albeit indirectly, in setting this rate. In addition, there was opportunity for the AMA RUC to provide comment on this code in response to the solicitation for comment on the CY 2013 proposed rule.

After consideration of the public comments we received, we are finalizing the proposed a work RVU of 0.45 and a time of 30 minutes for HCPCS code G0445. For malpractice expense, we are finalizing our proposed crosswalk for HCPCS code G0445 to CPT code 97803. We are also finalizing the direct PE inputs as proposed. The direct PE inputs associated with this code are included in the CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *www.cms.gov/PhysicianFeeSched/*. Additionally, we note that the PE RVUs included in Addendum B reflect the values that result from the finalization of this policy. HCPCS code G0446 (Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes) was created for the reporting and payment of intensive behavioral therapy for cardiovascular disease. As we explained in the proposed rule, we believe that the behavioral therapy service described by HCPCS code G0446 requires similar physician work as CPT code 97803. Accordingly, we proposed a work RVU of 0.45 for HCPCS code G0446 for CY 2013, the same work RVU as CPT code

97803. For physician time, we proposed 15 minutes, which is the amount of time specified in the HCPCS code descriptor for G0446. For malpractice expense, we proposed a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs were reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *www.cms.gov/PhysicianFeeSched/*. We requested public comment on this CY 2013 proposed value for HCPCS code G0446.

Comment: Commenters supported the proposed payment for HCPCS code GO446. In addition, a commenter urged a change in our policy to allow billing of multiple units of this code in one encounter. We also received a comment that in the future CMS should use the AMA RUC to assist us in valuing new codes.

Response: In response to the suggestion regarding billing multiple units of HCPCS code G0446, this proposal deals only with the payment rate for this service, not coverage issues. We note that the NCD is clear that only one visit annually is covered. In response to the suggestion that we rely upon AMA RUC input in valuing new codes, we agree with the commenter that the input of the AMA RUC is extremely useful in valuing new codes and in general, we obtain its recommendations in establishing the original values for new codes. However, because this new code was added through an NCD effective as of October 14, 2011, public commenters, including the AMA RUC, were not able to comment for consideration for CY 2012. We note that since this code was valued based upon CPT code 97803 and AMA RUC had provided recommendation on this code previously, the AMA RUC was involved, albeit indirectly, in setting this rate. In addition, there was opportunity for the AMA RUC to provide comment on this code in response to the solicitation for comment on the CY 2013 proposed rule.

Based upon the comments we received, we are finalizing the proposed rate for HCPCS code G0446. It will be valued with a work RVU of 0.45, and with a time of 15 minutes. For malpractice expense, we are finalizing our proposed crosswalk for HCPCS code G0446 to CPT code 97803. We are also finalizing the direct PE inputs as proposed. The direct PE inputs associated with this code are included in the CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *www.cms.gov/PhysicianFeeSched/*. Additionally, we note that the PE RVUs included in Addendum B reflect the values that result from the finalization of this policy. HCPCS G0447 (Face-to-face behavioral counseling for obesity, 15 minutes) was created for the reporting and payment of intensive behavioral therapy for obesity. As we explained in the proposed rule, we believe that the behavioral counseling service described by HCPCS code G0447 requires similar physician work to CPT code 97803. Accordingly, we proposed a work RVU of 0.45 for HCPCS code G0447 for CY 2013, the same work RVU as CPT code 97803. For physician time, we proposed 15 minutes, which is the amount of time specified in the HCPCS code descriptor for G0447. For malpractice expense, we proposed a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs were reflected in the CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *www.cms.gov/PhysicianFeeSched/*. We requested public comment on this CY 2013 proposed value for HCPCS code G0447.

Comment: Commenters supported the proposed payment for HCPCS code GO447. In addition, a commenter urged a change in our policy to allow billing of multiple units of this code in one encounter. We also received a comment that in the future CMS should use the AMA RUC to assist us in valuing new codes.

Response: With regard to billing for multiple units of HCPCS code G0447 in the same encounter, this proposal addresses only the payment rate for, not the coverage of this code. We note that the NCD establishes that coverage is for one visit per day of service. In response to the suggestion that we rely upon AMA RUC input in valuing new codes, we agree with the commenter that the input of the AMA RUC is extremely useful in valuing new codes and in general, we obtain its recommendations in establishing the original values for new codes. However, because this new code was added through an NCD effective as of October 14, 2011, public commenters, including the AMA RUC, were not able to comment for consideration for CY 2012. We note that since this code was valued in CY 2012 based upon CPT code 97803 and AMA RUC had provided recommendation on this code previously, the AMA RUC was involved, albeit indirectly, in setting this rate. In addition, there was opportunity for the AMA RUC to provide comment on this code in the response to the solicitation for comment on the CY 2013 proposed rule.

After the consideration of the public comments we received, we are finalizing the proposed work RVU of 0.45 and a time of 15 minutes for HCPCS G0447 code. For malpractice expense, we are finalizing our proposal to crosswalk HCPCS code G0447 to CPT code 97803. We are also finalizing the direct PE inputs as proposed. The direct PE inputs associated with this code are included in the CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*. Additionally, we note that the PE RVUs included in Addendum B reflect the values that result from the finalization of this policy.

K. Certified Registered Nurse Anesthetists Scope of Benefit

The benefit category for services furnished by a certified registered nurse anesthetist (CRNA) was added in section 1861(s)(11) of the Act by section 9320 of the Omnibus Budget Reconciliation Act (OBRA) of 1986. Since this benefit was implemented on January 1, 1989, CRNAs have been eligible to bill Medicare directly for services within this benefit category. Section 1861(bb)(2) of the Act defines a CRNA as ''a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists.''

Section 410.69(b) defines a CRNA as a registered nurse who: (1) Is licensed as a registered professional nurse by the State in which the nurse practices; (2) meets any licensure requirements the State imposes with respect to nonphysician anesthetists; (3) has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and (4) meets one of the following criteria: (i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or (ii) is a graduate of a program described in paragraph (3) of

this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.

Section 1861(bb)(1) of the Act defines services of a CRNA as ''anesthesia services and related care furnished by a certified registered nurse anesthetist (as defined in paragraph (2)) which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished.'' CRNAs are paid at the same rate as physicians for furnishing such services to Medicare beneficiaries. Payment for services furnished by CRNAs only differs from physicians in that payment to CRNAs is made only on an assignment-related basis (§ 414.60) and supervision requirements apply in certain circumstances.

At the time that the Medicare benefit for CRNA services was established, anesthesia practice, for anesthesiologists and CRNAs, largely occurred in the surgical setting and services other than anesthesia (medical and surgical) were furnished in the immediate pre- and post-surgery timeframe. The scope of ''anesthesia services and related care'' as delineated in section 1861(bb)(1) of the Act reflected that practice. As anesthesiologists and CRNAs have moved into other practice settings, questions have arisen regarding what services are encompassed under the benefit category's characterization of ''anesthesia and related care.'' As an example, some CRNAs now offer chronic pain management services that are separate and distinct from a surgical procedure. We recently received additional information about upcoming changes to CRNA curricula to include specific training regarding chronic pain management services. Such changes in CRNA practice have prompted questions as to whether these services fall within the scope of section 1861(bb)(1) of the Act.

As we noted in the CY 2013 proposed rule (77 FR 44788), Medicare Administrative Contractors (MACs) have reached different conclusions as to whether the statutory benefit category description of ''anesthesia services and related care'' encompasses the chronic pain management services furnished by CRNAs. The scope of the benefit category determines the scope of services for which a physician, practitioner, or supplier may receive Medicare payment. In order for the specific services to be paid by Medicare, the services must be reasonable and necessary for treatment of the patient's illness or injury.

To address what is included in the benefit category for CRNAs in the CY 2013 proposed rule, we assessed our current regulations and subregulatory guidance, and determined that the existing guidance does not specifically address whether chronic pain management is included in the CRNA benefit. In the Internet Only Manual (Pub 100–04, Ch 12, Sec 140.4.3), we discuss the medical or surgical services that fall under the ''related care'' language stating: ''These may include the insertion of Swan Ganz catheters, central venous pressure lines, pain management, emergency intubation, and the pre-anesthetic examination and evaluation of a patient who does not undergo surgery.'' Some have interpreted the reference to ''pain management'' in this language as authorizing direct payment to CRNAs for chronic pain management services, while others have taken the view that the services highlighted in the manual language are services furnished in the perioperative setting and refer only to acute pain management associated with the surgical procedure.

After assessing in the proposed rule (see 77 FR 44788) the information available to us, we concluded that chronic pain management was an evolving field, and we recognized that certain states have determined that the scope of practice for a CRNA should include chronic pain management to meet health care needs of their residents and ensure their health and safety. We also found that several states, including California, Colorado, Missouri, Nevada, South Carolina, and Virginia, were debating whether to include pain management in the CRNA scope of practice. After determining that the scope of practice for CRNAs was evolving and that there was not a clear answer on pain management specifically, we proposed to revise our regulations at § 410.69(b) to define the statutory benefit for CRNA services with deference to state scope of practice laws. Specifically, we proposed to add the following language: ''Anesthesia and related care includes medical and surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the state in which the services are furnished.'' We explained that this proposed definition would set a Medicare standard for the services that can be furnished and billed by CRNAs while allowing appropriate flexibility to meet the unique needs of each state. The proposal also dovetailed with the language in section 1861(bb)(1) of the Act requiring the state's legal authorization to furnish CRNA services as a key component of the CRNA benefit category. Finally, we stated that the proposed benefit category definition was also consistent with our policy to recognize state scope of practice as defining the services that can be furnished and billed by other NPPs.

The following is a summary of the comments we received regarding the proposal to revise our regulations at § 410.69(b) to define the statutory description of CRNA services. We received a significant volume of comments from specialty groups, individual physicians, and practitioners, including CRNAs and Student Registered Nurse Anesthetists (SRNAs), educational program directors, and patients, who strongly supported defining the CRNA benefit broadly. There were also many commenters who strongly opposed this proposal, including specialty groups, individual physicians and practitioners, patients, educational program directors, and a patient advocacy group.

Comment: Among those supporting the concept of our proposal, we received several comments suggesting alternative regulatory definitions of the statutory benefit category phrase, ''anesthesia and related care.'' Many commenters said that CMS should allow CRNAs to practice to the full extent of state law. Some commenters provided alternative definitions for anesthesia and related care. These included ''medical and surgical services that are related to anesthesia or that a CRNA is legally authorized to perform by the State in which the services are furnished,'' ''medical and surgical services that are related to anesthesia, including chronic pain management services unless specifically prohibited or outside the scope of the CRNA's license to practice,'' ''medical services, surgical services, and chronic and acute pain management services that a CRNA is legally authorized to perform by the State in which the services are furnished,'' ''medical and surgical services a CRNA is legally authorized to perform by the state in which services are furnished and which are done to provide surgical or obstetrical anesthesia or alleviate post-operative or chronic pain,'' and ''medical and surgical services that are related to anesthesia, including chronic pain management, unless a CRNA is legally prohibited to perform by the State in which the services are furnished.'' One commenter made the point that Medicare should use a definition that included coverage of advanced practice registered nurse services that are within the scope of practice under applicable state law, just as physicians' services are now covered.

Other commenters referenced preamble text in our 1992 final rule, which states ''we describe related care services as * * * pain management services, and other services not directly connected with the anesthesia service or associated with the surgical service'' and noted that historically, related care services have been recognized as a different class of anesthesia services, which may or may not be related to anesthesia. One commenter requested that we define ''related care'' separately from anesthesia, as ''medical and surgical services not directly related to anesthesia, including but not limited to the insertion of arterial lines, central venous pressure lines, and Swan Ganz catheters, acute and chronic pain management and emergency intubation, and that a CRNA is legally authorized to perform by the state in which the services are furnished.''

Some commenters pointed to Medicare policies allowing other advanced practice nurses such as nurse practitioners or clinical nurse specialists to furnish and bill for physicians' services as support for recognizing a similar interpretation of the scope of CRNA practice. Commenters stated that CRNAs should be able to practice to the full extent of state law. Commenters cited the Institute of Medicine report [The Future of Nursing: Leading Change, Advancing Health, 11/17/10] that stated that nurses should be able to practice to the full extent of their education and training.

Our proposal to define related care as ''related to anesthesia'' resulted in various views as to whether this would include pain management and other services. Some stated that it restricted the benefit category, but others believed that it expanded it. The commenters further stated that there are no chronic, long-term, anesthesia related services that occur outside the operating room or recovery room where the practice of anesthesia is appropriate. Others stated that chronic pain management services are outside the scope of perioperative related care defined in the Act, and that chronic pain is not related to anesthesia.

Response: After reviewing comments regarding our proposed definition of ''anesthesia and related care,'' we believe that the proposed regulation language stating that ''Anesthesia and related care includes medical and surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the state in which the services are furnished'' would not accomplish our goals. It would require updating as health care evolves and as CRNA practice changes. It also would continue Medicare's differentiation between CRNAs and other NPPs because the Medicare benefit for other NPPs relies more heavily on the NPPs' authority under state law. In addition, we agree with commenters that the primary responsibility for establishing the scope of services CRNAs are sufficiently trained and, thus, should be authorized to furnish, resides with the states. We agree with commenters that, as CRNA training and practice evolve, the state scope of practice laws for CRNAs serve as a reasonable proxy for what constitutes ''anesthesia and related care.'' Therefore, we are revising § 410.69(b) to define the statutory benefit category for CRNAs, which is specified as ''anesthesia and related care,'' as ''those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished.'' By this action, we are defining the Medicare benefit category for CRNAs as including any services the CRNA is permitted to furnish under their state scope of practice. In addition, this action results in CRNAs being treated similarly to other advanced practice nurses for Medicare purposes. This policy is consistent with the Institute of Medicine's recommendation that Medicare cover services provided by advanced practice nurses to the full extent of their state scope of practice. CMS will continue to monitor state scope of practice laws for CRNAs to ensure that they do not expand beyond the appropriate bounds of ''anesthesia and related care'' for purposes of the Medicare program.

Comment: Some commenters suggested that the proposal expands the scope of practice of CRNAs into the practice of medicine, and that the proposal undermines medical education, the practice of medicine, and the pain medicine specialty by equating nurses with physicians. Commenters further stated that such proposals, which lead to privileging and reimbursement for nonphysician practitioners that are identical to that of physicians, decrease the incentives to complete the rigorous training involved in medical school. Others stated that the proposal would interfere with the authority of states to regulate scope of practice.

Response: We acknowledge the concerns of the physician community; however, the intent of the proposal is not to undermine medical education, the practice of medicine, or the pain medicine specialty, but to establish parity between the scope of the Medicare benefit category for CRNAs and the CRNA authority to practice under state law. This proposal does not address payment rates for anesthesiologists or CRNAs. The statutory provisions that establish payment rates for CRNAs at the same rate as anesthesiologists are relatively longstanding. Our proposal in no way is intended to interfere with the authority of individual states; rather, it largely defers to individual states to determine the scope of practice for CRNAs. We believe that using state scope of practice law as a proxy for services encompassed in the statutory benefit language ''anesthesia and related care'' is preferable to choosing among individual interpretations of whether particular services fall within the scope of ''anesthesia and related care.'' Moreover, we believe states are in an ideal position to gauge the status of, and respond to changes in, CRNA training and practice over time that might warrant changes in the definition of the scope of ''anesthesia services and related care'' for purposes of the Medicare program. As such, we believe it is appropriate to look to state scope of practice law as a proxy for the scope of the CRNA benefit.

Comment: Many commenters addressed the extent to which the standards for nurse anesthesia curricula and the content of nurse anesthesia educational programs do or do not prepare CRNAs to practice outside the perioperative setting, and specifically, to furnish chronic pain services. We received detailed comments regarding the necessary components of chronic pain services and conflicting information about whether CRNAs are trained or licensed to furnish such services. We received thorough descriptions of the skills required to furnish chronic pain services and the necessity of medical education to prepare one to furnish such services. Commenters also provided information about the inherent dangers involved in chronic pain services, the manner in which technical skills in chronic pain procedures are obtained, and the ways in which chronic pain services are or are not similar to other procedures performed by CRNAs in the perioperative setting and for labor epidurals. We received many comments from the physician community with concerns about the possibility of the furnishing of procedures that are not indicated due to lack of medical knowledge required to screen out patients who are not appropriate candidates for procedures.

Some commenters pointed to the long period of time during which CRNAs have furnished chronic pain services with no documented differences in

patient outcomes, while others expressed concern about negative outcomes observed from inadequately trained providers. Descriptions were also provided regarding lawsuits at the state level that have debated whether CRNAs are qualified to furnish chronic pain services, the importance of medical regulation in protecting patients who may not be able to differentiate between different types of providers, and the role of the medical education process in ensuring competency of physicians. Other commenters opined that it is the responsibility of the individual provider to assure his or her competency for any and all procedures furnished.

Response: We acknowledge the varying perspectives about the education and training of CRNAs to furnish chronic pain management services as well as differences of opinion regarding the safety of chronic pain management services furnished by CRNAs. We are unable, at this time, to assess the appropriateness of the CRNA training relating to specific procedures. We are also unaware of any data regarding the safety of chronic pain management services when furnished by different types of professionals. However, we expect that states take into account all appropriate practitioner training and certifications, as well as the safety of their citizens, when making decisions about the scope of services CRNAs are authorized to furnish and providing licenses to individual practitioners in their jurisdictions.

We note that we did not address the services that CRNAs are trained and qualified to furnish in our proposal or in this final rule with comment period. Our proposal and this final rule merely define what services are included in the scope of the Medicare benefit established in section 1861(bb)(1) of the Act. The definition that we are adopting uses the state scope of practice as a proxy for what the term ''anesthesia and related care'' in section 1861(bb)(1) of the Act means and thus leaves decisions about what services constitute anesthesia and related care to be resolved by the state. This appropriately recognizes the actions of state bodies formed specifically to address the issue of what constitutes the scope of practice for a CRNA. We believe that determining whether or not CRNAs are adequately trained and can safely furnish chronic pain management is an appropriate decision for state bodies. This proposal is consistent with the Institute of Medicine's report on advanced practice nursing, which recommends that Medicare should ''include coverage of advanced practice registered nurse services that are within the scope of practice under applicable state law, just as physicians' services are now covered.''

We agree with commenters that it also is the responsibility of individual practitioners (physicians and CRNAs) to ensure that they are adequately trained and qualified to furnish any and all procedures that they furnish.

Comment: We received comments about the cost of CRNA services relative to those furnished by anesthesiologists. Commenters stated that chronic pain management services are less costly than surgical interventions, and that the services of CRNAs are more cost-effective for the Medicare program. Others stated that allowing CRNAs to furnish these services could increase spending due to the provision of inappropriate services and the complications that could result from procedures furnished by CRNAs who are not adequately trained.

Response: We do not have sufficient evidence to determine that chronic pain management interventions reduce the need for surgical interventions, or that there would be increased provision of inappropriate services and complications under a definition of the Medicare benefit category that defines ''anesthesia and related care'' as services a CRNA is authorized to furnish in his or her state. Spending for services under Medicare is not a factor in determining whether the statutory benefit encompasses particular services. However, we would note that CRNAs are generally paid at the same rate as anesthesiologists so there are no direct cost savings when services are furnished by CRNAs.

Comment: We received comments regarding special concerns about access in rural areas. Commenters stated that CRNAs help patients avoid traveling long distances and long waits for appointments by having local providers available. Furthermore, commenters noted that as the population ages, the demand for chronic pain management services will increase. Commenters stated that decreased access to chronic pain management services (which would result if CRNAs are not permitted to furnish and bill for these services) would result in more institutionalization, reduced quality of life, longer wait times, and increased costs. Others stated that chronic pain management services are not emergent care services; that chronic pain management is a specialty that should be furnished by those with a high degree of sub-specialty training, and that pain physicians can be spread out over large areas since only a small minority of patients need procedural care. Some commenters cited a shortage of pain management physicians qualified to treat chronic pain, others stated that there is no shortage of such providers, while still others stated that the proposal may increase access, but at the expense of having unqualified providers. Finally, some commenters stated that procedures furnished improperly pose a greater danger than a lack of available services.

Response: While assuring access for beneficiaries in rural areas is a priority for Medicare, we do not have sufficient data to evaluate the presence or degree of problems of access to chronic pain management services in rural areas. We also do not have evidence that CRNAs have furnished chronic pain management services in quantities sufficient to improve any access problems in rural areas. We further lack sufficient data to determine whether beneficiaries who lack access to a CRNA care are more likely to suffer the negative outcomes cited by commenters. This lack of information does not deter us taking action to define the statutory benefit as it is not necessary to conclude that beneficiaries will suffer negative consequences to prompt us to act. Rather we are issuing this regulation based upon the factors we described above.

Comment: We received comments regarding those services included in the definition of anesthesia and related care, as well as services ''related to anesthesia.'' Some commenters stated that chronic pain management services are not directly ''related to anesthesia'' but still constitute ''related care''. Other commenters stated that CMS has already acknowledged in early preamble language that CRNAs may furnish services not directly related to anesthesia. Still other commenters stated that chronic pain services are not related to anesthesia in any way. One commenter suggested that CMS has already differentiated between anesthesia related acute pain and interventional chronic pain based on the creation of different specialty codes for anesthesia and chronic pain. One commenter requested that CMS make a regulatory change to allow CRNAs to order diagnostic tests in order to effectively provide chronic pain management services.

Response: We believe that the statutory intent was to include services not directly related to the peri-anesthetic setting in the CRNA benefit category. We believe that relying on state scope of practice to define the services encompassed in anesthesia and related care is preferable to choosing among conflicting definitions of

''anesthesia and related care'' or listing the specific services that fall within that benefit category. Rather, we believe states are in a better position to gauge the status of, and respond to changes in, CRNA training and practice over time that might warrant changes in the definition of the scope of ''anesthesia services and related care'' for purposes of the Medicare program. As such, we believe it is appropriate to look to state scope of practice law as a proxy for the scope of the CRNA benefit.

Comment: Several commenters expressed concern with the wording of our proposal; specifically, that the term ''related to anesthesia'' was unclear and subject to interpretation. States do not typically define services ''related to anesthesia'' in their state scope of practice acts.

Response: We agree with commenters that the wording of the proposal was unclear. In response to these and other commenter concerns, we are adopting a modification of our proposal to rely on state scope of practice to define the services encompassed in ''anesthesia and related care'' under section 1861(bb)(1) of the Act.

Comment: One commenter requested that we provide clarification for the payment of CRNA services furnished; specifically, which medical and/or surgical CRNA services are eligible for cost-based reimbursement (for CRNA pass-through payments or Method II billing for Critical Access Hospitals).

Response: We will be modifying the Internet Only Manual to reflect the change we are making in this final rule with comment period. The request for the list of services that are eligible for cost-based reimbursement is beyond the scope of this rule, as it pertains to hospital billing. We anticipate this matter will be addressed separately in a forthcoming transmittal.

Comment: Commenters requested that CMS instruct Medicare contractors to review prior denials of claims for CRNA services prior to any final rule determination of the scope of the CRNA Medicare benefit category.

Response: This definition of the Medicare benefit for CRNAs will be effective for services furnished on or after January 1, 2013. It does not apply to services furnished prior to this point so we will not be instructing contractors to review prior denials of claims.

After consideration of all comments, we are finalizing our proposal with modification to revise our regulations at § 410.69(b) to define ''Anesthesia and related care'' under the statutory benefit for CRNA services as follows: ''Anesthesia and related care means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished.'' We will continue to monitor the state scope of practice laws for CRNAs in order to insure that the use of state scope of practice as a proxy to define ''anesthesia services and related care'' is consistent with the goals and needs of Medicare program.

L. Ordering of Portable X-Ray Services

Portable x-ray suppliers furnish diagnostic imaging services at a beneficiary's location. These services are most often furnished in residences, including private homes and alternative living facilities (for example, nursing homes) rather than in a traditional clinical setting (for example, a doctor's office or hospital). The supplier transports mobile diagnostic imaging equipment to the beneficiary's location, sets up the equipment, and administers the test onsite. The supplier may interpret the results itself or it may furnish the results to an outside physician for interpretation. Portable x-ray services may avoid the need for expensive ambulance transport of frail beneficiaries to a radiology facility or hospital.

Our Medicare Conditions for Coverage (CfC) regulations require that ''portable x-ray examinations are performed only on the order of a doctor of medicine (MD) or doctor of osteopathy (DO) licensed to practice in the state * * *'' (§ 486.106(a)). With the exception of portable x-ray services, Medicare payment regulations at § 410.32(a) allow physicians, as defined in section 1861(r) of the Act, and certain nonphysician practitioners at § 410.32(a)(2) to order diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests as long as those nonphysician practitioners are operating within the scope of their authority under state law and within the scope of their Medicare statutory benefit. Physicians other than an MD or DO recognized to order diagnostic tests under § 410.32(a) include the following limited-license practitioners: Doctor of optometry, doctor of dental surgery and doctor of dental medicine, and doctor of podiatric medicine. Nonphysician practitioners authorized to order diagnostic tests under § 410.32(a)(2) include nurse practitioners, physician assistants, clinical nurse specialists, certified nurse-midwives, clinical psychologists, and clinical social workers. Nonphysician practitioners have become an increasingly important component of clinical care, and we believe that delivery systems should take full advantage of all members of a healthcare team, including nonphysician practitioners.

Although current Medicare regulations limit the ordering of portable x-ray services to a MD or a DO, the Office of the Inspector General (OIG) in its December 2011 report entitled *Questionable Billing Patterns of Portable X-Ray Suppliers* (OEI–12–10–00190) found that Medicare was paying for portable x-ray services ordered by physicians other than MDs and DOs, including podiatrists and chiropractors, and by nonphysician practitioners. We issued a special education article on January 20, 2012, through the Medicare Learning Network (MLN) ''*Important Reminder for Providers and Suppliers Who Provide Services and Items Ordered or Referred by Other Providers and Suppliers,*'' reiterating our current policy that portable x-ray services can only be ordered by a MD or DO. The article is available at *http://www.cms.gov/MLNMattersArticles/downloads/SE1201.pdf* on the CMS Web site. Since the publication of the above mentioned article, several stakeholders have told us that members of the healthcare community fail to distinguish ordering for portable x-ray services from ordering for other diagnostic services where our general policy is to allow nonphysician practitioners and physicians other than MDs and DOs to order diagnostic tests within the scope of their authority under state law and their Medicare statutory benefit. They report finding the different requirements confusing.

We proposed to revise our current regulations, which limit ordering of portable x-ray services to only a MD or DO, to allow other physicians and nonphysician practitioners acting within the scope of their Medicare benefit and state law to order portable x-ray services. Specifically, we proposed revisions to the CfC at § 486.106(a) and § 486.106(b) to permit portable x-ray services to be ordered by a physician or nonphysician practitioner in accordance with the ordering policies for other diagnostic services under § 410.32(a).

This proposed change would allow a MD or DO, as well as a nurse practitioner, clinical nurse specialist, physician assistant, certified nurse-midwife, doctor of optometry, doctor of dental surgery and doctor of dental medicine, doctor of podiatric medicine, clinical psychologist, and clinical social worker to order portable x-ray services within the scope of their authority under state law and the scope of their Medicare benefit. Although all of these physicians and nonphysician practitioners are authorized to order

diagnostic services in accordance with § 410.32(a), their Medicare benefit and state scope of practice delimits the services that they can furnish. For example, the state scope of practice for clinical psychologists typically is limited to the diagnosis and treatment of mental health disorders and related services. The scope of the Medicare benefit for clinical social workers under 1861(hh) of the Act limits their ability to order diagnostic tests to mental health related tests.

Comment: The majority of commenters supported allowing additional nonphysician and limited-license practitioners to order portable x-ray services. The commenters stated that this proposal is consistent with the increasing role for practitioners other than MDs or DOs in health care delivery today, with nonphysician and limited license practitioner training and practice, with staffing decisions for care furnished in nursing homes and other home care settings, and with the scope of practice for various practitioners under state law.

Response: We thank the commenters for their support and agree with these comments. As we stated in the CY 2013 PFS proposed rule, we believe nonphysician practitioners have become an increasingly important component of clinical care, and we believe that delivery systems should take full advantage of all members of a healthcare team, including nonphysician practitioners. Allowing limited-license and nonphysician practitioners to order portable x-ray services within the scope of their practice will enhance the role of those practitioners.

Comment: Some commenters either questioned or opposed the ability of certain nonphysician or limited-license practitioners to order portable x-ray services. The commenters stated that by including clinical psychologists and clinical social workers, our proposal was too broad as these nonphysician practitioners do not have the appropriate education or training to order portable x-ray services. In addition, they noted that the ordering of portable x-ray services is not within clinical psychologists' and clinical social workers' state scopes of practice. One commenter stated that the ordering authority for portable x-ray services should only be expanded to physician assistants, nurse practitioners, and doctors of podiatric medicine, stating that there is no convincing or clinically supportable rationale for other practitioners identified in § 410.32(a), including certified nurse-midwives, doctors of optometry, doctors of dental surgery and doctors of dental medicine, clinical social workers, and clinical psychologists, to order portable x-ray services. A few commenters stated that some nonphysician and limited-license practitioners have not been trained to diagnose an illness, to use x-rays as part of the diagnosis and treatment of a beneficiary, to know how to interpret an x-ray, and to plan a course of medically appropriate follow-up treatment. Commenters requested the clinical rationale and FY 2011 data on portable x-ray ordering by select nonphysician practitioners. One commenter stated that deferring to state scope of practice laws for limited- license and nonphysician practitioners did not constitute sufficient stewardship by Medicare to ensure payment for appropriate services.

Response: We disagree. We proposed to modify our rule for ordering portable x-ray services to make it consistent with rules for ordering all other diagnostic tests. Our proposed policy would eliminate the specific requirements limiting the types of practitioners who can order portable x-ray services, and instead place ordering for portable x-ray services under the general regulations governing ordering of diagnostic tests in § 410.32(a)(2). Under § 410.32(a)(2), limitations on the ability of various practitioners to order diagnostic tests are established by the practitioner's scope of practice under state law and the scope of the practitioner's Medicare benefit. The current regulation applies to x-rays (other than portable x-rays), MRI, CT scans, and a host of other diagnostic tests that are more complex and potentially higher risk than portable x-ray services. We do not believe that nonphysician and limited-license practitioners who can routinely order and employ the results of reasonable and necessary x-rays, MRIs, and CT scans should continue to be precluded from ordering and utilizing portable x-ray imaging in the same manner. Further, most of the nonphysician practitioners listed in § 410.32(a)(2) are authorized by statute to furnish physician services under the scope of their Medicare benefit and state scope of practice, including ordering, interpreting, and using test results to treat a beneficiary.

With regard to clinical social workers, under section 1861(hh) of the Act, the scope of their Medicare benefit is further limited to services ''for the diagnosis and treatment of mental illnesses.'' Therefore, the proposed change to our regulations to allow clinical social workers to order portable x-ray services in the same way that they are permitted to order other diagnostic tests under § 410.32(a) would not allow clinical social workers to order portable x-ray services. Portable x-ray services fall within the scope of the Medicare benefit for the remaining nonphysician and limited-license practitioners, including clinical psychologists. As noted above, we believe state scope of practice laws might limit ordering of portable x-ray services by clinical psychologists or other practitioners. Additionally, certain other practitioners are unlikely to have a reason to order portable x-ray services, such as doctors of optometry. We have no evidence to suggest that clinical psychologists or other limited license or nonphysician practitioners are ordering significant numbers of x-rays, CTs, and MRIs under § 410.32(a) authority at this time. We do not expect any marked change in ordering patterns following the change in regulation to allow for ordering of portable x-ray services.

With regard to the request for FY 2011 data on portable x-ray ordering by select nonphysician practitioners, we do not believe this or any recent data on portable x-ray ordering patterns for limited-license or nonphysician practitioners would be meaningful information regarding future potential ordering patterns for portable x-ray services because these practitioners are not permitted to order portable x-ray services under the current regulation. We believe our proposal is consistent with our current regulations that generally allow nonphysician practitioners to order diagnostic services, and the agency's interest in having delivery systems take full advantage of all members of a healthcare delivery team. We describe below our intention to design monitoring systems that will capture excessive ordering.

Comment: Several commenters requested that CMS clarify that the proposal for CY 2013 is actually a clarification of long standing policy that nonphysician practitioners have been able to order portable x-ray services since implementation of the their authority to order diagnostic tests under § 410.32(a)(2) and requested that CMS indicate that this authority is not a change in policy effective January 1, 2013. Commenters stated that the regulations at § 410.32(a), established as a result of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33), were promulgated long after the 1969 CfC requirement at § 486.106 and that the more recent regulation trumps older requirements. These commenters stated that it was merely an oversight on the part of CMS when the agency failed to update the regulations at § 486.106. They also stated that some manual language and educational materials have

been inconsistent in communicating that only MDs or DOs can order portable x-ray services over the years. Commenters requested that if CMS does conclude that allowing nonphysician and limited-license practitioner ordering of portable x-ray services is a change in policy for CY 2013, then CMS should specify in the preamble that no repayments or other actions are required, including recoupment efforts as a result of the OIG's findings in the December 2011 report entitled *Questionable Billing Patterns of Portable X-ray Suppliers* (OEI 12–10–00190).

Response: There is a longstanding regulation requiring ordering of portable x-ray services by an MD or DO at § 486.106(a) and § 486.106(b). There is a specific section of the regulation under § 410.32 dedicated to portable x-ray services, § 410.32(c), that explicitly cross-references the requirements under § 486.106. As such, we do not believe that, when revising the regulation at § 410.32 to expand the general rules for ordering diagnostic tests under the BBA, the agency simply failed to notice the requirement in the same section relating to portable x-ray tests. Further, the specific requirement for MD or DO ordering of portable x-ray services under § 410.32(c) explicitly excepts portable x-ray services from the general ordering rules under § 410.32(a). The only means to revise the regulations containing this longstanding CfC is through notice and comment rulemaking, which was the purpose of the proposal we made in the CY 2013 proposed rule. The change in policy to allow limited-license and nonphysician practitioners to order portable x-ray services will be effective beginning in CY 2013.

The OIG report concluded, and CMS concurred, that CMS should recoup payment for portable x-ray services identified under the report as ordered by limited-license physicians and nonphysician practitioners, other than a MD or DO in accordance with our regulations at § 410.32(c) and § 486.106 since this was consistent with this recommendation. We will continue our recoupment efforts in response to the OIG report. However, we have instructed our payment contractors that the ordering of portable x-ray services should not be made a priority for additional medical review activity beyond claims identified in the OIG audit.

After considering the public comments received, we are finalizing our CY 2013 proposal to revise the CfC at § 486.106(a) and § 486.106(b) to permit portable x-ray services to be ordered by physicians or nonphysician practitioners in accordance with the general ordering policies for other diagnostic services as specified under § 410.32(a). Therefore, effective for services furnished on or after January 1, 2013, the following practitioners will be permitted to order portable x-rays in accordance with Medicare regulations and subject to their scope of practice under state law and their applicable Medicare statutory benefit: A physician (including an MD or a DO, doctor of optometry, doctor of dental surgery and doctor of dental medicine, and doctor of podiatric medicine), or a nurse practitioner, clinical nurse specialist, physician assistant, certified nurse-midwife, or clinical psychologist, where the ordering of portable x-ray services is within the scope of their practice under state law. As discussed above, although clinical social workers are permitted to order diagnostic tests under § 410.32(a)(2), the scope of their Medicare benefit is limited to services for the diagnosis and treatment of mental illnesses. As such, we do not believe these nonphysician practitioners would need to order portable x-ray services. We also are finalizing revisions to the language included under § 410.32(c) specific to portable x-ray services to recognize the same authority for physicians and nonphysician practitioners to order diagnostic tests as is prescribed for other diagnostic services under § 410.32(a). Finally, we are finalizing two technical corrections that we proposed to make in the CY 2013 PFS proposed rule. One is to § 410.32(d)(2), where we currently cite paragraph (a)(3) for the definition of a qualified nonphysician practitioner. The definition of a qualified nonphysician practitioner is currently found in paragraph (a)(2), while paragraph (a)(3) does not exist; therefore, we are correcting the citation. The second technical correction is in § 410.32(b)(2)(iii) to better reflect the statutory authority to furnish neuropsychological testing in addition to psychological testing. We did not receive any comments on these proposed technical corrections. The documentation requirement for this paragraph remains unchanged.

Although we believe it is appropriate to finalize policy to allow nonphysician practitioners and limited-license practitioners to order portable x-ray services within the scope of their authority under state law and the scope of their Medicare statutory benefit given overall changes in health care delivery practice patterns since the beginning of the Medicare program, we remain concerned about the OIG's recent findings. The OIG observed other questionable billing patterns for portable x-ray services in addition to ordering by nonphysician practitioners. Of specific note was the observation that some portable x-ray suppliers are furnishing services on the same day that the beneficiary also receives services in a clinical setting, such as the physician office or hospital. Under current regulations at § 486.106(a)(2), the order for portable x-ray services must include a statement concerning the condition of the beneficiary which indicates why portable x-ray services are necessary. If, on the same day that a portable x-ray service was furnished, the patient was able to travel safely to a clinical setting, we believe the statement of need for portable x-ray services could be questionable. We also are concerned that the OIG observed some portable x-ray suppliers billing for multiple trips to a facility on the same day Medicare makes a single payment for each trip the portable x-ray supplier makes to a particular location. We make available several modifiers to allow the portable x-ray supplier to indicate the number of beneficiaries served on a single trip to a facility. We expect portable x-ray suppliers to use those modifiers and not to bill multiple trips to the same facility on a single day when only one trip was made. Additionally, we strongly encourage portable x-ray suppliers to make efficient use of resources and consolidate trips, to the extent it is clinically appropriate to do so, rather than making multiple trips on the same day.

Comment: Several stakeholders provided scenarios where a portable x-ray service would be medically necessary on the same day as a hospital, physician office, or other clinical setting.

Response: We agree that there may be unusual circumstances when portable x-ray services could be appropriate with a same day visit to a hospital, physician office, or other clinical setting. Proper documentation of the rationale for such same day occurrences would be required to substantiate the necessity for those services.

In conjunction with our proposal to expand the scope of physicians and nonphysician practitioners who can order portable x-ray services, we intend to develop, as needed, monitoring standards predicated by these and other OIG findings. In addition, we will be conducting data analysis of ordering patterns for portable x-ray and other diagnostic services to determine if additional claims edits, provider audits, or fraud investigations are required to prevent abuse of these services and to allow for the collection of any potential

overpayments. We encourage physicians and practitioners, as with any diagnostic test, to proactively determine and document the medical necessity for this testing.

Comment: One commenter noted that our proposal to expand the scope of ordering for portable x-ray services was at odds with our statements indicating our intent to engage in greater monitoring of the delivery of portable x-ray services overall. The commenter recommended that we target any new program integrity efforts to practitioner groups where there is evidence of abuse.

Response: We disagree. We believe allowing nonphysician and limited-license practitioners to order portable x-ray services is consistent with statutory authority and changes in health care delivery. Any monitoring effort would target more generally, the utilization and delivery of portable x-ray services, of which of the actual x-ray service is only one small component.

In the proposed rule (77 FR 44791), we solicited comments and suggestions for updating the current regulations at 42 CFR Part 486, Subpart C—Conditions for Coverage: Portable X-Ray Services through future rulemaking. Below are our responses to public comments on suggestions for future rulemaking at 42 CFR Part 486, Subpart C—Conditions for Coverage: Portable X-Ray Services.

Comment: One commenter suggested CMS clarify the differences between portable x-ray providers and mobile independent diagnostic testing facilities (IDTFs). The commenter specifically recommended that CMS clarify whether portable x-ray suppliers and mobile IDTFs can furnish the same services to Medicare beneficiaries or whether there are limitations on the types of services that portable x-ray suppliers and IDTFs can furnish. The commenter also recommended that CMS establish educational and training requirements for portable x-ray suppliers and IDTF technicians.

Response: We appreciate these comments and will take them into consideration when undertaking future rulemaking.

M. Addressing Interim Final Relative Value Units (RVUs) From CY 2012 and Establishing Interim Final RVUs for CY 2013

Section 1848(c)(2)(B) of the Act requires that we review RVUs for physicians' services no less often than every 5 years. Under section 1848(c)(2)(K) of the Act (as added by section 3134 of the Affordable Care Act), we are required to identify and revise RVUs for services identified as potentially misvalued. To facilitate the review and appropriate adjustment of potentially misvalued services, section 1848(c)(2)(K)(iii) specifies that the Secretary may use existing processes to receive recommendations; conduct surveys, other data collection activities, studies, or other analyses as the Secretary determined to be appropriate; and use analytic contractors to identify and analyze potentially misvalued services, conduct surveys or collect data. In accordance with section 1848(c)(2)(K)(iii) of the Act, we identify potentially misvalued codes, and develop and propose appropriate adjustments to the RVUs, taking into account the recommendations provided by the AMA RUC, the Medicare Payment Advisory Commission (MedPAC), and other public commenters.

For many years, the AMA RUC has provided CMS with recommendations on the appropriate relative values for PFS services. Over the past several years, CMS and the AMA RUC have identified and reviewed a number of potentially misvalued codes on an annual basis, based on various identification screens for codes at risk for being misvalued. This annual review of work RVUs and direct PE inputs for potentially misvalued codes was further bolstered by the Affordable Care Act mandate to examine potentially misvalued codes, with an emphasis on the following categories specified in section 1848(c)(2)(K)(ii) (as added by section 3134 of the Affordable Care Act):

- Codes and families of codes for which there has been the fastest growth.
- Codes or families of codes that have experienced substantial changes in practice expenses.
- Codes that are recently established for new technologies or services.
- Multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes which have not been subject to review since the implementation of the RBRVS (the ''Harvard-valued'' codes).
- Other codes determined to be appropriate by the Secretary.

In addition to providing recommendations to CMS for work RVUs, the AMA RUC's Practice Expense Subcommittee reviews, and then the AMA RUC recommends, direct PE inputs (clinical labor, medical supplies, and medical equipment) for individual services. To guide the establishment of malpractice RVUs for new and revised codes before each Five-Year Review of Malpractice, the AMA RUC also provides malpractice crosswalk recommendations, that is, ''source'' codes with a similar specialty mix of practitioners furnishing the source code and the new/revised code.

CMS reviews the AMA RUC recommendations on a code-by-code basis. For AMA RUC recommendations regarding physician work RVUs, after conducting a clinical review of the codes, we determine whether we agree with the recommended work RVUs for a service (that is, whether we agree the AMA RUC-recommended valuation is accurate). If we disagree, we determine an alternative value that better reflects our estimate of the physician work for the service.

Because of the timing of the CPT Editorial Panel decisions, the AMA RUC recommendations, and our rulemaking cycle, we publish these work RVUs in the PFS final rule with comment period as interim final values, subject to public comment. Similarly, we assess the AMA RUC's recommendations for direct PE inputs and malpractice crosswalks, and establish PE and malpractice interim final values, which are also subject to comment. We note that, with respect to interim final PE RVUs, the aspect of our valuation that is open for public comment for a new, revised, or potentially misvalued code is the direct PE inputs and not the other elements of the PE valuation methodology, such as the indirect cost allocation methodology, that also contribute to establishing the PE RVUs for a code.

If we receive public comments on the interim final work RVUs for a specific code indicating that refinement of the interim final work value is warranted based on sufficient and new information from the commenters concerning clinical aspects of the physician work associated with the service (57 FR 55917) that were not already considered in making the interim valuation or the AMA RUC deliberations, we refer the service to a refinement panel, as discussed in further detail in section III.M.1.a. of this final rule with comment period.

In the interval between closure of the comment period and the subsequent year's PFS final rule with comment period, we consider all of the public comments on the interim final work, PE, and malpractice RVUs for the new, revised, and potentially misvalued codes and the results of the refinement panel, if applicable. Finally, we address the interim final RVUs (including the interim final direct PE inputs) by providing a summary of the public comments and our responses to those comments, including a discussion of any changes to the interim final work or

malpractice RVUs or direct PE inputs, in the following year's PFS final rule with comment period. We typically finalize the direct PE inputs and the work, PE, and malpractice RVUs for the service in that year's PFS final rule with comment period, unless we determine it would be more appropriate to continue their interim final status for another year and solicit further public comment.

1. Methodology

We conducted a clinical review of each code identified in this section and reviewed the current and recommended work RVUs, intensity, and time to furnish the pre-service, intra-service, and post-service activities, as well as other components of the service that contribute to the value. Our clinical review generally includes, but is not limited to, a review of information provided by the AMA RUC and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the Medicare PFS, consultation with other physicians and healthcare professionals within CMS and the Federal Government, and the views based on clinical experience of the physicians on the PFS clinical review team. We also assessed the methodology and data used to develop the recommendations submitted to us by the AMA RUC and other public commenters and the rationale for the recommendations. As we noted in the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), there are a variety of methodologies and approaches used to develop work RVUs, including building block, survey data, crosswalk to key reference or similar codes, and magnitude estimation. The building block methodology is used to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Components may include pre-, intra-, or post-service time and post-procedure visits, or, when referring to a bundled CPT code, the components could be considered to be the CPT codes that make up the bundled code. Magnitude estimation refers to a methodology for valuing physician work that determines the appropriate work RVU for a service by gauging the total amount of physician work for that service relative to the physician work for similar service across the physician fee schedule without explicitly valuing the components of that work. The resource-based relative value system (RBRVS) has incorporated into it cross-specialty and cross-organ system relativity. This RBRVS requires assessment of relative value and takes into account the clinical intensity and time required to perform a service. In selecting which methodological approach will best determine the appropriate value for a service, we consider the current and recommended physician work and time values, as well as the intensity of the service, all relative to other services.

Several years ago, to aid in the development of pre-service time recommendations for new and revised CPT codes, the AMA RUC created standardized pre-service time packages. The packages include pre-service evaluation time, pre-service positioning time, and pre-service scrub, dress and wait time. Currently there are six pre-service time packages for services typically furnished in the facility setting, reflecting the different combinations of straightforward or difficult procedure, straightforward or difficult patient, and without or with sedation/anesthesia. Currently there are two pre-service time packages for services typically furnished in the nonfacility setting, reflecting procedures without and with sedation/anesthesia care.

We have developed several standard building block methodologies to appropriately value services when they have very common billing patterns. As we have discussed in past rulemaking, most recently in the CY 2012 PFS final rule with comment period (76 FR 73107 through 73108), in cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the pre-service evaluation and post-service time. We believe that at least one-third of the physician time in both the pre-service evaluation and post-service period is duplicative of work furnished during the E/M visit. Accordingly, in cases where we believe that the AMA RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service times the intensity of the work. Pre-service evaluation time and post-service time both have a long-established intensity of work per unit of time (IWPUT) of .0224, which means that 1 minute of pre-service evaluation or post-service time equates to .0224 of a work RVU. Therefore, in many cases where we remove 2 minutes of pre-service time and 2 minutes of post-service time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of .09 (4 minutes × .0224 IWPUT) if we do not believe the overlap in time has already been accounted for in the work RVU. We continue to believe this adjustment is appropriate. The AMA RUC has recognized this valuation policy and, in many cases, addresses the overlap in time and work when a service is typically provided on the same day as an E/M service.

We appreciate the creation and use of these standardized pre-service time packages. However, we believe that services that involve only a local anesthetic agent do not typically involve the same amount of pre-service time as procedures involving sedation or non-local anesthesia care. We request that the AMA RUC consider assigning services that require only local anesthesia without sedation to the ''no sedation/anesthesia care'' pre-service time package, or that the AMA RUC create one or more new pre-service time packages to reflect the pre-service time typically involved in furnishing local anesthesia without sedation.

For many CPT codes that are typically billed on the same day as an E/M service, the recommendations from the AMA RUC state that the AMA RUC reviewed the work associated with the procedure, and adjusted the pre-service and/or post-service time to account for the work that is furnished as a part of the E/M service. For many codes, the AMA RUC made this adjustment from the pre-service evaluation time included in the AMA RUC-selected pre-service time package. However, as we noted above, we believe that the pre-service time packages for procedures with sedation or anesthesia care may overstate the time involved in furnishing services that involve only local or topical anesthesia without sedation. As a result, though the AMA RUC may have removed some pre-service time from the package to account for the same day E/M service, in a few instances, consistent with our established same day E/M reduction methodology discussed above, we further reduced the AMA RUC-recommended pre-service evaluation time to fully account for the overlapping time with the same day E/M service.

2. Finalizing CY 2012 Interim and CY 2013 Proposed Values for CY 2013

In this section, we address the interim final values published in the CY 2012 PFS final rule with comment period (76 FR 73026 through 73474), as subsequently corrected in the January 4, 2012 (77 FR 227 through 232) correction notice; and the proposed values published in the CY 2013 PFS proposed

rule (77 FR 44722 through 45061). We discuss the results of the CY 2012 refinement panels for certain CY 2012 interim final code values, respond to public comments received on specific interim final and proposed values (including direct PE inputs), and address the other new, revised, or potentially misvalued codes with interim final or proposed values. The final CY 2013 direct PE database that lists the direct PE inputs is available on the CMS Web site under the downloads for the CY 2013 PFS final rule with comment period at: *www.cms.gov/PhysicianFeeSched/*. The final CY 2013 work, PE, and malpractice RVUs are displayed in Addendum B to this final rule with comment period at: *www.cms.gov/PhysicianFeeSched/*.

a. Finalizing CY 2012 Interim and Proposed Work RVUs for CY 2013

i. Refinement Panel

(1) Refinement Panel Process

As discussed in the 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel process to assist us in reviewing the public comments on CPT codes with interim final work RVUs for a year and in developing final work values for the subsequent year. We decided the panel would be comprised of a multispecialty group of physicians who would review and discuss the work involved in each procedure under review, and then each panel member would individually rate the work of the procedure. We believed establishing the panel with a multispecialty group would balance the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services.

Depending on the number and range of codes that are subject to refinement in a given year, we establish refinement panels with representatives from four groups of physicians: Clinicians representing the specialty most identified with the procedures in question; physicians with practices in related specialties; primary care physicians; and contractor medical directors (CMDs). Typical panels have included 8 to 10 physicians across the four groups.

Following the addition of section 1848(c)(2)(K) to the Act by Section 3134 of the Affordable Care Act, which authorized the Secretary to review potentially misvalued codes and make appropriate adjustments to the RVUs, we reassessed the refinement panel process. As detailed in the CY 2011 PFS final rule with comment period (75 FR 73306), we believed that the refinement panel process may provide an opportunity to review and discuss the proposed and interim final work RVUs with a clinically diverse group of experts, who then provide informed recommendations. Therefore, we indicated that we would continue the refinement process, but with administrative modification and clarification. We also noted that we would continue using the established composition that includes representatives from the four groups of physicians—clinicians representing the specialty most identified with the procedures in question, physicians with practices in related specialties, primary care physicians, and CMDs.

One change relates to the calculation of the refinement panel results. The basis of the process is that following discussion of the information but without an attempt to reach a consensus, each member of the panel votes independently. Historically, the refinement panel's recommendation to change a work value or to retain the interim value had hinged solely on the outcome of a statistical test on the ratings (an F-test of panel ratings among the groups of participants). Over time, we found the statistical test used to evaluate the RVU ratings of individual panel members became less reliable as the physicians in each group tended to select a previously discussed value, rather than developing a unique value, thereby reducing the observed variability needed to conduct a robust statistical test. In addition, reliance on values developed using the F-test also occasionally resulted in rank order anomalies among services (that is, a more complex procedure is assigned lower RVUs than a less complex procedure). As a result, we eliminated the use of the statistical F-test and instead indicated that we would use the median work value of the individual panel members' ratings. We said that this approach would simplify the refinement process administratively, while providing a result that reflects the summary opinion of the panel members based on a commonly used measure of central tendency that is not significantly affected by outlier values. At the same time, we clarified that we have the final authority to set the RVUs, including making adjustments to the work RVUs resulting from the refinement process, and that we will make such adjustments if warranted by policy concerns (75 FR 73307).

As we continue to strive to make the refinement panel process as effective an efficient as possible, we would like to remind readers that the refinement panels are not intended to review every code for which we did not propose to accept the AMA RUC-recommended RVUs. Rather the refinement panels are designed for situations where there is new information available that might provide a reason for a change in work values and for which a multi-specialty panel of physicians might provide input that would assist us in making work RVU decisions. To facilitate the selection of services for the refinement panels, we would like to remind specialty societies seeking reconsideration of proposed or interim final work RVUs, including consideration by a refinement panel, to specifically state they are requesting refinement panel review in their public comment letters.

Furthermore we have asked commenters requesting refinement panel review to submit sufficient new information concerning the clinical aspects of the work assigned for a service to indicate that referral to the refinement panel is warranted (57 FR 55917). We note that the majority of the information presented during the CY 2012 refinement panel discussions was duplicative of the information provided to the AMA RUC during its development of recommendations. As detailed in section III.B. of this final rule with comment period, we consider information and recommendations from the AMA RUC when assigning proposed and interim final RVUs to services. Thus, if the only information that a commenter has to present is information already considered by the AMA RUC, referral to a refinement panel is not appropriate. To facilitate selection of codes for refinement, we request that commenters seeking refinement panel review of work RVUs submit supporting information that has not already been considered the AMA RUC in creating recommended work RVUs or by CMS in assigning proposed and interim final work RVUs. We can make best use of our resources as well as those of the specialties involved and physician volunteers, by avoiding duplicative consideration of information by the AMA RUC, CMS, and a refinement panel. To achieve this goal, CMS will continue to critically evaluate the need to refer codes to refinement panels in future years, specifically considering any new information provided by commenters.

(2) Interim Final Work RVUs Referred to the Refinement Panel in CY 2012

We referred to the CY 2012 refinement panel 17 CPT codes with interim final work values for which we

received a request for refinement that met the process described above. For these 17 CPT codes, all commenters requested increased work RVUs. For ease of discussion, we will be referring to these services as ''refinement codes.'' Consistent with the process described above, we convened a multi-specialty panel of physicians to assist us in the review of the comments. The panel was moderated by our physician advisors, and consisted of the following voting members:

- One to two clinicians representing the commenting organization;
- One to two primary care clinicians nominated by the American Academy of Family Physicians and the American College of Physicians;
- Four contractor medical directors (CMDs); and
- One to two clinicians with practices in related specialties who were expected to have knowledge of the services under review.

The panel process was designed to capture each participant's independent judgment and his or her clinical experience which informed and drove the discussion of the refinement code during the refinement panel proceedings. Following the discussion, each voting participant rated the physician work of the refinement code and submitted those ratings to CMS individually and confidentially, with no attempt to achieve consensus among the panel members. As finalized in the CY 2011 PFS final rule with comment period (75 FR 73307), we reviewed the ratings from each panel member and determined the median value for each service that was reviewed by the refinement panel.

We note that the individual codes reviewed by the CY 2012 refinement panel, and their final work RVUs are discussed in section III.B.1.b. of this final rule with comment period. Also, see Table 29 for the refinement panel ratings and the final work RVUs for the codes reviewed by the CY 2012 refinement panel.

TABLE 29—CODES REVIEWED UNDER THE CY 2012 REFINEMENT PANEL PROCESS

CPT code	Short descriptor	CY 2012 interim final WRVU	AMA RUC/ HCPAC recommended work RVU	2012 refinement median panel rating	CY 2013 final WRVU
26341	Manipulat palm cord post inj	0.91	1.66	1.30	0.91
29581	Apply multlay comprs lwr leg	0.25	0.60	0.50	[3] 0.25
32096	Open wedge/bx lung infiltr	13.75	17.00	17.00	13.75
32097	Open wedge/bx lung nodule	13.75	17.00	17.00	13.75
32098	Open biopsy of lung pleura	12.91	14.99	14.99	12.91
32100	Exploration of chest	13.75	17.00	17.00	13.75
32505	Wedge resect of lung initial	15.75	18.79	18.79	15.75
38230	Bone marrow harvest allogen	3.09	4.00	4.00	3.50
38232	Bone marrow harvest autolog	3.09	3.50	3.50	3.50
62370	Anl sp inf pmp/mdreprg&fil	0.90	1.10	1.10	0.90
92587	Evoked auditory test limited	0.35	0.45	0.45	0.35
92588	Evoked auditory tst complete	0.55	0.60	0.60	0.55
94060	Evaluation of wheezing	0.26	0.31	0.27	0.27
94726	Pulm funct tst plethysmograp	0.26	0.31	0.26	0.26
94727	Pulm function test by gas	0.26	0.31	0.26	0.26
94728	Pulm funct test oscillometry	0.26	0.31	0.26	0.26
94729	C02/membane diffuse capacity	0.17	0.19	0.19	0.19

ii. Code-Specific Issues

In this section, we discuss all code families for which we received a comment on an interim final physician work value in CY 2012 PFS final rule with comment period or on a proposed value in the CY 2013 PFS proposed rule. Refer to Addendum B for a comprehensive list of all final values.

(1) Integumentary System: Skin, Subcutaneous, and Accessory Structures (CPT Code 11056)

For discussion on CY 2013 interim final work values for CPT code 11056 refer to section III.M.3. of this final rule with comment period.

(2) Integumentary System: Nails (CPT Code 11719)

For discussion on CY 2013 interim final work values for CPT code 11719 refer to section III.M.3. of this final rule with comment period.

(3) Integumentary System: Repair (Closure) (CPT Codes 12035–12057)

For discussion on CY 2013 interim final work values for CPT codes 12035 through12057 refer to section III.M.3. of this final rule with comment period.

(4) Integumentary System: Repair (Closure) (CPT Codes 15272 and 15276)

As detailed in the CY 2012 final rule with comment period (76 FR 73112), for CY 2012, the CPT Editorial Panel deleted 24 skin substitute codes and established a 2-tier structure with 8 new codes (CPT codes 15271 through 15278) to report the application of skin substitute grafts, which are distinguished according to the anatomic location and surface area rather than by product description.

We assigned a work RVU of 0.33 to CPT code 15272 (Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)) on an interim final basis for CY 2012. After clinical review of CPT code 15272, we believed that a work RVU of 0.33 accurately reflected the work associated with this service. The AMA RUC reviewed the survey results for CPT code 15272 and recommended the survey 25th percentile work RVU of 0.59 for this service. However, we believed this value overstated the work of this procedure when compared to the base CPT code 15271 (Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area). We believed that CPT code 15272 is similar in intensity to CPT code 15341 (Tissue cultured allogeneic skin substitute; each additional 25 sq cm, or part thereof (List separately in addition to code for primary procedure)), and that the primary factor distinguishing the work of these two services is the

[3] This value is interim for CY 2013.

intra-service physician time. CPT code 15341 has a work RVU of 0.50, 15 minutes of intra-service time, and an IWPUT of 0.0333. CPT code 15272 has 10 minutes of intra-service time. Ten minutes of intra-service work at the same intensity as CPT code 15341 is equal to a work RVU of 0.33 (10 minutes x 0.0333 IWPUT). Therefore, we assigned a work RVU of 0.33 to CPT code 15272 on an interim final basis for CY 2012.

Comment: Commenters opposed the CMS-recommended interim final work RVU of 0.33 assigned to CPT code 15272. Commenters disagreed with our rationale to crosswalk CPT code 15272 to CPT code 15341 and stated that CPT code 15003 (Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure), which has a work RVU of 0.80, is a more suitable comparison code. Commenters noted that although CPT code 15003 requires 15 minutes of intra-service time whereas CPT code 15272 requires 10 minutes, it is a more appropriate comparison for valuation of the services under this code. Commenters stated that the AMA RUC-recommended work RVU places this service in the proper rank order with the base code, CPT code 15271. Furthermore, commenters noted that if all the AMA RUC recommendations for the family of CPT codes 15271 through15278 were accepted, the result would be financial savings for Medicare. Therefore, commenters recommended that we accept the AMA RUC-recommended work RVU of 0.59 for CPT code 15272.

Response: Based on the comments received, we re-reviewed CPT code 15272 and continue to believe that CPT code 15272 is similar in intensity to CPT code 15341. The primary distinguishing factor between the two services is that CPT code 15272 has 10 minutes of intra-service time and CPT code 15341 has 15 minutes. We continue to believe that the AMA RUC-recommended work RVU overstates the intensity of this procedure compared to the base procedure CPT code 15271. We maintain that valuing the 10 minutes of intra-service work at the same intensity as CPT code 15341, which equates to a work RVU of 0.33, is appropriate. We believe that this resulting work RVU maintains appropriate relativity with the base code and the entire family of CPT codes (15271 through15278). Therefore, we are finalizing a work RVU of 0.33 for CPT code 15272.

We assigned a work RVU of 0.50 to CPT code 15276 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)) on an interim final basis for CY 2012 based on our clinical review of the work associated with this service. The AMA RUC reviewed the survey results for CPT code 15276 and recommended a work RVU of 0.59, which corresponds to the AMA RUC's recommended work RVU for CPT code 15272. We disagreed with the AMA RUC that these two CPT codes should be valued the same. We assigned an interim final work RVU of 0.33 to CPT code 15272 but believed that the work associated with CPT code 15276, which describes work on the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, is more intense than the work associated with CPT code 15272, which describes work on the trunk, arms, and legs. Accordingly, we noted that our interim final work RVU for CPT code 15276 accurately captured the work associated with this service and established the appropriate relativity between the services. Therefore, we assigned a work RVU of 0.50 to CPT code 15276 on an interim final basis for CY 2012.

Comment: Commenters disagreed with the CMS-recommended interim final work RVU for CPT code 15276. Commenters suggested that CPT code 15276 is analogous to CPT code 15272, for which the AMA RUC originally recommended a work RVU of 0.59, both in physician work and time and recommended that CPT code 15276 should be directly crosswalked to CPT code 15272. Further, the commenters agreed with the AMA RUC key reference to CPT code 15003 (Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children), which has a work RVU of 0.80, and stated that CPT code 15276 requires 5 minutes less intra-service time, 10 minutes versus 15 minutes, and requires less physician work to perform. Commenters recommended that we value CPT code 15276 based upon the AMA RUC-recommended work RVU of 0.59 for CPT code 15276.

Response: Based on the comments received, we re-evaluated whether CPT code 15003 was an appropriate comparison code for CPT code 15276. However, we concluded that the services of CPT code 15276 are more intense than those of CPT code 15272 accordingly; CPT code 15276 should be valued to reflect the difference in intensity. We believe a work RVU of 0.50 establishes the appropriate difference in intensity between these two services. Additionally, we believe this work RVU value maintains appropriate relativity with the base code, CPT code 15271, and maintains relatively within the entire family of CPT codes (15271 through15278). Therefore, we are finalizing a work RVU of 0.50 for CPT code 15276.

(5) Musculoskeletal: Hand and Fingers (CPT Code 26341)

CPT code 26341 (Manipulation, palmar fascial cord (ie, Dupuytren's cord), post enzyme injection (eg, collagenase), single cord) was created by the CPT Editorial Panel along with CPT code 20517 to describe a technique for treating Dupuytren's contracture by injecting an enzyme into the Dupuytren's cord for full finger extension and manipulation, effective January 1, 2012.

As detailed in the CY 2012 final rule with comment period, we assigned an interim final work RVU of 0.91 to CPT code 26341 (76 FR 73192). After reviewing survey results for CPT code 26341, the AMA RUC recommended a work RVU of 1.66, which corresponds to the survey 25th percentile value. After clinical review of CPT code 26341, we believed the service described by CPT code 26341 is analogous to that of CPT code 97140 (Manual therapy techniques (eg, mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes), which has a work RVU of 0.43. However, since CPT code 97140 has no post-service visits (global period = XXX), while CPT code 26341 includes 1 CPT code 99212 (level 2 office or outpatient visit) (global period = 010), we added the work RVU of 0.48 for CPT code 99212, to the work RVU of 0.43 for CPT code 97140 to obtain the work RVU of 0.91 for CPT code 26341.

Comment: Commenters disagreed with our decision to crosswalk the work RVU of CPT code 26341 to that of CPT code 97140, stating that the codes do not have comparable work because CPT code 97140 is performed by physical therapists while surgeons perform CPT code 26341. Commenters also stated that the work associated with CPT code 26341 includes local or regional

anesthesia and the procedure may result in skin rupture, requiring physician attention to manipulation. In addition, commenters noted that the post-procedure neurovascular assessment involved in CPT code 26341 is added physician work that is distinctly different from the manual therapy techniques furnished in CPT code 97140. Commenters asserted that the difference in physician work, intensity, and complexity distinguishes the two codes. Commenters also disagreed with our use of a reverse building block methodology to value the additional work and complexity and said that we arbitrarily reduced the value of the surgeon's work involved. Commenters recommended we instead value the code based upon the AMA RUC-recommended work RVU of 1.66 for CPT code 26341 and requested refinement panel review of the code.

Response: Based on comments received, we referred CPT code 26341 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 26341 was 1.30. We believe that the refinement panel median work RVU would create a rank order anomaly between this code and similar codes. Although CPT code 97140 is typically furnished by a physical therapist, we do not believe that the difference in the provider specialty typically furnishing the service results in a difference in intensity of the service. Commenters stated that the post-procedure assessment involved in CPT code 26341 added physician work that is distinctly different from the manual therapy techniques furnished in CPT code 97140. We disagree; both services require an assessment following manipulation appropriate to the provided service to determine the adequacy and outcome, both positive and negative, of the intervention and attention to an atypical response to treatment. We continue to believe that the crosswalk and reverse building block methodologies that we used in assigning the interim final work value are appropriate and the resulting work RVU accurately reflects the work associated with this service. After consideration of the public comments, refinement panel median, and our clinical review, we are finalizing a work RVU of 0.91 for CPT code 26341.

(6) Musculoskeletal: Application of Casts and Strapping (CPT Codes 29581–29584)

For discussion on interim final work values for CPT codes 29581, 29582, 29583, and 29584 refer to section III.M.3. of this final rule with comment period.

(7) Respiratory: Lungs and Pleura (CPT Codes 32096–32100, 32505)

In the CY 2012 final rule with comment period, we assigned an interim final work RVU of 13.75 for CPT code 32096 (Thoracotomy, with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral) (76 FR 73193). As we noted, the CPT Editorial Panel reviewed the lung resection family of codes and deleted eight, revised five, and created 18 new codes to describe thoracoscopic procedures effective January 1, 2013. For the wedge resection procedures, the revisions were based on three tiers; first, the approach, thoracotomy or thoracoscopy; second, the target to remove nodules or infiltrates; and lastly the intent, diagnostic or therapeutic (for nodules only, all infiltrates will be removed for diagnostic purposes).

As we noted in the CY 2012 final rule with comment period, after clinical review of CPT code 32096, we believed a work RVU of 13.75 accurately reflected the work associated with this service compared to other related services. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the survey 25th percentile work RVU of 17.00 appropriately accounted for the work and physician time required to perform this procedure. We determined that the work associated with CPT code 32096 was similar in terms of physician time and intensity to CPT code 44300 (Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)). Therefore, we assigned the same work RVU to CPT code 32096 as that of CPT code 44300 on an interim final basis for CY 2012.

Comment: Commenters stated that CPT code 44300 is an arbitrary crosswalk, noting that CPT code 32096 describes an open thoracic procedure whereas CPT code 44300 is the placement of a feeding tube. A commenter shared a regression analysis of physician time and physician work of all thoracic surgery codes, which showed that the interim final work RVU value falls below the regression line and stated that this indicated an inappropriate work value. Commenters stated our work values are lower for equivalent physician time than virtually all our prior decisions for the specialty. Additionally, commenters noted that the values result in IWPUT values that are approximately half of those ordinarily associated with major surgical procedures. Therefore, commenters stated that the interim final work RVU of 13.75 for CPT code 32096 would result in rank order anomalies with other codes in the physician fee schedule. Commenters recommended we use the AMA RUC-recommended work RVU of 17.00 and requested refinement panel review of the code.

Response: Based on comments received, we referred CPT code 32096 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 32096 was 17.00. Following the refinement panel, we again conducted a clinical review and continue to believe a work RVU of 13.75 accurately reflected the work associated with this service. For CY 2012, the CPT Editorial Panel deleted CPT code 32095 which had a work RVU of 10.14 and created CPT codes 32096, 32097, and 32100 to replace CPT code 32095. Upon our clinical review, we do not believe that there is a significant difference in intensity between deleted CPT code 32095 and replacement CPT code 32096. We believe that the appropriate work RVU for CPT code 32096 should be close to a work RVU of 10.14, but should account for the increase in 15 minutes of total time between deleted CPT code 32095 and new CPT code 32096. We believe that the refinement panel median work RVU of 17.00 far overstates this difference. Additionally, we continue to believe that the work associated with 32096 is similar in terms of physician time and intensity to CPT code 44300. Therefore, we still believe the work RVU of 13.75 appropriately values this service. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 13.75 as the final value for CPT code 32096.

As detailed in the CY 2012 final rule with comment period, we assigned an interim final work RVU of 13.75 for CPT code 32097 (Thoracotomy, with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral) (76 FR 73194). We noted that after clinical review of CPT code 32097, we believed a work RVU of 13.75 accurately reflected the work associated with this service compared to other related services. We also noted that the AMA RUC had reviewed the specialty society survey results, compared the code to other services, and recommended the survey 25th percentile work RVU of 17.00. We stated that we determined that the work associated with CPT code 32097 was similar to CPT code 32096, to which we assigned a work RVU of 13.75 on an interim final basis for CY 2012.

Therefore, we assigned a work RVU of 13.75 for CPT code 32097 on an interim final basis for CY 2012.

Comment: Commenters stated that CPT code 44300 is an arbitrary crosswalk for CPT code 32097 because it describes an open thoracic procedure whereas CPT code 44300 is the placement of a feeding tube. Commenters shared a regression analysis of physician work and time for all thoracic surgery codes, which shows that the interim final work RVU value falls below the regression line and noted that this indicates inappropriately low work intensity. Commenters stated our interim final work RVU values are lower for equivalent physician time than virtually all prior work RVU decisions for this specialty. Commenters noted that the interim final work RVU values result in IWPUT values that are approximately half of those ordinarily associated with major surgical procedures. Commenters added that the interim final work RVU of 13.75 for CPT code 32097 result in rank order anomalies with other codes. Commenters recommended we instead use the AMA RUC-recommended work RVU of 17.00 for CPT code 32097 and requested refinement panel review of the code.

Response: Based on comments received, we referred CPT code 32097 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 32097 was 17.00. CPT codes 32096, 32097, and 32100 were created to replace CPT code 32095, which was deleted, effective January 1, 2012. We believe these three services involve the same amount of physician work and should have the same work RVU. Thus, the same rationale that we used to value CPT code 32096 applies to CPT code 32097. We continue to believe that the work associated with CPT code 32097 is similar in terms of physician time and intensity to CPT code 44300 and thus, still believe the work RVU of 13.75 is appropriate. Additionally, we continue to believe that a work RVU of 17.00 overstates the increase in work between deleted CPT code 32095 and its replacement CPT codes. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 13.75 as the final value for CPT code 32097.

As detailed in the CY 2012 final rule with comment period, we assigned an interim final work RVU of 12.91 to CPT code 32098 (Thoracotomy, with biopsy(ies) of pleura) (76 FR 73194). We noted that after clinical review, we believed a work RVU of 12.91 accurately reflected the work associated with this service as compared to other related services. After reviewing survey results and comparing the code to other services, the AMA RUC recommended the survey 25th percentile work RVU of 14.99. We noted that the work associated with CPT code 32098 was similar in terms of physician time and intensity to CPT code 47100 (Biopsy of liver, wedge) and therefore we believed that crosswalking to the work RVU of CPT code 47100 appropriately accounted for the work associated with CPT code 32098. Therefore, we assigned a work RVU of 12.91 to CPT code 32098 on an interim final basis for CY 2012.

Comment: Commenters shared a regression analysis of physician time and physician work of all thoracic surgery codes, and indicated that our interim final work RVU value falls below the regression line, which commenters noted indicated inappropriately low work intensity. Commenters stated that a work RVU of 12.91 results in an IWPUT of 0.0741, which is insufficient intensity compared to other similar procedures. Commenters stated that our interim final work RVU of 12.91 for CPT code 32098 placed this service out of relativity with the CPT codes in this family for which we accepted the AMA RUC recommendations and requested refinement panel review of the code.

Response: Based on comments received, we referred CPT code 32098 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median was a work RVU of 14.99. This service would be out of rank order with the other services in the family described by CPT codes 32096, 32097, 32100, and 32505 if we adopted a work RVU of 14.99. As noted above, we continue to believe a work RVU of 13.75 is appropriate for CPT code 32096. Since CPT code 32098 describes a more limited procedure that takes less time than the other codes in the family (CPT codes 32096, 32097, 32100, and 32505) it should have a lower work RVU. After consideration of the public comments, refinement panel results, and our clinical review, we believe that that the work associated with 32098 is similar in terms of physician time and intensity to CPT code 47100 and therefore we are assigning a work RVU of 12.91 as the final value for CY 2013 for CPT code 32098.

We assigned a work RVU of 13.75 for CPT code 32100 (Thoracotomy; with exploration) on an interim final basis in the CY 2012 final rule with comment period (76 FR 73194). After clinical review of CPT code 32100, we believed a work RVU of 13.75 accurately reflected the work associated with this service as compared to other related services. The AMA RUC reviewed the specialty society survey results, compared the code to other services, and recommended a work RVU of 17.00. We noted that the affected specialty society and AMA RUC asserted that CPT code 32100 should be valued the same as CPT codes 32096 and 32097 because they believe that the work is similar for these three services. We noted that we assigned a work RVU of 13.75 to CPT codes 32096 and 32097, and therefore a work RVU of 13.75 to CPT code 32100 as well.

Comment: Commenters stated that CPT code 44300 is an inappropriate crosswalk for CPT code 32100 because it describes an open thoracic procedure whereas CPT code 44300 is the placement of a feeding tube. Commenters shared a regression analysis of physician work and time all thoracic surgery codes that shows the interim final work RVU value falls below the regression line and stated that this indicates inappropriately low work intensity. Commenters stated the interim final work RVU value is lower for equivalent physician time than virtually all prior work RVU assignments for this specialty. Commenters noted that the interim final work RVU value results in IWPUT values that are approximately half of those ordinarily associated with major surgical procedures. Therefore, commenters stated that the interim final work RVU of 13.75 for CPT code 32100 would result in rank order anomalies with other codes in the fee schedule. Commenters recommended we value the work based upon the AMA RUC-recommended work RVU of 17.00 for CPT code 32100 and requested refinement panel review of the code.

Response: Based on comments received, we referred CPT code 32100 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 32100 was 17.00. CPT codes 32096, 32097, and 32100 were created to replace CPT code 32095, which was deleted, effective January 1, 2012. We believe these three services involve the same amount of physician work and should have the same work RVU. Thus, the same rationale that we used to value CPT codes 32096 and 32097 applies to CPT code 32100. We continue to believe that the work associated with 32100 is similar in terms of physician time and intensity to CPT code 44300. In addition, we agree with the specialty society and AMA RUC's assertion that CPT code 32100 should be valued the same as CPT codes 32096 and 32097.

Furthermore, we continue to believe that a work RVU of 17.00 overstates the increase in work between deleted CPT code 32095 and its replacement CPT codes. Thus, we maintain that the interim final work RVU of 13.75 is still appropriate. After consideration of the public comments, refinement panel results, and our clinical review, we are assigning a work RVU of 13.75 as the final value for CY 2013 for CPT code 32100.

We assigned a work RVU of 15.75 for CPT code 32505 (Thoracotomy; with therapeutic wedge resection (eg, mass, nodule), initial) on an interim final basis in the CY 2012 final rule with comment period (76 FR 73194). We noted that after clinical review of CPT code 32505, we believed a work RVU of 15.75 accurately reflected the work associated with this service compared to other related services. After reviewing the survey results, comparing the code to other services, the AMA RUC recommended the survey 25th percentile work RVU of 18.79. We explained that we assigned the interim final work RVU of 15.75 in recognition of the greater physician work and intensity involved in CPT 32505 as compared to CPT code 32096. We valued the additional 30 minutes of intra-service work associated with CPT code 32505 at 2.00 work RVUs. Accordingly, we assigned a work RVU of 15.75 for CPT code 32505 on an interim final basis for CY 2012.

Comment: Commenters stated that they entirely disagreed with the methods used to value CPT code 32096 and therefore, disagreed with the value assigned to 32505 that was based upon the value assigned to CPT code 32096. Commenters said that the methods used for valuing CPT code 32505 have never been employed to determine a code's work value. Further, commenters explained that our value results in an IWPUT of 0.06, which is lower than the AMA RUC recommendation. Commenters recommended we value CPT code 32505 based upon the AMA RUC-recommended work RVU of 18.79 for this code and requested refinement panel review.

Response: Based on comments received, we referred CPT code 32505 to the CY 2012 multi-specialty refinement panel for further review. We determined that the refinement panel median work RVU of 18.79 was relatively high in relation to the other codes in the family. We maintain that the incremental difference between CPT code 32096 and CPT code 32505 is 2.00 RVUs and, therefore continue to believe that a work RVU value of 15.75 accurately reflects the value of the service. As a result of the refinement panel results, the public comments, and our clinical review, we are assigning a work RVU of 15.75 as the final value for CPT code 32505.

(8) Respiratory: Lungs and Pleura (CPT Codes 32663, 32668–32673)

For discussion on interim final work values for CPT codes 32663, 32668 through 32673 refer to section III.M.3. of this final rule with comment period.

(9) Cardiovascular: Heart and Pericardium (CPT Code 36247)

In the Fourth Five-Year Review of Work (76 FR 32445), we discussed CPT code 36247 (Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family) and proposed a CY 2012 work RVU of 6.29 and a global period change from 90 days (Major surgery with a 1-day pre-operative period and a 90-day postoperative period included in the fee schedule amount) to XXX (the global concept does not apply). In the CY 2012 PFS final rule with comment period (76 FR 73132), we agreed with commenters to the Fourth Five-Year Review of Work that our discussion of the global period was incorrect and should have indicated a change in global period from XXX to 000 (Minor procedure-includes RVUs for pre- and post-operative procedures on the same day). We stated that, based on comments received, we referred CPT code 36247 to the CY 2011 multi-speciality refinement panel for further review. The refinement panel median value was a work RVU of 7.00, the AMA RUC-recommended value. We went on to state that upon clinical review, we believed that our proposed work RVU of 6.29 was more appropriate. We stated that we observed a significant decrease in the physician times reported for this service that argue for a lower work RVU, notwithstanding that the survey was conducted for a 0-day global period, which includes an E/M service on the same day. Therefore, we assigned work RVUs of 6.29 and a global period of 000 to CPT code 36247 on an interim basis for CY 2012 and invited additional public comment on this code in the CY 2012 final rule with comment period.

Comment: A commenter appreciated that we acknowledged that we made an inadvertent error when we referred to the original global period of the code as 90 global days rather than XXX global days. However, this commenter stated that the new 0-day global period, which includes an E/M service on the same day, justified the refinement panel's median value of a work RVU of 7.00. Additionally, commenters stated that the change from a global period of XXX (global concept does not apply) to a global period of 000 (Minor procedure-includes RVUs for pre- and post-operative procedures on the same day) added additional pre-service work. Other commenters stated that with the removal of the lower extremity intervention patients from the code, the procedures now coded with this procedure are more complex and warrant an increased value. Commenters also pointed out that the CY 2011 refinement panel median for the code was 7.00 work RVUs. Commenters requested that we accept the AMA RUC recommendation of 7.00 work RVUs for CPT code 36247.

Response: Based on comments received, we re-reviewed CPT code 36247. We continue to believe that our proposed work RVU of 6.29 accurately reflects the work associated with this service. Based on the significant reduction in the physician intra-service time assigned to this service from 86 minutes to 60 minutes, if this CPT code had maintained a global period of XXX, we believe it would have been appropriate to reduce the work RVU below the current value of 6.29 to reflect the reduction in time. We do not believe that the potential increase in intensity due to the complexity of the patient mix counter balances the decrease in intra-service time. We understand that this service now includes the work of a same day E/M visit, and we believe this additional work is accounted for by maintaining the current work RVU of 6.29 rather than reducing the work RVU, as would have been appropriate if the service had maintained global period of XXX. Therefore, we are finalizing a work RVU of 6.29 and a 000 global period for CPT code 36247.

(10) Renal Angiography Codes (CPT Code 36251)

As detailed in the CY 2012 final rule with comment period (76 FR 73196), the CPT Editorial Panel created four bundled renal angiography services (CPT codes 36251, 36252, 36253, and 36254), effective January 1, 2012.

We assigned a work RVU of 5.35 to CPT code 36251 (Selective catheter placement (first-order), main renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture and catheter placement(s), fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiologic supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral) on an interim final basis for CY 2012 based upon our

clinical review of the code. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the work value for CPT code 36251 should be directly crosswalked to CPT code 31267 (Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus) endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus), which has a work RVU of 5.45, and recommended a work RVU of 5.45 for CPT code 36251. We determined that the work associated with CPT code 36251 is closely aligned in terms of physician time and intensity with that of CPT code 52341 (Cystourethroscopy; with treatment of ureteral stricture (eg, balloon dilation, laser, electrocautery, and incision), which has a work RVU of 5.35. We believed crosswalking to the work RVU of CPT code 52341 appropriately accounted for the work associated with CPT code 36251. Therefore, we assigned a work RVU of 5.35 to CPT code 36251 on an interim final basis for CY 2012.

Comment: Commenters disagreed with the interim final work RVU of 5.35 for CPT code 36251, stating that the family of CPT codes (36251, 36252, 36253, and 36254) was carefully reviewed by the AMA RUC and the rank order was appropriately established by the AMA RUC recommendations. Commenters recommended CPT code 36251 should be directly crosswalked to CPT code 31267 as the AMA had recommended and requested that we use 5.45 work RVUs for CPT code 36251.

Response: Based on the comments received, we re-reviewed CPT code 36251 and considered the commenters' recommendation that it be directly crosswalked to CPT code 31267. After re-considering the crosswalk, we continue to believe that the work associated with CPT code 36251 is closely aligned in terms of physician time and intensity with CPT code 52341 and that crosswalking to CPT code 52341 appropriately results in a work RVU of 5.35. Therefore, we are finalizing a work RVU of 5.35 for CPT code 36251 for CY 2013.

We assigned an interim final work RVU of 6.99 to CPT code 36252 (Selective catheter placement (first-order), main renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture and catheter placement(s), fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiologic supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; bilateral), for CY 2012 after clinical review. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the work value for CPT code 36252 should be directly crosswalked to CPT code 43272 (Endoscopic retrograde cholangiopancreatography (ERCP); with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique), which has a work RVU of 7.38. Although the AMA RUC recommended a work RVU of 7.38 for CPT code 36252, we found that the intensity of this service is more similar to CPT code 58560 (Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)), which has a work RVU of 6.99. Accordingly, we assigned an interim final work RVU of 6.99 to CPT code 36252 for CY 2012.

Comment: Commenters stated that this family of CPT codes 36251, 36252, 36253, and 36254 were carefully reviewed by the AMA RUC, that the rank order was appropriately established based on the AMA RUC recommendations, and that CPT code 36252 should be crosswalked to CPT code 43272 (Endoscopic retrograde cholangiopancreatography (ERCP); with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique), which has a work RVU of 7.38, as the AMA recommended.

Response: Based on the comments received, we re-reviewed CPT code 36252. Although commenters recommended a direct crosswalk to CPT code 43272, we continue to believe that the work of the services is similar to the reference CPT code 58560. Accordingly, we find that the resulting work RVUs of 6.99 is still appropriate and accounts for the work associated with this service and we are finalizing a work RVU value of 6.99 for CPT code 36252.

(11) IVC Transcatheter Procedures (CPT Codes 37192 and 37193)

As discussed in the CY 2012 final rule with comment period (76 FR 73197), for CPT code 37192 (Repositioning of intravascular vena cava filter, endovascular approach inclusive of vascular access, vessel selection, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy)), we assigned a work RVU of 7.35 to CPT code 37192, with a refinement to 45 minutes of intra-service time, on an interim final basis for CY 2012.

After clinical review of CPT code 37192, we believed a work RVU of 7.35 accurately reflected the work associated with this service. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the survey 75th percentile intra-service time of 60 minutes and the 25th percentile of work RVU of 8.00 accurately described the physician work involved in the service. We determined that the work associated with CPT code 37192 is similar to CPT code 93460 (Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed), which has a work RVU of 7.35, 48 minutes pre-service time, 50 minutes intra-service time, and 30 minutes post-service time. By comparing the times assigned to those of CPT code 93460, we determined that the survey median intra-service time of 45 minutes appropriately accounted for the time required to furnish the intra-service work of CPT code 37192. Therefore, we assigned it a work RVU of 7.35, with a refinement to 45 minutes of intra-service time on an interim final basis for CY 2012. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

Comment: A commenter disagreed with our valuation for CPT code 37192, but did not provide information as to why the valuation was inappropriate. The commenter urged that we accept the AMA RUC-recommended work RVU and times.

Response: After clinical re-review of CPT code 37192, we maintain that the work associated with CPT code 37192 is similar to CPT code 93460, which has the following times: 48 minutes pre-service, 50 minutes intra-service, and 30 minutes post-service. As a result, we continue to believe that the survey median intra-service time of 45 minutes appropriately accounts for the time involved in furnishing the intra-service work of this procedure. We believe that the crosswalk work RVU of 7.35 more appropriately values the services furnished in this code than the AMA RUC recommended value of 8.00 RVUs. We are finalizing a work RVU of 7.35 to CPT code 37192, with a refinement to 45 minutes of intra-service time. A complete listing of the times associated with this code is available on the CMS Web site at *www.cms.gov/PhysicianFeeSched/*.

As discussed in the CY 2012 final rule with comment period (76 FR 73197), for CPT code 37193 (Retrieval (removal) of intravascular vena cava filter, endovascular approach inclusive of vascular access, vessel selection, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy)), we assigned a work RVU of 7.35 to CPT code 37193, with a refinement to 45 minutes of intra-service time, on an interim final basis for CY 2012. After clinical review of CPT code 37193, we believed a work RVU of 7.35 accurately reflected the work associated with this service. The AMA RUC reviewed the survey results, compared the code to other services, and concluded that the survey 75th percentile intra-service time of 60 minutes and the 25th percentile of work RVU of 8.00 accurately described the physician work involved in the service. We believed that the work associated with CPT code 37193 is similar to CPT code 93460 (Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed), which has a work RVU of 7.35, 48 minutes pre-service time, 50 minutes intra-service time, and 30 minutes post-service time. Based upon these times, we believed that the survey median intra-service time of 45 minutes appropriately accounted for the time required to furnish the intra-service work associated with CPT code 37193. Therefore, we assigned a work RVU of 7.35 to CPT code 37193, with a refinement to 45 minutes of intra-service time, on an interim final basis for CY 2012. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

Comment: Without providing more information, a commenter disagreed with the work RVUs assigned and refinement to time for CPT code 37193 and urged that we accept the AMA RUC-recommended work RVU of 8.00, and recommended time.

Response: After clinical re-review of CPT code 37193, we maintain that the work associated with CPT code 37193 is similar to CPT code 93460, which has the following times: 48 minutes pre-service, 50 minutes intra-service, and 30 minutes post-service. We continue to believe that the survey median intra-service time of 45 minutes appropriately accounted for the time required to furnish the intra-service work of this CPT code 37193 rather than the AMA RUC-recommended intra-service time of 60 minutes. We also continue to believe that the work RVU of 7.35 more appropriately values the services furnished in this code than the AMA-recommended work RVU of 8.00. Therefore, we are finalizing a work RVU of 7.35 to CPT code 37132, with a refinement to 45 minutes of intra-service time. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

(12) Hemic and Lymphatic Systems: General, Bone Marrow or Stem Cell Services/Procedures (CPT Codes 38230 and 38232)

On an interim final basis, we assigned a work RVU of 3.09 to CPT codes 38230 (Bone marrow harvesting for transplantation; allogeneic) and 38232 (Bone marrow harvesting for transplantation; autologous) for CY 2012 (76 FR 73197). In the CY 2012 final rule with comment period we noted that for CY 2012, the CPT Editorial Panel split CPT code 38230 into two separate CPT codes: 38230 and 38232 to more accurately reflect current medical practice. We noted that we changed the global period from 010 to 000 for CPT code 38230, and assigned a global period of 000 to CPT code 38232, as these services rarely required overnight hospitalization and physician follow-up in the days following the procedure.

We noted that after clinical review of CPT codes 38230 and 38232, we believed that a work RVU of 3.09 appropriately accounted for the work associated with these services. The AMA RUC reviewed the survey results and, after comparison to similar CPT codes, the AMA RUC recommended the survey median work RVU of 4.00 for CPT code 38230, and the survey median work RVU of 3.50 for CPT code 38232. Notwithstanding the AMA–RUC recommendation, we noted that the work for these services is very similar and should be valued the same. In CY 2011, CPT code 38230 had a work RVU of 4.85 with a ten-day global period that included a CPT code 99213 (Level 3 office or outpatient visit, established patient), and a CPT code 99238 (discharge day management service). We explained that we considered converting the value of CPT code 38230 from a 10-day global period to a 0-day global period by subtracting the work RVUs for CPT code 99213 (work RVU=0.97) and CPT code 99238 (work RVU=1.28), but believed that the resulting work RVU of 2.60 would result in this code being valued too low compared to other similar services. Instead, we found that the CPT code 38230 survey 25th percentile work RVU of 3.09 accurately captured the intensity of this service with the revised global period. Therefore, we assigned a work RVU of 3.09 to CPT code 38230 on an interim final basis for CY 2012. Since, as explained above, we believed that CPT code 38232 should have the same work RVU as CPT code 38230, we also assigned a work RVU of 3.09 to CPT code 38230 on an interim final basis for CY 2012.

Comment: Commenters acknowledged that the intra-service times of CPT codes 38230 and 38232 are similar; however, they stated that the service described by CPT code 38230 is typically more intense and stressful since it is being performed on a donor, who does not directly benefit from the procedure. Commenters also noted that collecting donor cells is typically prolonged to ensure that enough cells have been collected. Commenters stated that although the survey did not reflect the intra-service time for CPT code 38230, the AMA RUC-recommended values appropriately accounted for the lower time reported in the survey with a higher work RVU value. Additionally, commenters stated that the reverse building block methodology was an inappropriate policy to apply to any services with changing global day periods and in this case, particularly inappropriate because the post-operative visits built into the code were initially valued by the Harvard study several years ago. Given these arguments, commenters requested the AMA RUC recommended work RVUs of 4.00 for CPT code 38230 and 3.50 for CPT code 38232 be used to value these codes and requested refinement panel review of these codes.

Response: Based on comments received, we referred CPT codes 38230 and 32832 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 38230 was 4.00, and the median work RVU for CPT code 38232 was 3.50. We continue to believe that CPT codes 38232 and 38230 require the same amount of physician work and should be valued the same. After reviewing the public comments and the refinement panel ratings, we agree that the refinement panel median work RVU of 3.50 for CPT code 38232 more appropriately reflects the work of CPT codes 38230 and 38232 than the interim final work RVU of 3.09. We believe the refinement panel median work RVU of 4.00 for CPT code 38230 overstates the work associated with these services, especially considering that for CPT code

38230 the survey 25th percentile work RVU was 3.09 and a building block methodology based on the CY 2011 work RVU and global period yielded work RVU of 2.60 for this service. As a result of the refinement panel ratings, the public comments, and our clinical review, we are finalizing a work RVU of 3.50 for CPT codes 32830 and 32832.

(13) Digestive: Abdomen, Peritoneum, and Omentum (CPT Code 49084)

As detailed in the CY 2012 final rule with comment period (76 FR 73198), the CPT Editorial Panel deleted CPT codes 49080 and 49081and created three new CPT codes, 49082, 49083, and 49084, effective January 1, 2012, to more accurately describe the current medical practice.

After clinical review, we assigned a work RVU of 2.00 to CPT codes 49083 (Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance) and 49084 (Peritoneal lavage, including imaging guidance, when performed) on an interim final basis for CY 2012. The AMA RUC recommended a work RVU of 2.00 for CPT code 49083 and a work RVU of 2.50 for CPT code 49084. We agreed with the AMA RUC-recommended work RVU of 2.00 for CPT code 49083, but disagreed that CPT 49084 should be valued more. Instead, we believed that CPT code 49084 requires similar work to code 49083 and should be valued the same. Therefore, we assigned a work RVU of 2.00 to CPT codes 49083 and 49084 on an interim final basis for CY 2012.

Comment: One commenter disagreed with our valuation of CPT code 49084 and the resulting work RVU recommendation but did not describe why.

Response: After clinical re-review of CPT code 49084, we continue to believe that CPT code 49084 requires similar work as CPT code 49083 and should be valued the same. Accordingly, we are finalizing a work RVU of 2.00 for CPT codes 49083 and 49084.

(14) Nervous: Spine and Spinal Cord (CPT Codes 62370)

CPT code 62370 (Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status)); with reprogramming and refill (requiring physician's skill)) newly created by the CPT Editorial Panel for CY 2012, was assigned an interim final work RVU of 0.90 for CY 2012 as discussed in the CY 2012 final rule with comment period (76 FR 73199).

As we noted in the CY 2012 final rule with comment period, after clinical review of CPT code 62370, we believed that a work RVU of 0.90 accurately accounted for the work associated with this service. We noted that after a comparison to similar services, the AMA RUC recommended a work RVU of 1.10 for CPT code 62370 based on a crosswalk to CPT code 56605 (Biopsy of vulva or perineum (separate procedure); 1 lesion) however, we believed that a work RVU of 1.10 for CPT code 62370 was too high compared to similar services in this family. Instead, we found CPT code 62370 to be similar in intensity and complexity to CPT code 93281 (Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; multiple lead pacemaker system), which has a work RVU of 0.90. We noted that this value, which is between the specialty society survey 25th percentile and median work RVU, appropriately reflected the work of CPT code 62370. Therefore, we assigned a work RVU of 0.90 to CPT code 62370 on an interim final basis for CY 2012.

Comment: Commenters disagreed with the value, explaining that CPT code 93281 was not an appropriate crosswalk because it was a programming only code while CPT code 62370, is a procedure and programming code. Commenters noted that the interim final work RVU of 0.90 does not account for the work in refilling the pump, which requires a sterile puncture in a patient whose complexities preclude provision of these services by a nonphysician. Therefore, commenters requested that CPT code 62370 be valued based upon the AMA RUC recommended value of 1.10 work RVUs and requested refinement panel review of this code.

Response: Based on comments received, we referred CPT code 62370 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 62370 was 1.10. In subsequent review, we determined that valuing this code at the refinement panel median work RVU value would result in too high a value as compared to the other codes in the family. CPT code 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) has a work RVU of 0.67. CPT code 62369 describes the same procedure as CPT code 62370, except in CPT code 62369 the reprogramming and refill does not require physician skill and in CPT code 62370 the reprogramming and refill does require physician skill. We believe a work RVU of 0.90 for CPT code 62370 reflects the appropriate incremental increase in physician work for reprogramming and refill by a physician, versus a nonphysician. We also continue to believe that CPT code 93281, which was recently reviewed, has similar intensity and complexity to CPT code 62370, and that CPT codes 93281 and 62370 include the same amount of intra-service physician time. We believe that CPT codes 93281 and 62370 involve the same amount of physician work and maintain that a work RVU of 0.90 appropriately captures the physician work of these procedures. After reviewing the public comments, the refinement panel ratings, and our clinical review, we are finalizing a work RVU of 0.90 as for CPT code 62370.

(15) Diagnostic Radiology: Abdomen (CPT Codes 74174)

For discussion on CY 2013 interim final work values for CPT code 74174 refer to section III.M.3. of this final rule with comment period.

(16) Pathology and Laboratory: Urinalysis (CPT Codes 88120 and 88121)

For discussion on CY 2013 interim work values for CPT codes 88120–88121, refer to section III.M.3. of this final rule with comment period.

(17) Psychiatry: Psychiatric Therapeutic Procedures (CPT Codes 90845 and 90869)

For discussion on interim work values for CPT codes 90845 and 90869, refer to section III.M.3. of this final rule with comment period.

(18) Ophthalmology: Special Ophthalmological Services (CPT Codes 92071)

As detailed in the CY 2012 final rule with comment period (76 FR 73202), for the Fourth Five-Year Review, we identified CPT code 92070 through the Harvard-Valued—Utilization over 30,000 screen as a potentially misvalued code. Upon review of this service, the CPT Editorial Panel deleted CPT code 92070 and created two new CPT codes (92071 and 92072) to distinguish reporting of fitting of contact lens for treatment of ocular surface disease and fitting of contact lens for management of keratoconus.

We assigned an interim final work RVU of 0.61, with refinement to time as noted above to CPT code 92071 (Fitting of contact lens for treatment of ocular surface disease) for CY 2012. We

determined that CPT code 92071 is expected to capture the utilization of the deleted code CPT code 92070 (Fitting of contact lens for treatment of disease, including supply of lens). Since CPT code 92070 was typically billed with an E/M service on the same day, we believed that CPT code 92071 would also typically be billed with an E/M service on the same day. We concluded that some of the activities conducted during the pre- and post-service times of the procedure code and the E/M visit overlapped and, therefore, should not be counted twice in developing the procedure's work value. To account for this overlap, we reduced the pre-service evaluation time and post-service time by one-third each. Specifically, we reduced each the pre-service evaluation time and the post-service time from 5 minutes to 3 minutes. To determine the appropriate work RVU for CPT code 92071, we calculated the value of the extracted time and subtracted it from the AMA RUC-recommended work RVU of 0.70, which equals the CY 2011 work RVU for the deleted code, CPT 92070. In valuing CPT code 92071, we removed a total of 4 minutes (as described above) at an intensity of 0.0224 per minute, which amounted to the removal of 0.09 work RVUs. Therefore, we assigned an interim final work RVU of 0.61, with refinement to time as noted above to CPT code 92071 for CY 2012. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

Comment: Commenters disagreed with the rationale used to lower the value for CPT code 92071 and further disagreed with the reverse building block methodology used. Commenters stated that the AMA RUC and the affected specialty society had reviewed and valued CPT code 92071 with the assumption that an E/M service would be billed in conjunction with the service and cited the AMA summary of recommendations as evidence. Therefore, none of the pre- and post-time allocated to this code overlapped with the E/M service. They pointed out that the AMA RUC-recommended work RVU of 0.70 was lower than the survey median work RVU of 1.11. Commenters preferred the AMA RUC comparison of CPT code 92071 to CPT code 65205 (Removal of foreign body, external eye; conjunctival superficial) with a work RVU of 0.71 and noted that both services have identical physician time components and should be valued similarly. Therefore, commenters requested the AMA RUC recommended work RVU of 0.70 and the AMA RUC recommended pre-service and immediate post-service physician time of 5 minutes, each.

Response: After clinical re-review, we continue to believe that the reverse building block methodology is an appropriate way to value the services described by CPT code 92071. We maintain that some of the activities conducted during the pre- and post-service times of the procedure code and the E/M visit overlap and, therefore, should not be counted twice in developing the procedure's work value. To account for the overlap in work between CPT code 92071 and the same day E/M service, the AMA RUC removed 2 minutes pre-service time from the pre-service package time of 7 minutes. We believe that the pre-service package overstates the time involved in this procedure and that a more appropriate starting point for the same day E/M reduction for this procedure is the survey median pre-service time. We believe that removing 2 minutes of pre-service time from the survey median pre-service time of 5 minutes, as well as 2 minutes from the post-service time of 5 minutes better reflects the time involved in furnishing the work of this procedure alongside an E/M service. We continue to believe that a work RVU of 0.61 accurately reflects the work of the service relative to similar services. Therefore, we are finalizing a refinement to time and a work RVU of 0.61 for CPT code 92071. The times assigned to this CPT code are available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

(19) Special Otorhinolaryngologic Services: Audiologic Function Tests (CPT Codes 92587 and 92588)

On an interim final basis for CY 2012, we assigned a work RVU of 0.35 to CPT code 92587 (Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3–6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report) as detailed in the CY 2012 final rule with comment period (76 FR 73202). We identified CPT code 92587 as a potentially misvalued code through the Fastest Growing screen. The specialty society surveyed this service to create a new recommendation for CY 2011. However, after reviewing the survey data, it concluded that more than one service is represented by this code and requested the service be referred back to the CPT Editorial Panel for further clarification. As a result, the CPT Editorial Panel created CPT code 92558 (Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report) to describe evoked otoacoustic emissions screening, and revised CPT codes 92587 and 92588 clarify the otoaucoustic emissions evaluations, effective January 1, 2012. After clinical review of CPT code 92587, we believed that the survey 25th percentile work RVU of 0.35 accurately described the work associated with this service. The HCPAC reviewed the survey results, and after a comparison to similar CPT codes, recommended a work RVU of 0.45 for CPT code 92587, which was between the survey 25th percentile and median values. We believed that CPT code 92587 was similar in time and intensity to CPT code 97124 (Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)), which has a work RVU of 0.35, and that the survey 25th percentile value appropriately reflected the relativity of this service. Therefore, we assigned a work RVU of 0.35 to CPT code 92587 on an interim final basis for CY 2012.

Comment: Commenters disagreed with the interim final work RVU of 0.35 and urged CMS to use the HCPAC recommendation of 0.45 since it is between the survey 25th percentile and median values. Commenters stated that although 25th percentile might be reasonable in situations where the accuracy of the survey data is in doubt, in this case the overall distribution of the data, the size of the sample, and response rate made the median a better guide. Commenters noted the importance of cross specialty comparisons, but stated that a crosswalk to CPT code 97124 was not appropriate. Commenters stated that CPT code 92587 is a cognitive diagnostic service that requires the audiologist to review and interpret data resulting from numerous tonal pair samples administered to a patient's inner ear whereas CPT code 97124 is a therapeutic service involving hands-on manipulation of tissue and muscles. As a result, a more appropriate comparison code listed within the physical therapy section is the cognitive diagnostic work required to perform CPT code 97001 (Physical Therapy Evaluation), which has a work RVU of 1.20 and an intra-service time of 30 minutes. Commenters stated that it was, therefore, comparable to the requested 0.45 for 12 minutes of intra-service work for CPT code 92587. Commenters requested that we accept the HCPAC-

recommended work RVU of 0.45 for CPT code 92587 and requested refinement panel review of the code.

Response: Based on comments received, we referred CPT code 92587 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median value for CPT code 92587 was a work RVU of 0.45. We note that prior to our assignment of interim final work RVUs for CY 2012, CPT code 92587 had a work RVU of 0.13 because the work of this service was captured in the practice expense RVU as clinical labor, rather than in the work RVU as professional work. For CY 2012, the work of this service was moved from the PE RVU to the work RVU. In re-valuing the service to reflect this shift, we believe the survey 25th percentile work RVU of 0.35 captured the intensity of the professional work. While CPT codes 97124 and 92587 describe different services, we believe they involve the same time and have a very similar level of intensity and complexity and therefore should be valued the same. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing a work RVU of 0.35 for CPT code 92587.

On an interim final basis for CY 2012, we assigned a work RVU of 0.55 to CPT code 92588 (Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report) (76 FR 73202). After clinical review of CPT code 92588, we believed that the survey 25th percentile work RVU of 0.55 accurately described the work associated with this service. The HCPAC reviewed the survey results, and after a comparison to similar CPT codes, recommended the survey median work RVU of 0.62 for CPT code 92588. We believed that CPT code 92588 is similar in work to CPT code 92570 (Acoustic immittance testing, includes tympanometry (impedance testing), acoustic reflex threshold testing, and acoustic reflex decay testing), which has a work RVU of 0.55, and that the survey 25th percentile work RVU of 0.55 appropriately reflected the relativity of this service. Therefore, we assigned a work RVU of 0.55 to CPT code 92588 on an interim final basis for CY 2012.

Comment: Commenters agreed with us that CPT code 92588 involves a higher level of professional work and should be valued incrementally higher than CPT code 92587. However, commenters disagreed with the interim final work RVU values and believe the services furnished under the code involve a greater degree of professional work. Commenters stated that CPT code 92570 is not an appropriate comparison code because it is a bundled code that includes three different audiology tests, acoustic reflex threshold testing and acoustic reflex decay, as currently represented individually by CPT codes 92567 and 92568. As a bundled service, the work RVU for 92570 was reduced below the level of the combined services to account for efficiencies involved in conducting the three tests together. Commenters noted it is not appropriate to compare a bundled service, for which the work RVU has been reduced, with a test intended to evaluate overall outer hair cell function, using a minimum of 12 frequencies. Therefore, commenters requested the code be reviewed by the refinement panel.

Response: Based on comments received, we referred CPT code 92588 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median value for CPT code 92588 was a work RVU of 0.60. We note that prior to our assignment of interim final work RVUs for CY 2012, CPT code 92588 had a work RVU of 0.36 because the work of this service was captured in the practice expense RVU as clinical labor, rather than in the work RVU as professional work. For CY 2012, the work of this service was moved from the PE RVU to the work RVU. In re-valuing the service to reflect this shift, we believe the survey 25th percentile work RVU of 0.55 captured the intensity of the professional work. While CPT codes 92570 is a bundled service, we believe CPT codes 92570 and 92588 involve very similar time and intensity and should be valued the same. Furthermore, we believe a work RVU of 0.55 for CPT code 92588 reflects the appropriate incremental difference over the work RVU of 0.35 for CPT code 92587. After consideration of the public comments, refinement panel results, and our clinical review, we are finalizing a work RVU of 0.55 for CPT code 92588.

(20) Cardiovascular: Cardiac Catheterization (CPT Codes 93451–93568)

For CY 2012, we assigned the following interim final work RVUs for the following CPT codes: 2.72 for CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed), 4.75 for CPT code 93452 (Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed), 6.24 for CPT code 93453 (Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed), 4.79 for CPT code 93454 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation), 5.54 for CPT code 93455 (with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography), 6.15 for CPT code 93456 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with right heart catheterization), 6.89 for CPT code 93457 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization), 5.85 for CPT code 93458 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed), 6.60 for CPT code 93459 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography), 7.35 for CPT code 93460 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed), 8.10 for CPT code 93461 (Catheter placement in coronary artery(s) including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when

performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography), 1.11 for CPT code 93563 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization), 1.13 for CPT code 93564 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization, when performed), 0.86 for CPT code 93565 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for selective left ventricular or left arterial angiography), 0.86 for CPT code 93566 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for selective right ventricular or right atrial angiography), 0.97 for CPT code 93567 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for supravalvular aortography), and 0.88 for CPT code 93568 (Injection procedure during cardiac catheterization including image supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization for pulmonary angiography). As discussed in the CY 2011 final rule with comment period, the AMA RUC provided CMS with recommendations for several categories of new diagnostic cardiac catheterization services codes that previously were reported under multiple component codes. These AMA RUC-recommended values for the comprehensive diagnostic cardiac catheterization codes did not appear to reflect the efficiencies in work and/or PE that occur when component services are furnished together. The AMA RUC generally recommended the lower of either the sum of the current RVUs for the component services or the specialty society survey 25th percentile value for the comprehensive cardiac catheterization. In most cases, the AMA RUC's recommendation for the comprehensive service was actually the sum of the current work RVUs for the component services, and we stated in the CY 2011 final rule with comment period that we were unsure how this approach is resource-based with respect to physician work. As we noted in the CY 2011 final rule with comment period, in valuing these comprehensive services, we used a conservative estimate of 10 percent for the work efficiencies we would expect to occur when multiple component cardiac catheterization services are bundled together. In the CY 2011 final rule with comment period, we requested that the AMA RUC reexamine the cardiac catheterization codes.

As discussed in the CY 2012 final rule with comment period (76 FR 73202), the AMA RUC reviewed these codes again for CY 2012 and reiterated its previous recommendations, maintaining that there are negligible work efficiencies gained in the bundling of these services. However, we continued to believe that there would be efficiencies when these services are performed together that should be reflected in the values assigned. In lieu of a more specific estimate from the AMA RUC, and using the best information available to us at the time, we noted that we believed it was appropriate to assign as interim final for CY 2012 the AMA RUC CY 2011 recommendation with a 10 percent reduction in work to reflect the efficiencies described above.

Comment: Commenters noted that at CMS's second request, the AMA RUC workgroup reviewed significant documentation of the valuation and coding history of the codes and after this extensive review, still found the original work value recommendations for these codes to be appropriate. Commenters stated that maintaining the diagnostic catheterization codes at their CY 2011 work RVU levels is arbitrary and that instead we should accept the AMA RUC recommendation for these new set of codes for diagnostic cardiac catheterization.

Response: Based on the comments we received, we re-reviewed the cardiac catheterization codes (CPT codes 93451 through 93568). We appreciate that the AMA RUC reviewed the code set again; however, we still maintain that there are work efficiencies gained in the bundling of these services, and all services. The AMA RUC used a variety of methodologies in developing RVUs for the comprehensive services reviewed for CY 2012. The AMA RUC-recommended RVUs for the comprehensive codes for diagnostic cardiac catheterization were an average of only one percent lower than the original component codes. Given that the AMA RUC recommendations for the bundling of endovascular revascularization and CT codes resulted in average reductions in the RVUs of 27 percent and 25 percent, respectively, we continue to believe an approximation of work efficiencies garnered through the bundling of the component codes could be as high as 27 percent. Thus, in the absence of more precise information, we believe that a 10 percent reduction in the AMA RUC-recommended work RVUs is an appropriate and conservative approximation of these efficiencies. Therefore, we are finalizing the CY 2012 interim final values for the cardiac catheterization codes as the final work RVU values for CY 2013. Specifically, we are finalizing the following work RVUs for the following CPT codes: a work RVU of 2.72 for CPT code 93451; a work RVU of 4.75 for CPT code 93452; a work RVU of 6.24 for CPT code 93453; a work RVU of 4.79 for CPT code 93454; a work RVU of 5.54 for CPT code 93455; a work RVU of 6.15 for CPT code 93456; a work RVU of 6.89 for CPT code 93457; a work RVU of 5.85 for CPT code 93458; a work RVU of 6.60 for CPT code 93459; a work RVU of 7.35 for CPT code 93460; a work RVU of 8.10 for CPT code 93461; a work RVU of 1.11 for CPT code 93563; a work RVU of 1.13 for CPT code 93564; a work RVU of 0.86 for CPT code 93565; a work RVU of 0.86 for CPT code 93566; a work RVU of 0.97 for CPT code 93567; and a work RVU of 0.88 for CPT code 93568.

(21) Pulmonary: Other Procedures (CPT Codes 94060, 94726–94729)

CPT code 94060 (Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration) was assigned an interim final work RVU of 0.26 in the CY 2012 final rule with comment period (76 FR 73206). After CPT code 94060 was identified for review because it was on the Multispecialty Points of Comparison List, and also was identified as potentially misvalued through Codes Reported Together 75 percent or More screen, the CPT Editorial Panel reviewed the code and created CPT codes 94060, 94726 (Plethysmography for determination of lung volumes and, when performed, airway resistance), 94727 (Gas dilution or washout for determination of lung volumes and, when performed, distribution of ventilation and closing volumes), 94728 (Airway resistance by impulse

oscillometry), and 94729 (Diffusing capacity (eg, carbon monoxide, membrane) (List separately in addition to code for primary procedure)). For CY 2012, the CPT Editorial Panel also created CPT codes 94780 and 94781 to report car seat testing administered to the patient in the private physician's office.

For CY 2012, we assigned a work RVU of 0.26 to CPT codes 94060, 94726, 94727, and 94728 on an interim final basis (76 FR 73206). After clinical review, we determined that CPT codes 94060, 94726, 94727, and 94728, involve similar work and should have the same work RVUs. We noted that CPT code 94240 (Functional residual capacity or residual volume: helium method, nitrogen open circuit method, or other method) (work RVU=0.26) was deleted and the utilization associated with that service would be captured under the CPT codes 94726 and 92727. We also noted that we believed that a work RVU of 0.26 appropriately reflected the work associated with CPT codes 94060, 94726, 94727, and 94728 and that the AMA RUC had recommended the same work RVU (0.31) for all four codes, based upon each survey's 25th percentile work RVU. We explained that this value was further supported by CPT code 97012 (Application of a modality to 1 or more areas; traction, mechanical), which has a work RVU of 0.25) and which had similar time and intensity. Therefore, we assigned a work RVU of 0.26 to CPT codes 94060, 94726, 94727, and 94728 on an interim final basis for CY 2012.

Comment: Commenters disagreed with the work RVU assignments for these codes and stated that CPT code 94375 (Respiratory flow volume loop), which has a work RVU of 0.31, is the appropriate reference code, as the AMA RUC recommended. Although CPT code 94375 has more intra-service time (7 minutes compared to 5 minutes), the survey respondents rated the surveyed codes as more intense and complex than the reference code. Commenters stated that the appropriate value for the level of physician work involved in CPT codes 94060, 94726, 94727, and 94728 is 0.31 work RVUs. Therefore, commenters urged that we value CPT codes 94060, 94726, 94727, and 94728 based upon the AMA RUC-recommended work RVU of 0.31 and requested these codes be reviewed by the refinement panel.

Response: Based on comments received, we referred CPT codes 94060, 94726, 94727, and 94728 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVUs for the CPT codes were 0.27, 0.26, 0.26, and 0.26, respectively. As a result of the refinement panel ratings and our clinical review, we are assigning a work RVU of 0.27 as the final value for CPT code 94060 and 0.26 work RVUs as the final value for CPT code 94726, 94727, and 94728.

After clinical review of CPT code 94729 (Diffusing capacity (eg, carbon monoxide, membrane) (List separately in addition to code for primary procedure)), we believed that a work RVU of 0.17 accurately reflected the work associated with this service. Based on a comparison to similar services, the AMA RUC recommended a work RVU of 0.19. We believed that CPT code 94010 (Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation), which has a work RVU of 0.17, was similar in time and intensity to CPT code 94729, and that the codes should have the same work RVUs. Therefore, we assigned a work RVU of 0.17 to CPT code 94729 on an interim final basis for CY 2012.

Comment: Commenters disagreed that CPT code 94010 was similar in time and intensity to CPT code 94729, explaining that the service furnished under CPT code 94010, simple spirometry, is considered the foundation of pulmonary function testing and does not involve the same physician work as services furnished under CPT code 94729 a diffusing capacity including the membrane. Commenters suggested that the AMA RUC-recommended crosswalk code 93352 (Use of echocardiographic contrast agent during stress echocardiography), which has a work RVU of 0.19 has identical physician time of 5 minutes and comparable physician work and intensity to CPT code 94729. Commenters requested that we value the code based upon the AMA RUC-recommended work RVU of 0.19 for CPT code 94729 and requested this code be reviewed by the refinement panel.

Response: Based on comments received, we referred CPT code 94729 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 94729 was 0.19. As a result of the refinement panel ratings and our clinical review, we are finalizing a work RVU of 0.19 for CPT code 94729.

Furthermore, for CY 2013, we received no public comments on the CY 2012 interim final work RVUs for CPT codes 94780 and 94781. We believe these values continue to be appropriate and are finalizing them without modification.

(22) Neurology and Neuromuscular Procedures: Autonomic Function Tests (CPT Codes 95938–95939)

For discussion on interim work values for CPT codes 95938 and 95939, refer to section III.M.3. of this final rule with comment period.

(23) Central Nervous System Assessments/Tests (CPT Codes 96110, HCPCS Code G0451)

For CY 2012, the CPT Editorial Panel revised CPT code 96110 (Developmental screening, with interpretation and report, per standardized instrument form) to reflect current practice and avoid use of inaccurate terms associated with this code. For CY 2012 we created HCPCS code G0451 (Development testing, with interpretation and report, per standardized instrument form) to replace CPT code 96110, which is discussed in the CY 2012 final rule with comment period (76 FR 73265). In the CY 2012 final rule correction notice (77 FR 227), we noted that the discussion of CPT codes 96110 and G0451 was omitted from the CY final rule with comment period due to an inadvertent error, and we included our intended discussion in subsequent the correction notice. Additionally, we corrected the PFS status indicator in Addendum B for CPT code 96110 to N (Non-covered service. These codes are noncovered services. Medicare payment is not made for these codes. If RVUs are shown, they are not used for Medicare payment.), from X (Statutory exclusion. These codes represent an item or service that is not within the statutory definition of ''physicians' services'' for PFS payment purposes (for example, ambulance services). No RVUs are shown for these codes and no payment may be made under the PFS.). The discussion and information in this section reflects the changes made in CY 2012 final rule correction notice.

The CPT Editorial Panel revised the long descriptor for CPT code 96110 from (Developmental testing; limited (for example, Developmental Screening Test II, Early Language Milestone Screen), with interpretation and report) to (Developmental screening, with interpretation and report, per standardized instrument form), effective January 1, 2012. With this change, we believed that the services described by CPT code 96110 consisted of screening services, and thus was not within the scope of benefits of the Medicare program, as defined by the Act. Therefore, we assigned CPT code 96110 a PFS procedure status indicator of N. To continue to make payment under the PFS for the testing services described

under CPT code 96110 prior to revision of the long descriptor, we created HCPCS code G0451 (Developmental testing, with interpretation and report, per standardized instrument form). To calculate resource-based RVUs for HCPCS code G0451, we crosswalked the utilization, direct practice expense inputs, and malpractice risk factor from CPT code 96110 to HCPCS code G0451. We noted in the CY 2012 final rule with comment period that CPT code 96110 did not have physician work RVUs, therefore no physician work RVUs had been assigned to HCPCS code G0451. The CY 2012 interim final RVUs assigned to G0451 were included in Addendum B of the CY 2012 final rule correction notice.

Comment: We received notice from many commenters that they did not believe a procedure status of X was appropriate for CPT code 96110. Commenters stated that the change in the code description from ''developmental testing; limited'' to ''developmental screening'' should not preclude payment for this service. Additionally, other commenters raised concerns that this code is used for early developmental screening in pediatric offices and worried that our decision not to cover this code under the Medicare program would influence Medicaid coverage. Commenters recommended that this testing service should continue to be paid under the Medicare PFS.

Response: We thank commenters for bringing the error in the status indicator for CPT code 96110 to our attention. As noted above, we corrected the PFS status indicator in a correction notice (77 FR 227) to N (Noncovered service. These codes are noncovered services. Medicare payment may not be made for these codes. If RVUs are shown, they are not used for Medicare payment) is more appropriate for this code. Regarding commenters concern that the testing services previously reported under CPT code 96110 continue to be payable, we point out that while these service are no longer payable using CPT code 96110, they continue to be payable using HCPCS code G0451, effective January 1, 2012. We understand that our lack of discussion of these services in the CY 2012 PFS final rule with comment period may have furthered this concern. We received no public comments on the CY 2012 interim final work RVUs for HCPCS code G0451. We believe these values continue to be appropriate and are finalizing them without modification.

b. Finalizing CY 2012 Interim Direct PE Inputs

i. Background and Methodology

In this section, we address interim final direct PE inputs as presented in the CY 2012 PFS final rule with comment period and displayed in the final CY 2012 direct PE database available on the CMS Web site under the downloads at *http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage*.

On an annual basis, the AMA RUC provides CMS with recommendations regarding direct PE inputs, including clinical labor, supplies, and equipment, for new, revised, and potentially misvalued codes. We review the AMA RUC-recommended direct PE inputs on a code-by-code basis, including the recommended facility PE inputs and/or nonfacility PE inputs, as clinically appropriate for the code. We determine whether we agree with the AMA RUC's recommended direct PE inputs for a service or, if we disagree, we refine the PE inputs to represent inputs that better reflect our estimate of the PE resources required for the service in the facility and/or nonfacility settings. We also confirm that CPT codes should have facility and/or nonfacility direct PE inputs, and make changes based on our clinical judgment and any PFS payment policies that would apply to the code.

As we explained in the CY 2012 PFS final rule (76 FR 73212), we generally only establish interim final direct PE inputs for services when we receive direct PE input recommendations in the context of new, revised or potentially misvalued codes. However, for CY 2012, we established interim final direct PE inputs for several codes for which we did not receive direct PE recommendations. In the case of these codes, we believed it was necessary to establish new interim final direct PE inputs in order to maintain appropriate relativity among those codes and other related codes or between the PE, work and malpractice components of the PFS payment for the codes.

Comment: Several commenters stated that they understood CMS' rationale for refining the direct PE inputs on an interim final basis as we explained above, but urged CMS to bring the AMA RUC's attention to these codes during the AMA RUC process so that these interim final refinements by CMS could be avoided.

Response: We appreciate the commenters' suggestion. We also encourage the AMA RUC and other public commenters to consider issues related to maintaining appropriate relativity among related codes or between the PE, work, and malpractice components of the PFS payment for individual codes in the development of the recommendations that they provide to us. We believe that the AMA RUC and medical specialty societies, in light of CPT code descriptors and other language, as well as the guiding principles established through PFS rulemaking, are in a good position to identify, review, and develop direct PE input recommendations for coherent sets of codes, including component and combined codes, that ought to be developed or updated concurrently.

In the CY 2012 PFS final rule with comment period (76 FR 73213), we addressed the general nature of some of our common refinements to the AMA RUC-recommended direct PE inputs as well as the reasons for refinements to particular inputs. In the following subsections, we respond broadly to comments we received regarding common refinements we made based on established principles or policies. Following those discussions, we summarize and respond to comments received regarding other refinements to particular codes.

We note that the interim final direct PE inputs for CY 2012 that are being finalized for CY 2013 are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*. The inputs displayed there have also been used in developing the CY 2013 PE RVUs as displayed in Addendum B of this final rule.

We also note that for several codes for which we established interim final direct PE inputs for CY 2012, we either made proposals in the CY 2013 PFS proposed rule with comment period as a result of those comments or we are establishing CY 2013 interim final direct PE inputs for the services based on new recommendations from the AMA RUC. We acknowledge receipt of those comments here and we note that those comments were taken into consideration in the development of CY 2013 PFS proposals and our consideration of the CY 2013 AMA RUC direct PE input recommendations.

ii Common Refinements

(1) Equipment Time

Prior to CY 2010, the AMA RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the AMA

RUC provide equipment times along with the other direct PE recommendations, and we provided the AMA RUC with general guidelines regarding appropriate equipment time inputs. We continue to appreciate the AMA RUC's willingness to provide us with these additional inputs as part of its direct PE recommendations.

In general, the equipment time inputs correspond to the intra-service portion of the clinical labor times. We have clarified that assumption to consider equipment time as the sum of the times within the intra-service period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. In addition, when a piece of equipment is typically used during additional visits included in a service's global period, the equipment time should also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the pre-service or post-service tasks performed by clinical labor on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of clinical staff may be occupied with a pre-service or post-service task related to the procedure.

Some commenters have repeatedly objected to CMS' rationale for refinement of equipment minutes on this basis. We acknowledge the comments we received that reiterate those objections to this rationale and refer readers to our extensive discussion regarding those objections in the CY 2012 PFS final rule with commenter period (76 FR 73182). In following paragraphs we address new comments on this policy.

Comment: One commenter suggested that ''CMS allows only a single staff type'' for certain services, so that when pre-service and post-service clinical labor tasks are assigned only to one type of clinical labor (a CT technologist, for example), the equipment otherwise used by that technologist (the CT room) is necessarily unavailable to another patient. Therefore, the commenter argued that in those cases CMS should also allocate the total number of minutes for all the clinical labor tasks on the day of the service to the CT room regardless of whether or not it is typical for the pre-service or post-service activities to actually take place in the room.

Response: We understand the commenter's argument, but we do not agree with the conclusion for several reasons. First, we do not agree that allocating a number of minutes to a particular type of clinical staff in the direct PE input database can be appropriately viewed as CMS ''allowing only a single staff type'' being used to furnish services to Medicare beneficiaries. We believe that the direct PE input database should reflect the resources typically required in furnishing particular services, but we have no reason to believe that the inputs included in the database are prescriptive as to what actually happens in a medical practice. Therefore, we do not think the direct PE database staff type is likely to be a determining factor for the division of labor in physician offices and other nonfacility settings. Furthermore, we do not believe that most free-standing centers that furnish highly technical services to Medicare beneficiaries typically only employ one clinical staff member at a time. Therefore, it would not be reasonable to assume that all capital equipment in a typical practice is unavailable for use whenever pre- or post-service tasks are being undertaken by any individual technologist.

We also note that there are hundreds of services in the direct PE input database that include more than one type of staff in the clinical labor inputs. For many services, for example, minutes are allocated for a standard nurse blend staff type for pre-service and post-service tasks, while technologists are only allocated intra-service period minutes. There is no standing CMS policy that would prevent consideration of dividing clinical labor tasks among different types of clinical labor in the direct PE input database.

Comment: One commenter expressed a concern regarding the relationship between the CMS refinement of recommended equipment minutes and the 75% equipment utilization rate assumption mandated by section 1848(b)(4)(C) of the Act. The commenter also stated that these refinements are arbitrary and will further widen the gap between Medicare payments determined by the Medicare hospital outpatient prospective payment system (OPPS) and the technical component of PFS services.

Response: As we have previously stated, we believe that many of the pre-service and post-service clinical labor tasks typically take place outside of resource-intensive equipment rooms to maximize use of capital-intensive resources. Monopolizing the room for fewer minutes per patient maximizes the availability of the machines. In turn, the assumed rate of use for the machine should be greater, and the resource cost of the machine is reduced through these efficiencies. Since the direct PE input database should reflect the typical resource costs of medical equipment, we believe that the reduced minutes and increased utilization rate are complementary, not contradictory.

In response to the commenter's second assertion, these refinements are far from arbitrary. We have consistently applied these principles in refining the direct PE inputs for services as we review equipment inputs through the potentially misvalued code initiative and our review of new and revised codes since the AMA RUC started providing equipment minute recommendations to CMS in 2010. We believe that imprecise allocation of equipment minutes may be a significant factor in certain potentially misvalued codes. We understand the importance of relativity within the equipment category of direct practice expenses and seek public comment on whether it might be necessary to consider making corresponding refinements to equipment minutes for services across the fee schedule for the sake of maintaining relativity.

Finally, as a general statement, differences in payment rates between different payment systems do not necessarily indicate a lack of appropriate relativity within each system. There can be legitimate reasons why a payment rate should vary in different payment systems (for example, higher indirect costs, different payment bundles). Nevertheless, excessive differences in payment rates between payment systems can be one indication of the need to examine the relativity between services in one or both systems. While we continue to examine this issue, we do not believe that it would be appropriate to establish or maintain inaccurate direct PE inputs for these services based on comparisons between the PFS and OPPS payment rates.

We will continue to work to improve the accuracy of the equipment minutes as reflected in the direct PE input database and will address any further improvements in future rulemaking.

After consideration of these comments, we are finalizing the current interim final direct PE inputs as refined based on this policy. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(2) Changes in Physician Time

Some direct PE inputs are directly affected by revisions in physician time. Specifically, changes in the intra-service portions of the physician time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. While the direct PE input recommendations generally correspond to the physician time values associated with services, we believe that in some cases inadvertent discrepancies between physician time values and direct PE inputs should be refined in the establishment of interim final direct PE inputs. In other cases, CMS refinement of recommended interim final physician times prompts necessary adjustments in the direct PE inputs. In the context of our establishment of interim final direct PE inputs for CY 2013, we explain those refinements in section III.M.3.b of this final rule with comment period.

Comment: One commenter requested an explanation regarding why CMS assumes that the clinical time allocated for assisting the physician performing the procedure should conform to the physician intra-service time.

Response: As we have explained in previous rulemaking (76 FR 73213), for most codes valued in the nonfacility setting, a portion of the clinical labor time allocated to the intra-service period reflects minutes assigned for assisting the physician with the procedure. This time is usually allocated at some proportion of the physician time for a procedure. Frequently, the allocation is for the full physician intraservice time; this reflects the assumption that the clinical staff is assisting the physician during the entire procedure. For other services, the allocation is two-thirds or one-half of the physician time; this reflects the assumption that clinical staff is assisting the physician for a portion of the procedure time. In establishing interim final direct PE inputs, we note a change in clinical labor time (or corresponding change in equipment minutes) that results from a change in physician time as ''conforming to physician time.'' This note is not used to reflect a refinement to the recommended proportion for which the staff is assisting the physician performing the procedure. Instead, these refinements reflect a change in the base procedure time assumption for the service. After consideration of this comment, we are finalizing the current interim final direct PE inputs as refined based on this policy. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(3) Proxy Inputs for Digital Imaging

Comment: In the context of several codes, several commenters objected to CMS' not accepting certain recommended items as direct PE inputs since these items, though atypical, may be considered surrogate items for digital imaging technology.

Response: A variety of imaging services across the PFS include direct PE inputs that reflect film-based technology instead of digital technology. We have accepted the film-based technology inputs in the RUC recommendations as proxy inputs until a more comprehensive migration of such inputs from film to digital imaging can be executed. We anticipate updating all of the associated inputs in future rulemaking.

After consideration of these comments, we are finalizing the current interim final direct PE inputs as refined based on this policy. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

iii Code-Specific Direct PE Inputs

(1) Integumentary System: Repair (Closure) (CPT Codes 15271, 15273, 15275, 15277)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendation for CPT codes 15271 (Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area), 15273 (Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children), 15275 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area), and 15277 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children) to allocate the full service period minutes to the basic instrument pack (EQ137) by reducing the equipment allocation by 3 minutes to account for the overlapping time for cleaning the room and the pack.

Comment: One commenter disagreed with CMS' reduction of the recommended minutes and stated that since the pack is unavailable for other patients while the room is being cleaned, the pack should be allocated the full number of service period clinical labor minutes, including the time for cleaning both the room and the pack. The commenter also stated that cleaning of the instruments is discrete work, most often done after the patient's departure.

Response: Since clinical labor is allocated a specific number of minutes for cleaning surgical instrument packs, we do not believe that we should also allocate the clinical labor minutes for cleaning the other equipment associated with the services. Because we agree with the commenter that the task is discrete from the cleaning associated with the other equipment and the room itself, we do not think that the instrument pack is unavailable when the room is being cleaned.

CMS also refined the recommended direct PE inputs for CPT codes 15273 and 15275 by not including the post-op incision care (suture) pack (SA054) in each code because the code itself does not describe post-op care.

Comment: One commenter disagreed with the refinement and pointed out that CPT guidelines state: ''Skin replacement surgery consists of surgical preparation and topical placement of an autograft (including tissue cultured autograft) or skin substitute graft (ie, homograft, allograft, xenograft). The graft is anchored using the provider's choice of fixation. When services are performed in the office, routine dressing supplies are not reported separately. Removal of current graft and/or simple cleansing of the wound is included, when performed.'' The commenter also noted that CPT codes 15273 and 15277 typically involve large grafts that will be anchored by sutures, and although these codes have a 0-day global period, removal of the graft is included in the work and therefore a suture removal kit is appropriate as a supply item.

Response: Based on the rationale presented by the commenters, CMS agrees that one pack should be included as a supply item for CPT codes 15273 and 15277. After consideration of the comments received, we are finalizing the direct PE inputs for CPT codes 15271, 15273, 15275, and 15277 as established as interim final with the additional refinement of incorporating the supply item discussed above for CPT codes 15273 and 15277.

(2) Musculoskeletal: General: Introduction or Removal (CPT Code 20527)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendation for CPT code 20527 (Injection, enzyme (eg, collagenase), palmar fascial cord (ie, dupuytren's contracture)) by including a minimum multi-specialty visit pack (SA048) as a direct PE input for the service.

Comment: A commenter presented information indicating that the multi-specialty pack is not typically used in furnishing the service.

Response: We agree with the information presented by the commenter.

After consideration of this comment, we are finalizing the direct PE inputs for CPT code 20527 as established as interim final with the additional refinement of removing the supply item discussed above. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(3) Musculoskeletal: Spine (Vetebral Column) (CPT Code 22525)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendation for CPT code 22525 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure))by not including additional clinical labor and equipment time for preparing the room, equipment, and supplies since the CPT code 22525 is an add-on code and time for those tasks is already included in the base code.

Comment: A commenter disagreed with the removal of 2 minutes for preparing the room, equipment, and supplies and stated that since the add-on code requires more equipment than the base code the direct PE inputs should include additional minutes for preparing that equipment.

Response: Based on our clinical review, we believe that the standard number of minutes allocated for the clinical labor to prepare the room, equipment, and supplies in the base code approximates the typical number of minutes for such tasks including the cases where the add-on code is necessary. Were the minutes accounted for separately in the add-on code, the number of minutes included in the base code would need to be re-examined. At this time, we believe that it would be more appropriate to maintain the standard number of minutes in the base code and not allocate additional time in the add-on code.

Comment: A commenter informed CMS that the clinical labor codes associated with CPT Code 22525 were transposed in the direct PE input database.

Response: We appreciate being informed of the inadvertent assignment of labor codes.

After consideration of these comments, we are finalizing the direct PE inputs for CPT code 22525 as established as interim final with the additional refinement of assigning the appropriate labor codes.

(4) Musculoskeletal: Hand and Fingers (CPT Code 26341)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendation for CPT code 26341 (Manipulation, palmar fascial cord (ie, dupuytren's cord), post enzyme injection (eg, collagenase), single cord) by including a minimum multi-specialty visit pack (SA048) as a direct PE input for the service period in the nonfacility and the same pack in both settings to account for the post-service office visit included in the global period.

Comment: A commenter stated that while the pack was typically used in the nonfacility setting during the service period, it is not typically used for the post-service office visit.

Response: The allocation of the supply pack minutes in the facility setting reflects the standard allocation of direct PE inputs based on the office visits included in the global period for the service. We discuss the specifics related to these standard allocations in section III.M.3.b of this final rule with comment period. At this time, we do not believe it would be appropriate to deviate from these standards. We direct readers interested in the appropriate valuation of services with global periods to section III.B.2.d of this final rule with comment period.

After consideration of this comment, we are finalizing the direct PE inputs for CPT code 26341 as established as interim final. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(5) Respiratory: Lungs and Pleura (CPT Code 32405) and Digestive: Liver (CPT Code 47000)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendations for CPT codes 32405 (Biopsy, lung or mediastinum, percutaneous needle) and 47000 (Biopsy of liver, needle; percutaneous) by removing minutes allocated to the CT room (EL007) since these services are typically billed with radiological supervision and interpretation (S&I) services.

Comment: A commenter pointed out that the CT room time included with the S&I code 77012 is only 9 minutes, which reflects a convention for some S&I codes. On this basis, the commenter suggested that for these codes, the CT room should be allocated the standard number of minutes minus the 9 minutes that overlap with the S&I code.

Response: We appreciate the commenter pointing out this allocation of equipment minutes. We note that this convention does not apply consistently to all S&I codes and related procedure codes. We may address such inconsistencies in future rulemaking.

After consideration of this comment, we are finalizing the direct PE inputs for CPT codes 32405 and 47000 as established as interim final with the additional refinement of including the CT room as a direct PE input for the services, with the reduction of 9 minutes to account for the overlapping number of minutes allocated in the S&I code.

(6) Cardiovascular: Arteries and Veins (CPT Codes 36200, 36246, 36247)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendations for CPT codes 36200 (Introduction of catheter, aorta), 36246 (Selective catheter placement, arterial system; initial second order abdominal, pelvic, or lower extremity artery branch, within a vascular family), and 36247 (Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family) by reducing the number of clinical labor minutes allocated for preparing the room, equipment, and supplies used in the service to the standard number of minutes allocated to clinical labor for those tasks.

Comment: One commenter stated that since vascular procedures have more variable supplies than typical procedures, more minutes for preparing supplies should be allocated for the clinical labor direct PE inputs.

Response: Upon clinical review of these procedures, we believe that the standard number of minutes allocated for such tasks in similar services across the direct PE input database adequately accounts for the variability of supplies in these procedures.

After consideration of this comment, we are finalizing the direct PE inputs for CPT codes 36200, 36246, and 36247 as established as interim final. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(7) Digestive: Abdomen, Peritoneum, and Omentum (CPT Code 49083)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendations for CPT code 49083 (Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance) by reducing the number of clinical labor minutes recommended for a series of tasks to correspond with the standard minutes as allocated across PFS services. Additionally, CMS refined the minutes allocated to the equipment associated with the service based on the standard allocation of minutes for highly technical and resource-intensive equipment.

Comment: A commenter suggested that 42 minutes should be allocated to the equipment using CMS' methodologies and including the 25 minutes corresponding to the assist physician time.

Response: We agree with the commenter that the 25 minutes is the appropriate time allocated for assisting the physician. However, we do not agree with the final number of minutes that should be allocated for the equipment. Based on our standard review for such equipment, we believe that the equipment should be allocated the minutes assumed for preparing the room, equipment, and supplies, preparing and positioning the patient, the procedure time itself, and the time allocated to clean the room and the equipment. Based on the procedure-specific assist physician time and the standard number of minutes allocated for the additional pre-service and post-service tasks, we have calculated the appropriate equipment minutes to sum to 32.

After consideration of this comment, we are finalizing the direct PE inputs for CPT code 49083 as established as interim final, with the additional refinement of allocating 32 minutes for the equipment used in the service. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(8) Urinary: Bladder (CPT Code 51736)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendations for CPT code 51736 (Simple uroflowmetry (ufr) (eg, stop-watch flow rate, mechanical uroflowmeter)) by adding the following supplies to the direct PE inputs for the service based on CMS clinical review: paper towel (SK082), disinfectant spray (SM012), and sanitizing cloth wipe (SM022).

Comment: A commenter disagreed with this refinement and suggested instead that these supplies, as well as the digital uroflowmeter (EQ259), should instead only be included as direct PE inputs for CPT code 51741 (Complex uroflowmetry (eg, calibrated electronic equipment)).

Response: Upon further clinical review, and on the basis of the commenter's recommendation, we agree that the items should be removed from the service.

After consideration of this comment, we are finalizing the direct PE inputs for CPT code 51741 as established as interim final, with the additional refinement of removing the three supply items and one equipment item identified above. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(9) Nervous: Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System (CPT Codes 64633, 64635)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendations for CPT code 64633 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or ct); cervical or thoracic, single facet joint) and 64635 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or ct); lumbar or sacral, single facet joint) by not including the recommended radiofrequency probe kit (SA100) as a supply item. As we explained in the CY 2012 PFS final rule (76 FR 73214), the very expensive disposable item had not previously been included as a direct PE input for predecessor codes that described the same services, and the recommendation did not include any information suggesting that such a significant resource cost had become typical in furnishing the services. At that time, we noted that the direct PE inputs for these codes were considered interim for CY 2012, and we would consider any submitted information regarding the use of this supply in furnishing these services prior to finalizing the direct PE inputs for CY 2013.

Comment: One commenter responded to this refinement by explaining that furnishing the service requires a radiofrequency kit, but that the kit is reusable and typically has a useful life of several months.

Response: We appreciate the information from the commenter, though we generally prefer additional information, including paid invoices, in order to price supply or equipment items accurately. For CY 2013, we believe it would be appropriate to finalize the direct PE inputs for these services with a new equipment item based on the disposable item included in the original recommendation and the information supplied by the commenter. We encourage stakeholders to submit additional information through the public process for updating prices for supplies and equipment we established in the CY 2011 PFS final rule (75 FR 73205–73207). We believe that that process will allow us to describe the item and assign its price and useful life more accurately.

CMS also refined the recommended direct PE inputs for CPT codes 64633 and 64635 by allocating equipment minutes in the facility setting for the exam table (EF023) and the exam light (EQ168) based on the post-service office visits included in the global periods.

Comment: One commenter suggested that allocating this time was not appropriate.

Response: The allocation of equipment minutes in the facility setting reflects the standard allocation of direct PE inputs based on the office visits included in the global period for the service. We discuss the specifics related to these standard allocations in section III.M.3.b of this final rule with comment period. At this time, we do not believe it would be appropriate to deviate from these standards. We direct readers interested in the appropriate valuation of services with global periods to section III.B.2.d of this final rule with comment period.

After consideration of these comments, we are finalizing the direct PE inputs for CPT code 64633 and 64635 as established as interim final, with the additional refinement of establishing this equipment item, ''radiofrequency kit for destruction by

neurolytic agent'' (EQ354) as a placeholder direct PE input for the codes until we receive more information regarding the item. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(10) Diagnostic Radiology: Spine and Pelvis (CPT Code 72120, 72170)

In establishing interim final direct PE inputs for 2012, CMS refined the direct PE inputs for CPT codes 72120 (Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views) and 72170 (Radiologic examination, pelvis; 1 or 2 views) by reducing the number of minutes allocated to the clinical labor for cleaning the room and equipment to one.

Comment: A commenter disagreed with the revision and suggested that CMS should use the standard 3 minutes for this activity.

Response: We appreciate the commenter's interest in CMS using the standard number of minutes for clinical labor tasks. As we explained in our refinements regarding reducing recommendations that exceeded the standard number of minutes, we believe that the standard number of minutes generally accommodates the range of minutes likely to be typical for such activities. We agree that it would be appropriate to include the standard minutes for these services.

After consideration of these comments, we are finalizing the direct PE inputs for CPT codes 72120 and 72170, with the additional refinement of allocating two additional minutes to the clinical labor and the associated equipment inputs for cleaning the room and equipment. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(11) Nuclear Medicine: Diagnostic (CPT Codes 78226, 78227, 78579, 78580, 78582, 78597, 78598)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendations for CPT codes 78226 (Hepatobiliary system imaging, including gallbladder when present;), 78227(Hepatobiliary system imaging, including gallbladder when present; with pharmacologic intervention, including quantitative measurement(s) when performed), 78579 (Pulmonary ventilation imaging (eg, aerosol or gas)), 78580 (Pulmonary perfusion imaging (eg, particulate)), 78582 (Pulmonary ventilation (eg, aerosol or gas) and perfusion imaging), 78597 (Quantitative differential pulmonary perfusion, including imaging when performed), and 78598 (Quantitative differential pulmonary perfusion and ventilation (eg, aerosol or gas), including imaging when performed) by refining equipment time allocations as described in section III.M.2.b above.

Comment: One commenter disagreed with those refinements and urged CMS to identify the clinical labor tasks associated with the minutes excluded from the equipment allocation.

Response: We refer the commenter to the discussion above regarding the general principles of accurate assignment of equipment minutes. In the case of this family of codes, we believe that it is appropriate to allocate equipment minutes for clinical labor tasks of preparing the room, positioning the patient, placing the IV, acquiring images during the procedure itself, and cleaning the room, including additional minutes of cleaning for regulatory compliance. We do not believe that expensive equipment is typically unavailable for use for other patients while clinical staff performs such tasks as greeting and gowning the patient, reviewing mandatory radiation education, helping the patient to the waiting room, completing diagnostic forms or making lab and X-ray requisitions. The minutes allocated to the equipment in the direct PE input database reflect the application of these principles as specifically determined through CMS clinical review.

CMS also refined the recommended direct PE inputs for CPT codes 78226, 78227, 78579, 78580, 78582, 78597, 78598 by examining all of the educational tasks included in the AMA RUC's recommendation and refining the sum of those times to a total number of minutes considered accurate under CMS clinical review. The AMA RUC recommendation included 6 minutes of education by the nuclear medicine technologist. CMS refined the total number of minutes allocated for educational tasks to 4.

Comment: One commenter disagreed with the refinement to remove the minutes allocated for providing patient counseling while the patient is being taken back to the waiting area. This commenter suggested that CMS may be confusing the recommended minutes for this task with the concurrent recommendation to include the standard number of minutes for patient education. The commenter suggested that since nuclear medicine patients are radioactive when they leave departments, they require more education than other services, especially since patients need to be reminded about the dangers of radioactivity after they leave the office.

Response: We agree with the commenter that it is reasonable for more time to be allocated to these services for patient education. We also note that our interim refinements included more education time than typical for PFS services. However, we believe that it would be appropriate to include a total of 5 minutes for clinical labor patient education activities for these services in consideration of the comments received.

CMS also refined the recommended direct PE inputs for CPT codes 78226, 78227, 78579, 78580, 78582, 78597, 78598 by examining all of the cleaning tasks included in the AMA RUC's recommendation and refining the sum of those times to a total number of minutes considered accurate under CMS clinical review. The AMA RUC recommendation included 13 minutes of cleaning tasks by a nuclear medicine technologist. CMS refined the total number of minutes allocated for educational tasks to 10.

Comment: One commenter suggested that the full 13 minutes of cleaning per service should be allocated on a standard basis for these codes to account for the number of minutes required to meet cleaning regulatory cleaning standards for services that use radioactive pharmaceuticals. The commenter also noted that this allocation has been included in similar services.

Response: Upon clinical review, we continue to doubt that nuclear medicine technologists typically clean the room and equipment for 13 minutes following every service. However, we acknowledge that there is an additional cleaning burden for these services, and we also agree with the commenter that other services that use similar substances incorporate the same number of minutes for mandated cleaning. Therefore, we believe it is appropriate that these services include these additional minutes for cleaning.

After consideration of these comments, we are finalizing the direct PE inputs for CPT codes 78226, 78227, 78579, 78580, 78582, 78597, 78598 with the additional refinement of allocating 1 additional clinical labor minute for patient education tasks and an additional 3 minutes to the clinical labor and equipment items to account for mandatory cleaning tasks. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final

rule at *www.cms.gov/PhysicianFeeSched/*.

(12) Pulmonary: Diagnostic Testing and Therapies (CPT Codes 94728)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendations for CPT code 94728 (Airway resistance by impulse oscillometry) by adding the body plethysmograph autobox (EQ044) as direct equipment input for the service based on the item's inclusion as a direct PE input for related services.

Comment: One commenter noted that this code is used to describe services furnished primarily for children and that the equipment item cannot be used with pediatric patients.

Response: We appreciate the additional information regarding the appropriate use of the equipment.

After consideration of these comments, we are finalizing the direct PE inputs for CPT code 94728 with the additional refinement of removing the equipment item discussed above as a direct PE input for the service. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

(13) Hydration, Therapeutic, Prophylactic, Diagnostic Injections and Infusions, and Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration (CPT Codes 96413, 96416)

In establishing interim final direct PE inputs for 2012, CMS refined the AMA RUC's recommendations for CPT code 96413 (Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug) by not including the 6 clinical labor minutes in the pre-service period for completing pre-service diagnostic and referral forms and coordinating pre-surgery services since these tasks are not generally allocated for services without global periods.

Comment: Several commenters suggested that the recommended times for these tasks reflects the time for the oncology nurse to document the upcoming chemotherapy session based on the physician's orders, coordinate the service under the physician's direction, ensure that the planned infusion is consistent with physician's direction, and confirm that there is no change in the drugs to be infused, anti-emetics to be supplied, or post-treatment instructions. The commenter also noted that the minutes allocated for those tasks in CPT code 96416 (Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump) were removed in the same recommendation in order to account for the overlap in tasks since CPT code 96413 is typically also reported whenever CPT code 96416 is reported.

Response: We agree with the commenter's recommendation to include those six minutes in CPT code 96413 and exclude those minutes in CPT code 96416, consistent with the AMA RUC recommendation.

CMS refined the recommended direct PE inputs for CPT code 96416 by not including the 4 minutes assigned to the clinical labor for reviewing the charts and obtain chemotherapy-related medical history. This refinement reflected that CMS clinical review concluded that these tasks are already accounted for in the clinical labor minutes assigned to CPT code 96413 and would typically not be repeated when CPT code 96416 is reported.

Comment: Several commenters claimed that the nurse must perform these tasks and that the time is appropriately valued at 4 minutes.

Response: We agree with the commenters that the time for the tasks is appropriately estimated at 4 minutes, but we maintain our belief that the tasks fully overlap with the same tasks associated with CPT code 96413, which is typically also reported whenever CPT code 96416 is reported. Therefore, we do not believe those 4 minutes should be allocated to both services.

CMS also refined the recommended direct PE inputs for CPT code 96416 by examining all of the tasks described in the AMA RUC's recommendation for monitoring the patient and removing the minutes that overlap with monitoring included in CPT code 96413. This refinement assumed no monitoring was necessary beyond the monitoring time already associated with CPT code 96413.

Comment: One commenter objected to the refinement of the intra-service time since the clinical labor performs the procedure.

Response: We agree with the commenter that the recommendation reflects that the clinical staff is performing the procedure. The rationale for our refinement of the minutes for the task ''assist physician performing the procedure'' was described broadly as ''conforming to physician time'' in the CY 2012 PFS final rule (76 FR 73264), but was specifically intended to address the overlap in minutes allocated for monitoring the patient following the administration. We continue to believe that some of the 18 recommended minutes for monitoring tasks in CPT code 96416 overlap with the 24 minutes included in CPT code 96413 for monitoring. However, upon further clinical review, we believe that the overlap is not complete and that it would be appropriate to increase the total clinical labor minutes allocated in the service period by an additional 11 minutes to account for the additional monitoring that would typically occur when CPT code 96416 is furnished.

After consideration of these comments, we are finalizing the direct PE inputs for CPT codes 96413 and 96416 with the additional refinements of including an additional 6 minutes of clinical labor time in the pre-service period for CPT code 96413 and including an additional 11 minutes of clinical labor time in the service period for CPT code 96416. We also note that the minutes allocated to the equipment inputs will increase based on our standard allocation policies. The direct PE inputs are displayed in the final CY 2013 direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS final rule at *www.cms.gov/PhysicianFeeSched/*.

For all other CY 2012 new, revised, or potentially misvalued codes with CY 2012 interim final RVUs that are not specifically discussed in this final rule with comment period, we are finalizing, without modification, the interim final direct PE inputs that we initially adopted for CY 2012.

c. Finalizing CY 2012 Interim and Proposed Malpractice Crosswalks for CY 2013

Consistent with our malpractice methodology described in section III.C.1. of this final rule with comment period, for the CY 2012 PFS final rule, we assigned malpractice RVUs for CY 2012 new and revised codes by utilizing crosswalks to source codes that have a similar malpractice risk-of-service. After reviewing the AMA RUC-recommended malpractice source code crosswalks for CY 2012 new and revised codes, we accepted nearly all of them on an interim final basis for CY 2012. As detailed in the CY 2012 final rule with comment period (76 FR 73264 through 73265), for four CPT codes describing multi-layer compression systems, we assigned a malpractice crosswalk different from the malpractice crosswalk recommended by the AMA RUC and HCPAC.

In the CY 2012 PFS final rule with comment period, for CPT codes 29581 (Application of multi-layer compression

system; leg (below knee), including ankle and foot), 29582 (Application of multi-layer compression system; thigh and leg, including ankle and foot, when performed), 29583 (Application of multi-layer compression system; upper arm and forearm), and 29584 (Application of multi-layer compression system; upper arm, forearm, hand, and fingers), we assigned an interim final malpractice crosswalk from CPT code 97140 (Manual therapy techniques (eg, mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes). CPT codes 29582, 29583, and 29584 were new for CY 2012. The AMA RUC recommended, and we agreed, that the estimated utilization for CPT codes 29582, 29583, and 29584 would have previously been reported using CPT code 97140. After review, we believed that CPT code 97140 provides the most appropriate malpractice source code crosswalk for CPT codes 29582, 29583, and 29584. As discussed in section III.M.3 of this CY 2013 final rule with comment period, in the CY 2012 PFS final rule with comment period we stated that we believe CPT codes 29581, 29582, 29583, and 29584 all describe similar services from a resource perspective, and we assigned CPT code 29581 the same interim work RVU as CPT code 29583. Because we find these services to be so similar, we stated that we also believed that it is appropriate for CPT codes 29581 and 29583 to have the same malpractice source code crosswalk. Therefore, we assigned CPT code 97140 as the malpractice source code crosswalk for CPT codes 29581, 29582, 29583, and 29584.

Additionally, for CY 2012 we created HCPCS G-code G0451 (Development testing, with interpretation and report, per standardized instrument form) to replace CPT code 96110 (Developmental screening, with interpretation and report, per standardized instrument form). For CY 2012, we assigned CPT code 96110 as the malpractice source code crosswalk for HCPCS code G0451.

In accordance with our malpractice methodology, we adjusted the malpractice RVUs for the CY 2012 new/revised codes for the difference in work RVUs (or, if greater, the clinical labor portion of the fully implemented PE RVUs) between the source codes and the new/revised codes to reflect the specific risk-of-service for the new/revised codes. The interim final malpractice crosswalks were listed in Table 22 of the CY 2012 PFS final rule with comment period (76 FR 73266 through 73268).

We received no comments on the CY 2012 interim final malpractice crosswalks and are finalizing them without modification for CY 2013. The malpractice RVUs for these services are reflected in Addendum B of this CY 2013 PFS final rule with comment period.

d. Other New, Revised or Potentially Misvalued Codes With CY 2012 Interim Final RVUs or CY 2013 Proposed RVUs Not Specifically Discussed in the CY 2013 Final Rule With Comment Period

For all other new, revised, or potentially misvalued codes with CY 2012 interim final RVUs or CY 2013 proposed RVUs that are not specifically discussed in this final rule with comment period, we received no public comments and, as such, we are finalizing, without modification, the interim final or proposed work and direct PE inputs we initially adopted in the CY 2012 final rule with comment period or the CY 2013 proposed rule, respectively. The time values for all codes appear on the CMS Web site at *www.cms.gov/PhysicianFeeSched/*. Refer to Addenda B for a comprehensive list of all final values.

3. Establishing Interim Final RVUs for CY 2013

a. Establishing CY 2013 Interim Final Work RVUs

As previously discussed in section III.M.2 of this final rule with comment period, on an annual basis the AMA RUC and HCPAC, along with other public commenters, provide CMS with recommendations regarding physician work values for new and revised CPT codes. This section discusses services for which CMS disagreed with the recommended physician work RVU or time values for CY 2013 new or revised CPT codes, services that had interim or interim final values in CY 2012 and will continue to have interim or interim final values for CY 2013, as well as the physician work and time values for new and revised HCPCS G-codes. The interim or interim final work RVUs for all codes in this section, including those where CMS agreed with the recommended work RVU, appear in Table 2 at the start of this section. Unless otherwise indicated, we agreed with the time values recommended by the AMA RUC or HCPAC for all codes addressed in this section. The time values for all codes appear on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

We note that in addition to the CPT codes discussed in this section, the CPT Editorial created, and the AMA RUC reviewed, many new CPT codes for molecular pathology tests. These services will be payable on the Medicare Clinical Laboratory Fee Schedule and are discussed in detail in section III.I of this CY 2013 PFS final rule with comment period.

i. Code-Specific Issues

TABLE 30—WORK RVUS FOR CY 2013 NEW, REVISED, AND POTENTIALLY MISVALUED CODES

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU *	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU *	CMS refinement to AMA/HCPAC recommended time *
10120	Remove foreign body	1.25	1.25	1.22	Disagree	Yes.
11055	Trim skin lesion	0.43	0.43	0.35	Disagree	Yes.
11056	Trim skin lesions 2 to 4	0.50	0.50	0.50	Agree	No.
11057	Trim skin lesions over 4	0.79	0.79	0.65	Disagree	Yes.
11300	Shave skin lesion 0.5 cm/<	0.51	0.60	0.60	Agree	No.
11301	Shave skin lesion 0.6–1.0 cm	0.85	0.90	0.90	Agree	No.
11302	Shave skin lesion 1.1–2.0 cm	1.05	1.16	1.05	Disagree	No.
11303	Shave skin lesion >2.0 cm	1.24	1.25	1.25	Agree	No.
11305	Shave skin lesion 0.5 cm/<	0.67	0.80	0.80	Agree	No.
11306	Shave skin lesion 0.6–1.0 cm	0.99	1.18	0.96	Disagree	No.
11307	Shave skin lesion 1.1–2.0 cm	1.14	1.20	1.20	Agree	No.
11308	Shave skin lesion >2.0 cm	1.41	1.46	1.46	Agree	No.
11310	Shave skin lesion 0.5 cm/<	0.73	1.19	0.80	Disagree	No.
11311	Shave skin lesion 0.6–1.0 cm	1.05	1.43	1.10	Disagree	No.

TABLE 30—WORK RVUS FOR CY 2013 NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU *	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU *	CMS refinement to AMA/HCPAC recommended time *
11312	Shave skin lesion 1.1–2.0 cm	1.20	1.80	1.30	Disagree	No.
11313	Shave skin lesion >2.0 cm	1.62	2.00	1.68	Disagree	No.
11719	Trim nail(s) any number	0.17	0.17	0.17	Agree	No.
G0127	Trim nail(s)	0.17	N/A	0.17	N/A	N/A.
12035	Intmd wnd repair s/a/t/ext	3.50	3.60	3.50	Disagree	No.
12036	Intmd wnd repair s/a/t/ext	4.23	4.50	4.23	Disagree	Yes.
12037	Intmd wnd repair s/tr/ext	5.00	5.25	5.00	Disagree	No.
12045	Intmd wnd repair n-hf/genit	3.75	3.90	3.75	Disagree	Yes.
12046	Intmd wnd repair n-hf/genit	4.30	4.60	4.30	Disagree	Yes.
12047	Intmd wnd repair n-hf/genit	4.95	5.50	4.95	Disagree	Yes.
12055	Intmd wnd repair face/mm	4.50	4.65	4.50	Disagree	Yes.
12056	Intmd wnd repair face/mm	5.30	5.50	5.30	Disagree	Yes.
12057	Intmd wnd repair face/mm	6.00	6.20	6.00	Disagree	Yes.
13100	Cmplx rpr trunk 1.1–2.5 cm	3.17	3.00	3.00	Agree	Yes.
13101	Cmplx rpr trunk 2.6–7.5 cm	3.96	3.50	3.50	Agree	Yes.
13102	Cmplx rpr trunk addl 5cm/<	1.24	1.24	1.24	Agree	No.
13120	Cmplx rpr s/a/l 1.1–2.5 cm	3.35	3.23	3.23	Agree	Yes.
13121	Cmplx rpr s/a/l 2.6–7.5 cm	4.42	4.00	4.00	Agree	Yes.
13122	Cmplx rpr s/a/l addl 5 cm/>	1.44	1.44	1.44	Agree	No.
13131	Cmplx rpr f/c/c/m/n/ax/g/h/f	3.83	3.73	3.73	Agree	Yes.
13132	Cmplx rpr f/c/c/m/n/ax/g/h/f	6.58	4.78	4.78	Agree	Yes.
13133	Cmplx rpr f/c/c/m/n/ax/g/h/f	2.19	2.19	2.19	Agree	No.
13150	Cmplx rpr e/n/e/l 1.0 cm/<	3.85	N/A	3.58	N/A	N/A.
13151	Cmplx rpr e/n/e/l 1.1–2.5 cm	4.49	4.34	4.34	Agree	Yes.
13152	Cmplx rpr e/n/e/l 2.6–7.5 cm	6.37	5.34	4.90	Disagree	Yes.
13153	Cmplx rpr e/n/e/l addl 5cm/<	2.38	2.38	2.38	Agree	No.
20985	Cptr-asst dir ms px	2.50	2.50	2.50	Agree	No.
22586	Prescrl fuse w/instr l5/s1	New	N/A	28.12	N/A	N/A.
23350	Injection for shoulder x-ray	1.00	1.00	1.00	Agree	No.
23331	Remove shoulder foreign body	7.63	7.63	7.63	Interim	No.
23332	Remove shoulder foreign body	12.37	12.37	12.37	Interim	No.
23472	Reconstruct shoulder joint	22.65	22.13	22.13	Interim	No.
23473	Revis reconst shoulder joint	New	25.00	25.00	Interim	No.
23474	Revis reconst shoulder joint	New	27.21	27.21	Interim	No.
23600	Treat humerus fracture	3.11	3.00	3.00	Agree	No.
24160	Remove elbow joint implant	8.00	8.00	8.00	Interim	No.
24363	Replace elbow joint	22.65	22.00	22.00	Interim	Yes.
24370	Revise reconst elbow joint	New	23.55	23.55	Interim	No.
24371	Revise reconst elbow joint	New	27.50	27.50	Interim	No.
28470	Treat metatarsal fracture	2.03	2.03	2.03	Agree	No.
29075	Application of forearm cast	0.77	0.77	0.77	Agree	No.
29581	Apply multlay comprs lwr leg	0.25	0.60	0.25	Disagree	No.
29582	Apply multlay comprs upr leg	0.35	0.35	0.35	Agree	No.
29583	Apply multlay comprs upr arm	0.25	0.25	0.25	Agree	No.
29584	Appl multlay comprs arm/hand	0.35	0.35	0.35	Agree	No.
29824	Shoulder arthroscopy/surgery	8.98	8.98	8.98	Interim	No.
29826	Shoulder arthroscopy/surgery	3.00	3.00	3.00	Interim	No.
29827	Arthroscop rotator cuff repr	15.59	15.59	15.59	Interim	No.
29828	Arthroscopy biceps tenodesis	13.16	13.16	13.16	Interim	No.
31231	Nasal endoscopy dx	1.10	1.10	1.10	Agree	Yes.
31647	Bronchial valve init insert	New	4.40	4.40	Agree	No.
31648	Bronchial valve addl insert	New	4.20	4.20	Agree	No.
31649	Bronchial valve remov init	New	2.00	1.44	Disagree	No.
31651	Bronchial valve remov addl	New	1.58	1.58	Agree	No.
31660	Bronch thermoplsty 1 lobe	New	4.50	4.25	Disagree	No.
31661	Bronch thermoplsty 2/> lobes	New	5.00	4.50	Disagree	No.
32440	Remove lung pneumonectomy	27.28	N/A	27.28	Interim	N/A.
32480	Partial removal of lung	25.82	N/A	25.82	Interim	N/A.
32482	Bilobectomy	27.44	N/A	27.44	Interim	N/A.
32491	Lung volume reduction	25.24	N/A	25.24	Interim	N/A.
32551	Insertion of chest tube	3.29	3.50	3.29	Disagree	No.
32554	Aspirate pleura w/o imaging	New	1.82	1.82	Agree	No.
32555	Aspirate pleura w/imaging	New	2.27	2.27	Agree	Yes.
32556	Insert cath pleura w/o image	New	2.50	2.50	Agree	No.
32557	Insert cath pleura w/image	New	3.62	3.12	Disagree	Yes.
32663	Thoracoscopy w/lobectomy	24.64	24.64	24.64	Interim	No.
32668	Thoracoscopy w/w resect diag	3.00	4.00	3.00	Interim	No.
32669	Thoracoscopy remove segment	23.53	23.53	23.53	Interim	No.

TABLE 30—WORK RVUS FOR CY 2013 NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU *	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU *	CMS refinement to AMA/HCPAC recommended time *
32670	Thoracoscopy bilobectomy	28.52	28.52	28.52	Interim	No.
32671	Thoracoscopy pneumonectomy	31.92	31.92	31.92	Interim	No.
32672	Thoracoscopy for lvrs	27.00	27.00	27.00	Interim	No.
32673	Thoracoscopy w/thymus resect	21.13	21.13	21.13	Interim	No.
32701	Thorax stereo rad targetw/tx	New	4.18	4.18	Agree	No.
33361	Replace aortic valve perq	New	29.50	25.13	Disagree	Yes.
33362	Replace aortic valve open	New	32.00	27.52	Disagree	Yes.
33363	Replace aortic valve open	New	33.00	28.50	Disagree	Yes.
33364	Replace aortic valve open	New	34.87	30.00	Disagree	Yes.
33365	Replace aortic valve open	New	37.50	33.12	Disagree	No.
33367	Replace aortic valve w/byp	New	11.88	11.88	Agree	No.
33368	Replace aortic valve w/byp	New	14.39	14.39	Agree	No.
33369	Replace aortic valve w/byp	New	19.00	19.00	Agree	No.
33405	Replacement of aortic valve	41.32	41.32	41.32	Interim	No.
33430	Replacement of mitral valve	50.93	50.93	50.93	Interim	No.
33533	Cabg arterial single	33.75	34.98	33.75	Interim	No.
33990	Insert vad artery access	New	8.15	8.15	Agree	No.
33991	Insert vad art&vein access	New	11.88	11.88	Agree	No.
33992	Remove vad different session	New	4.00	4.00	Agree	No.
33993	Reposition vad diff session	New	4.17	3.51	Disagree	No.
35475	Repair arterial blockage	9.48	6.60	5.75	Disgaree	No.
35476	Repair venous blockage	6.03	5.10	4.71	Disagree	No.
36221	Place cath thoracic aorta	New	4.51	4.17	Disagree	Yes.
36222	Place cath carotid/inom art	New	6.00	5.53	Disagree	Yes.
36223	Place cath carotid/inom art	New	6.50	6.00	Disagree	Yes.
36224	Place cath carotd art	New	7.55	6.50	Disagree	Yes.
36225	Place cath subclavian art	New	6.50	6.00	Disagree	Yes.
36226	Place cath vertebral art	New	7.55	6.50	Disagree	Yes.
36227	Place cath xtrnl carotid	New	2.32	2.09	Disagree	No.
36228	Place cath intracranial art	New	4.25	4.25	Agree	No.
37197	Remove intrvas foreign body	New	6.72	6.29	Disagree	No.
37211	Thrombolytic art therapy	New	8.00	8.00	Agree	No.
37212	Thrombolytic venous therapy	New	7.06	7.06	Agree	No.
37213	Thromblytic art/ven therapy	New	5.00	5.00	Agree	No.
37214	Cessj therapy cath removal	New	3.04	2.74	Disagree	No.
38240	Transplt allo hct/donor	2.24	4.00	3.00	Disagree	No.
38241	Transplt autol hct/donor	2.24	3.00	3.00	Agree	No.
38242	Transplt allo lymphocytes	1.71	2.11	2.11	Agree	No.
38243	Transplj hematopoietic boost	New	2.13	2.13	Agree	No.
40490	Biopsy of lip	1.22	1.22	1.22	Agree	No.
43206	Esoph optical endomicroscopy	New	Contractor Priced.	Contractor Priced.	N/A	N/A.
43252	Uppr gi opticl endomicrscopy	New	Contractor Priced.	Contractor Priced.	N/A	N/A.
44705	Prepare fecal microbiota	New	1.42	Invalid	N/A	N/A.
G0455	Fecal microbiota prep instill	New	N/A	0.97	N/A	N/A.
45330	Diagnostic sigmoidoscopy	0.96	0.96	0.96	Agree	No.
47562	Laparoscopic cholecystectomy	11.76	11.76	10.47	Disagree	Yes.
47563	Laparo cholecystectomy/graph	11.47	11.47	11.47	Agree	No.
47600	Removal of gallbladder	17.48	20.00	17.48	Disagree	No.
47605	Removal of gallbladder	15.98	21.00	18.48	Disagree	No.
49505	Prp i/hern init reduc >5 yr	7.96	7.96	7.96	Agree	No.
50590	Fragmenting of kidney stone	9.77	9.77	9.77	Agree	No.
52214	Cystoscopy and treatment	3.70	3.50	3.50	Agree	No.
52224	Cystoscopy and treatment	3.14	4.05	4.05	Agree	Yes.
52234	Cystoscopy and treatment	4.62	4.62	4.62	Agree	No.
52235	Cystoscopy and treatment	5.44	5.44	5.44	Agree	No.
52240	Cystoscopy and treatment	9.71	8.75	7.50	Disagree	No.
52287	Cystoscopy chemodenervation	New	3.20	3.20	Agree	No.
52351	Cystouretero & or pyeloscope	5.85	5.75	5.75	Agree	No.
52352	Cystouretero w/stone remove	6.87	6.75	6.75	Agree	No.
52353	Cystouretero w/lithotripsy	7.96	7.88	7.50	Disagree	No.
52354	Cystouretero w/biopsy	7.33	8.58	8.00	Disagree	No.
52355	Cystouretero w/excise tumor	8.81	10.00	9.00	Disagree	No.
53850	Prostatic microwave thermotx	10.08	10.08	10.08	Agree	No.
60520	Removal of thymus gland	17.16	N/A	17.16	Interim	N/A.
60521	Removal of thymus gland	19.18	N/A	19.18	Interim	N/A.
60522	Removal of thymus gland	23.48	N/A	23.48	Interim	N/A.

TABLE 30—WORK RVUS FOR CY 2013 NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU *	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU *	CMS refinement to AMA/HCPAC recommended time *
64450	N block other peripheral	1.27	0.75	0.75	Agree	No.
64612	Destroy nerve face muscle	2.01	1.41	1.41	Interim	No.
64613	Destroy nerve neck muscle	2.01	N/A	2.01	Interim	N/A.
64614	Destroy nerve extrem musc	2.20	N/A	2.20	Interim	N/A.
64615	Chemodenerv musc migraine	New	1.85	1.85	Interim	No.
64640	Injection treatment of nerve	2.81	1.23	1.23	Agree	No.
65222	Remove foreign body from eye	0.93	0.93	0.84	Disagree	Yes.
65800	Drainage of eye	1.91	1.53	1.53	Agree	No.
66982	Cataract surgery complex	15.02	11.08	11.08	Agree	No.
66984	Cataract surg w/iol 1 stage	10.52	8.52	8.52	Agree	No.
67028	Injection eye drug	1.44	1.44	1.44	Agree	No.
67810	Biopsy eyelid & lid margin	1.48	1.18	1.18	Agree	Yes.
68200	Treat eyelid by injection	0.49	0.49	0.49	Agree	Yes.
69200	Clear outer ear canal	0.77	0.77	0.77	Agree	Yes.
69433	Create eardrum opening	1.57	1.57	1.57	Agree	No.
72040	X-ray exam neck spine 3/<vws	0.22	0.22	0.22	Agree	No.
72050	X-ray exam neck spine 4/5vws	0.31	0.31	0.31	Agree	No.
72052	X-ray exam neck spine 6/>vws	0.36	0.36	0.36	Agree	No.
72191	Ct angiograph pelv w/o&w/dye	1.81	N/A	1.81	Interim	N/A.
73221	Mri joint upr extrem w/o dye	1.35	1.35	1.35	Agree	No.
73721	Mri jnt of lwr extre w/o dye	1.35	1.35	1.35	Agree	No.
74170	Ct abdomen w/o & w/dye	1.40	1.40	1.40	Agree	No.
74174	Ct angio abd&pelv w/o&w/dye	2.20	2.20	2.20	Interim	No.
74175	Ct angio abdom w/o & w/dye	1.90	N/A	1.90	Interim	N/A.
74247	Contrst x-ray uppr gi tract	0.69	0.69	0.69	Agree	No.
74280	Contrast x-ray exam of colon	0.99	0.99	0.99	Agree	No.
74400	Contrst x-ray urinary tract	0.49	0.49	0.49	Agree	No.
75896	X-rays transcath therapy	1.31 (PC), Contractor Priced (TC).	Contractor Priced.	1.31 (PC), Contractor Priced (TC).	Interim	N/A.
75898	Follow-up angiography	1.65 (PC), Contractor Priced (TC).	Contractor Priced.	1.65 (PC), Contractor Priced (TC).	Interim	N/A.
76830	Transvaginal us non-ob	0.69	0.69	0.69	Agree	Yes.
76872	Us transrectal	0.69	0.69	0.69	Agree	No.
77001	Fluoroguide for vein device	0.38	N/A	0.38	Interim	N/A.
77002	Needle localization by xray	0.54	N/A	0.54	Interim	N/A.
77003	Fluoroguide for spine inject	0.60	0.60	0.60	Interim	No.
77080	Dxa bone density axial	0.20	0.20	0.20	Agree	No.
77082	Dxa bone density vert fx	0.17	0.17	0.17	Agree	No.
77301	Radiotherapy dose plan imrt	7.99	7.99	7.99	Agree	Yes.
78012	Thyroid uptake measurement	New	0.19	0.19	Agree	No.
78013	Thyroid imaging w/blood flow	New	0.37	0.37	Agree	No.
78014	Thyroid imaging w/blood flow	New	0.50	0.50	Agree	No.
78070	Parathyroid planar imaging	0.82	0.80	0.80	Agree	No.
78071	Parathyrd planar w/wo subtrj	New	1.20	1.20	Agree	No.
78072	Parathyrd planar w/spect&ct	New	1.60	1.60	Agree	No.
78278	Acute gi blood loss imaging	0.99	0.99	0.99	Agree	No.
78472	Gated heart planar single	0.98	0.98	0.98	Agree	No.
G0452	Molecular pathology interpr	New	N/A	0.37	N/A	N/A.
86153	Cell enumeration phys interp	New	0.69	0.69	Agree	Yes.
88120	Cytp urne 3–5 probes ea spec	1.20	1.20	1.20	Interim	No.
88121	Cytp urine 3–5 probes cmptr	1.00	1.00	1.00	Interim	No.
88312	Special stains group 1	0.54	0.54	0.54	Agree	No.
88365	Insitu hybridization (fish)	1.20	N/A	1.20	Interim	N/A.
88367	Insitu hybridization auto	1.30	N/A	1.30	Interim	N/A.
88368	Insitu hybridization manual	1.40	N/A	1.40	Interim	N/A.
88375	Optical endomicroscpy interp	New	Contractor Priced.	Contractor Priced.	N/A	N/A.
G0416	Sat biopsy 10–20	3.09	N/A	3.09	N/A	N/A.
90785	Psytx complex interactive	New	Contractor Priced.	0.11	Interim	N/A.
90791	Psych diagnostic evaluation	New	3.00	2.80	Interim	No.
90792	Psych diag eval w/med srvcs	New	3.25	2.96	Interim	No.
90832	Psytx pt&/family 30 minutes	New	1.50	1.25	Interim	No.
90833	Psytx pt&/fam w/e&m 30 min	New	1.50	0.98	Interim	No.
90834	Psytx pt&/family 45 minutes	New	2.00	1.89	Interim	No.
90836	Psytx pt&/fam w/e&m 45 min	New	1.90	1.60	Interim	No.

TABLE 30—WORK RVUS FOR CY 2013 NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU *	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU *	CMS refinement to AMA/HCPAC recommended time *
90837	Psytx pt&/family 60 minutes	New	3.00	2.83	Interim	No.
90838	Psytx pt&/fam w/e&m 60 min	New	2.50	2.56	Interim	No.
90839	Psytx crisis initial 60 min	New	Contractor Priced.	Contractor Priced.	N/A	N/A.
90840	Psytx crisis ea addl 30 min	New	Contractor Priced.	Contractor Priced.	N/A	N/A.
90845	Psychoanalysis	1.79	2.10	1.79	Interim	Yes.
90846	Family psytx w/o patient	1.83	2.40	1.83	Interim	Yes.
90847	Family psytx w/patient	2.21	2.50	2.21	Interim	Yes.
90853	Group psychotherapy	0.59	0.59	0.59	Interim	Yes.
90863	Pharmacologic mgmt w/psytx	New	Contractor Priced.	Invalid	N/A	N/A.
91112	Gi wireless capsule measure	New	2.10	2.10	Agree	No.
92083	Visual field examination(s)	0.50	0.50	0.50	Agree	No.
92100	Serial tonometry exam(s)	0.92	0.61	0.61	Agree	No.
92235	Eye exam with photos	0.81	0.81	0.81	Agree	No.
92286	Internal eye photography	0.66	0.40	0.40	Agree	No.
92920	Prq cardiac angioplast 1 art	New	9.00	10.10	Disagree	Yes.
92921	Prq cardiac angio addl art	New	4.00	Bundled	N/A	N/A.
92924	Prq card angio/athrect 1 art	New	11.00	11.99	Disagree	Yes.
92925	Prq card angio/athrect addl	New	5.00	Bundled	N/A	N/A.
92928	Prq card stent w/angio 1 vsl	New	10.49	11.21	Disagree	Yes.
92929	Prq card stent w/angio addl	New	4.44	Bundled	N/A	N/A.
92933	Prq card stent/ath/angio	New	12.32	12.54	Disagree	Yes.
92934	Prq card stent/ath/angio	New	5.50	Bundled	N/A	N/A.
92937	Prq revasc byp graft 1 vsl	New	10.49	11.20	Disagree	Yes.
92938	Prq revasc byp graft addl	New	6.00	Bundled	N/A	N/A.
92941	Prq card revasc mi 1 vsl	New	12.32	12.56	Disagree	No.
92943	Prq card revasc chronic 1vsl	New	12.32	12.56	Disagree	Yes.
92944	Prq card revasc chronic addl	New	6.00	Bundled	N/A	N/A.
93015	Cardiovascular stress test	0.75	0.75	0.75	Agree	No.
93016	Cardiovascular stress test	0.45	0.45	0.45	Agree	No.
93018	Cardiovascular stress test	0.30	0.30	0.30	Agree	No.
93308	Tte f-up or lmtd	0.53	0.53	0.53	Agree	No.
93653	Ep & ablate supravent arrhyt	New	15.00	15.00	Agree	No.
93654	Ep & ablate ventric tachy	New	20.00	20.00	Agree	No.
93655	Ablate arrhythmia add on	New	9.00	7.50	Disagree	No.
93656	Tx atrial fib pulm vein isol	New	20.02	20.02	Agree	No.
93657	Tx l/r atrial fib addl	New	10.00	7.50	Disagree	No.
93925	Lower extremity study	0.58	0.90	0.80	Disagree	Yes.
93926	Lower extremity study	0.39	0.70	0.50	Disagree	Yes.
93970	Extremity study	0.68	0.70	0.70	Agree	No.
93971	Extremity study	0.45	0.45	0.45	Agree	No.
95017	Perq & icut allg test venoms	New	0.07	0.07	Agree	No.
95018	Perq&ic allg test drugs/boil	New	0.14	0.14	Agree	No.
95076	Ingest challenge ini 120 min	New	1.50	1.50	Agree	No.
95079	Ingest challenge addl 60 min	New	1.38	1.38	Agree	No.
95782	Polysom <6 yrs 4/> paramtrs	New	3.00	2.60	Disagree	No.
95783	Polysom <6 yrs cpap/bilvl	New	3.20	2.83	Disagree	No.
95860	Muscle test one limb	0.96	0.96	0.96	Agree	No.
95861	Muscle test 2 limbs	1.54	1.54	1.54	Agree	No.
95863	Muscle test 3 limbs	1.87	1.87	1.87	Agree	No.
95864	Muscle test 4 limbs	1.99	1.99	1.99	Agree	No.
95865	Muscle test larynx	1.57	1.57	1.57	Agree	No.
95866	Muscle test hemidiaphragm	1.25	1.25	1.25	Agree	No.
95867	Muscle test cran nerv unilat	0.79	0.79	0.79	Agree	No.
95868	Muscle test cran nerve bilat	1.18	1.18	1.18	Agree	No.
95869	Muscle test thor paraspinal	0.37	0.37	0.37	Agree	No.
95870	Muscle test nonparaspinal	0.37	0.37	0.37	Agree	No.
95885	Musc tst done w/nerv tst lim	0.35	0.35	0.35	Agree	No.
95886	Musc test done w/n test comp	0.92	0.92	0.70	Disagree	No.
95887	Musc tst done w/n tst nonext	0.73	0.73	0.47	Disagree	No.
95905	Motor &/sens nrve cndj test	0.05	0.05	0.05	Agree	No.
95907	Motor&/sens 1–2 nrv cndj tst	New	1.00	1.00	Agree	No.
95908	Motor&/sens 3–4 nrv cndj tst	New	1.37	1.25	Disagree	Yes.
95909	Motor&/sens 5–6 nrv cndj tst	New	1.77	1.50	Disagree	Yes.
95910	Motor&sens 7–8 nrv cndj test	New	2.80	2.00	Disagree	No.
95911	Motor&sen 9–10 nrv cndj test	New	3.34	2.50	Disagree	No.

TABLE 30—WORK RVUS FOR CY 2013 NEW, REVISED, AND POTENTIALLY MISVALUED CODES—Continued

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU *	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU *	CMS refinement to AMA/HCPAC recommended time *
95912	Motor&sen 11–12 nrv cnd test	New	4.00	3.00	Disagree	No.
95913	Motor&sens 13/> nrv cnd test	New	4.20	3.56	Disagree	No.
95921	Autonomic nrv parasym inervj	0.90	0.90	0.90	Agree	No.
95922	Autonomic nrv adrenrg inervj	0.96	0.96	0.96	Agree	No.
95923	Autonomic nrv syst funj test	0.90	0.90	0.90	Agree	No.
95924	Ans parasymp & symp w/tilt	New	1.73	1.73	Agree	No.
95925	Somatosensory testing	0.54	N/A	0.54	Interim	N/A.
95926	Somatosensory testing	0.54	N/A	0.54	Interim	N/A.
95928	C motor evoked uppr limbs	1.50	N/A	1.50	Interim	N/A.
95929	C motor evoked lwr limbs	1.50	N/A	1.50	Interim	N/A.
95938	Somatosensory testing	0.86	0.86	0.86	Interim	No.
95939	C motor evoked upr&lwr limbs	2.25	2.25	2.25	Interim	No.
95940	Ionm in operatng room 15 min	New	0.60	0.60	Agree	No.
95941	Ionm remote/>1 pt or per hr	New	2.00	Invalid	N/A	N/A.
G0453	Cont intraop neuro monitor	New	N/A	0.50	N/A	N/A.
95943	Parasymp&symp hrt rate test	New	Contractor Priced.	Contractor Priced.	N/A	N/A.
96920	Laser tx skin < 250 sq cm	1.15	1.15	1.15	Agree	No.
96921	Laser tx skin 250–500 sq cm	1.17	1.30	1.30	Agree	No.
96922	Laser tx skin >500 sq cm	2.10	2.10	2.10	Agree	No.
97150	Group therapeutic procedures	0.27	0.29	0.29	Agree	No.
G0456	Neg pre wound <=50 sq cm	New	N/A	Contractor Priced.	N/A	N/A.
G0457	Neg pres wound >50 sq cm	New	N/A	Contractor Priced.	N/A	N/A.
99485	Suprv interfacilty transport	New	1.50	Bundled	N/A	N/A.
99486	Suprv interfac trnsport addl	New	1.30	Bundled	N/A	N/A.
99487	Cmplx chron care w/o pt vsit	New	1.00	Bundled	N/A	N/A.
99488	Cmplx chron care w/pt vsit	New	2.50	Bundled	N/A	N/A.
99489	Complx chron care addl30 min	New	0.50	Bundled	N/A	N/A.
99495	Trans care mgmt 14 day disch	New	2.11	2.11	Agree	No.
99496	Trans care mgmt 7 day disch	New	3.05	3.05	Agree	Yes.
G0454	MD document visit by NPP	New	N/A	0.18	N/A	N/A.

* Some of the CPT codes in this table were first reviewed for CY2011 and/or CY2012 and we held them interim pending the receipt of additional information. As a result, for some CPT codes, the AMA RUC/HCPAC recommendation reflects the CY2011 or CY2012 AMA RUC/HCPAC recommendation. For the majority of CPT codes in this table, the values reflect the CY 2013 AMA RUC/HCPAC recommendation. Where N/A is listed, either we did not receive a recommendation from the AMA RUC/HCPAC, the code is not nationally priced, or the code is not separately payable/payable.

(1) Integumentary System: Skin, Subcutaneous, and Accessory Structures

TABLE 31—INTEGUMENTARY SYSTEM: SKIN, SUBCUTANEOUS, AND ACCESSORY STRUCTURES

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
10120	Remove foreign body	1.25	1.25	1.22	Disagree	Yes.
11055	Trim skin lesion	0.43	0.43	0.35	Disagree	Yes.
11056	Trim skin lesions 2 to 4	0.50	0.50	0.50	Agree	No.
11057	Trim skin lesions over 4	0.79	0.79	0.65	Disagree	Yes.
11300	Shave skin lesion 0.5 cm/<	0.51	0.60	0.60	Agree	No.
11301	Shave skin lesion 0.6–1.0 cm	0.85	0.90	0.90	Agree	No.
11302	Shave skin lesion 1.1–2.0 cm	1.05	1.16	1.05	Disagree	No.
11303	Shave skin lesion >2.0 cm	1.24	1.25	1.25	Agree	No.
11305	Shave skin lesion 0.5 cm/<	0.67	0.80	0.80	Agree	No.
11306	Shave skin lesion 0.6–1.0 cm	0.99	1.18	0.96	Disagree	No.
11307	Shave skin lesion 1.1–2.0 cm	1.14	1.20	1.20	Agree	No.
11308	Shave skin lesion >2.0 cm	1.41	1.46	1.46	Agree	No.
11310	Shave skin lesion 0.5 cm/<	0.73	1.19	0.80	Disagree	No.
11311	Shave skin lesion 0.6–1.0 cm	1.05	1.43	1.10	Disagree	No.
11312	Shave skin lesion 1.1–2.0 cm	1.20	1.80	1.30	Disagree	No.
11313	Shave skin lesion >2.0 cm	1.62	2.00	1.68	Disagree	No.

CPT code 10120 was identified as potentially misvalued using the Harvard-valued—Utilization over 30,000 screen.

After clinical review of CPT code 10120 (Incision and removal of foreign body, subcutaneous tissues; simple) we believe that the specialty society survey 25th percentile work RVU of 1.22 accurately reflects the work of this service. Medicare claims data from 2011 indicate that this service is typically furnished to the beneficiary by the provider on the same day as an E/M visit. We believe that some of the activities furnished during the pre- and post-service period of the procedure code and the E/M visit overlap. After review, we believe that the AMA RUC appropriately accounted for this overlap in its recommendation of pre-service time, but failed to account for the overlap in post-service time. To account for this overlap, we reduced the AMA RUC-recommended post-service time for this procedure by one-third, from 5 minutes to 3 minutes. We believe that 3 minutes accurately reflects the post-service time involved in furnishing this procedure and is more in line with similar services. Because we reduced the AMA RUC-recommended procedure time for this code by 2 minutes, given a standard post-service work intensity of .0224 RVUs per minute, we believe that the specialty society survey 25th percentile work RVU of 1.22 is more appropriate for this service than the AMA RUC-recommended work RVU of 1.25. In sum, on an interim final basis for CY 2013, we are assigning a work RVU of 1.22 to CPT code 10120, with a refinement to the AMA RUC-recommended time. A complete list of the interim final times associated with this procedure is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

CPT code 11056 was identified for review because it is on the multispecialty points of comparison (MPC) list—a list of CPT codes commonly used as reference codes in the valuation of other codes.

We reviewed CPT code 11056 (Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); 2 to 4 lesions) in CY 2012, and accepted the HCPAC-recommended work RVU of 0.50, the specialty society survey 25th percentile value, on an interim basis for CY 2012. At that time, we requested that the specialty society re-review CPT code 11056 along with related CPT codes 11055 (Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); single lesion) and 11057 (Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); more than 4 lesions) to ensure appropriate relativity between the three services (76 FR 73190). The specialty society declined to survey CPT codes 11055 or 11057, and, in its recommendations to CMS, the AMA RUC noted that there are no apparent rank order anomalies among the three services.

For CY 2013, we reviewed CPT codes 11055, 11056, and 11057 together. After clinical review, we did not have evidence that the relativity of the services to each other had changed over time, and since the HCPAC and CMS agreed that the work associated with CPT code 11056 had decreased, we believe it is appropriate to reduce the work of CPT codes 11055 and 11057 relative to the decrease in work of CPT code 11056. In CY 2012, the HCPAC recommended that CPT code 11056 be reduced from a CY 2011 work RVU of 0.61 to a CY 2012 work RVU of 0.50. Therefore, to maintain relativity, we are reducing CPT code 11055 from a work RVU of 0.43 to a work RVU of 0.35, and we are reducing CPT code 11057 from a work RVU of 0.79 to a work RVU of 0.65 on an interim final basis for CY 2013.

Regarding physician time, CPT codes 11055 and 11057 currently (CY 2012) are assigned 2 minutes of pre-service time and 5 minutes of post-service time. Before it was reviewed by the HCPAC for CY 2012, CPT code 11056 was also assigned 2 minutes of pre-service time and 5 minutes of post service time. Through its review, the HCPAC recommended adjusting the time of CPT code to include 7 minutes of pre-service time and 2 minutes of post-service time, and we agreed. We believe that these are also the appropriate pre- and post-service times for CPT codes 11055 and 11057. On an interim final basis for CY 2013, we are refining the times of CPT codes 11055 and 11057 to 7 minutes of pre-service time and 2 minutes of post-service time. We believe the current intra-service times of 4 minutes for CPT code 11055 and 15 minutes for CPT code 11057 remain appropriate. A complete list of the interim final times associated with these procedures is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

For CY 2013 CPT codes 11300 through 11313, which describe procedures related to the shaving of epidermal or dermal lesions, were surveyed by their related specialty society to establish current relative values for these procedures. The specialty society and the AMA RUC reviewed the survey results for CPT codes 11300 through 11313 and recommended the survey 25th percentile work RVU for nearly all the codes in the family. After clinical review, we believe that the survey 25th percentile for all the codes in the family reflects the appropriate relativity of the services both within the family, as well as relative to other services on the PFS. On an interim final basis for CY 2013 we are assigning a work RVU of 0.60 for CPT code 11300 (Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.5 cm or less); a work RVU of 0.90 for CPT code 11301 (Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.6 to 1.0 cm); a work RVU of 1.05 for CPT code 11302 (Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 1.1 to 2.0 cm); a work RVU of 1.25 for CPT code 11303 (Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter over 2.0 cm); a work RVU of 0.80 for CPT code 11305 (Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less); a work RVU of 0.96 for CPT code 11306 (Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm); a work RVU of 1.20 for CPT code 11307 (Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 1.1 to 2.0 cm); a work RVU of 1.46 for CPT code 11308 (Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter over 2.0 cm); a work RVU of 0.80 for CPT code 11310 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less); a work RVU of 1.10 for CPT code 11311 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm); a work RVU of 1.30 for CPT code 11312 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm); and a work RVU of 1.68 for CPT code 11313 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter over 2.0 cm).

(2) Integumentary System: Repair (Closure)

TABLE 32—INTEGUMENTARY SYSTEM: REPAIR (CLOSURE)

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
12035	Intmd wnd repair s/a/t/ext	3.50	3.60	3.50	Disagree	No.
12036	Intmd wnd repair s/a/t/ext	4.23	4.50	4.23	Disagree	Yes.
12037	Intmd wnd repair s/tr/ext	5.00	5.25	5.00	Disagree	No.
12045	Intmd wnd repair n-hf/genit	3.75	3.90	3.75	Disagree	Yes.
12046	Intmd wnd repair n-hf/genit	4.30	4.60	4.30	Disagree	Yes.
12047	Intmd wnd repair n-hf/genit	4.95	5.50	4.95	Disagree	Yes.
12055	Intmd wnd repair face/mm	4.50	4.65	4.50	Disagree	Yes.
12056	Intmd wnd repair face/mm	5.30	5.50	5.30	Disagree	Yes.
12057	Intmd wnd repair face/mm	6.00	6.20	6.00	Disagree	Yes.
13100	Cmplx rpr trunk 1.1–2.5 cm	3.17	3.00	3.00	Agree	Yes.
13101	Cmplx rpr trunk 2.6–7.5 cm	3.96	3.50	3.50	Agree	Yes.
13102	Cmplx rpr trunk addl 5cm/<	1.24	1.24	1.24	Agree	No.
13120	Cmplx rpr s/a/l 1.1–2.5 cm	3.35	3.23	3.23	Agree	Yes.
13121	Cmplx rpr s/a/l 2.6–7.5 cm	4.42	4.00	4.00	Agree	Yes.
13122	Cmplx rpr s/a/l addl 5 cm/>	1.44	1.44	1.44	Agree	No.
13131	Cmplx rpr f/c/c/m/n/ax/g/h/f	3.83	3.73	3.73	Agree	Yes.
13132	Cmplx rpr f/c/c/m/n/ax/g/h/f	6.58	4.78	4.78	Agree	Yes.
13133	Cmplx rpr f/c/c/m/n/ax/g/h/f	2.19	2.19	2.19	Agree	No.
13150	Cmplx rpr e/n/e/l 1.0 cm/<	3.85	N/A	3.58	N/A	N/A.
13151	Cmplx rpr e/n/e/l 1.1–2.5 cm	4.49	4.34	4.34	Agree	Yes.
13152	Cmplx rpr e/n/e/l 2.6–7.5 cm	6.37	5.34	4.90	Disagree	Yes.
13153	Cmplx rpr e/n/e/l addl 5cm/<	2.38	2.38	2.38	Agree	No.

CPT codes 12031, 12051, and 13101 were identified as potentially misvalued using the Harvard-valued—Utilization over 30,000 screen. As a result of this screen, in the Fourth Five-Year Review of Work, we reviewed the family of intermediate wound repair CPT codes (12031 through 12057), along with two complex wound repair codes (13100 and 13101).

In the Fourth Five-Year Review, we disagreed with the AMA RUC-recommended work RVUs for the larger of the intermediate wound repair codes: CPT codes 12035 (Repair, intermediate, wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); 12.6 cm to 20.0 cm), 12036 (Repair, intermediate, wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); 20.1 cm to 30.0 cm), 12037 (Repair, intermediate, wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); over 30.0 cm), 12045 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 12.6 cm to 20.0 cm), 12046 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 20.1 cm to 30.0 cm), 12047 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; over 30.0 cm), 12055 (Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 12.6 cm to 20.0 cm), 12056 (Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 cm to 30.0 cm) and 12057 (Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm) (76 FR 32431 through 32432). As discussed in the CY 2012 PFS final rule with comment period, after review by the refinement panel, we maintained the proposed RVUs published in the Fourth Five-Year Review of Work (76 FR 73113 through 73114). We stated that we would hold these codes interim for another year rather than finalizing the codes, so that we could review these larger intermediate wound repair codes alongside the family complex wound repair codes, which we anticipated reviewing for CY 2013.

In the Fourth Five-Year Review of Work, we stated that we would maintain the current (CY 2011) work RVUs and times for complex wound repair CPT codes 13100 (Repair, complex, trunk; 1.1 cm to 2.5 cm) and 13101 (Repair, complex, trunk; 2.6 cm to 7.5 cm), and requested that the AMA RUC review the entire set of codes in the complex wound repair family together to assess the appropriate gradation of the work RVUs in the family (76 FR 32434 through 32435). For CY 2013, we received new recommendations from the AMA RUC on CPT codes 13100 and 13101, as well as recommendations on the rest of the CPT codes in the complex wound repair family CPT codes 13100 through 13102, 13120 through 13122, 13131 through 13133, and 13150 through 13153, excluding CPT code 13150 (Repair, complex, eyelids, nose, ears and/or lips; 1.0 cm or less), which the AMA RUC referred to the CPT Editorial Panel for deletion in CY 2014. We agree with the AMA RUC recommendations for all the codes in the complex wound repair family, except one. After reviewing CPT code 13152 (Repair, complex, eyelids, nose, ears and/or lips; 2.6 cm to 7.5 cm), we believe that the AMA RUC-recommended work RVU of 5.34 is too high relative to similar CPT code 13132 (Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 2.6 cm to 7.5 cm), which has an AMA RUC-recommended work RVU of 4.78, and CPT code 13151 (Repair, complex, eyelids, nose, ears and/or lips; 1.1 cm to 2.5 cm), which has an AMA RUC-recommended work RVU of 4.34. We believe that the specialty society 25th percentile work RVU of 4.90 more appropriately reflects the relative work involved in furnishing this service. On an interim final basis for CY 2013, we are assigning a work RVU of 4.90 to CPT code 13152.

The AMA RUC referred CPT code 13150 to the CPT Editorial Panel for deletion in CY 2014. Because of this, the AMA RUC did not review this service with the other codes in this family. For CY 2013, we believe it is appropriate to reduce the work RVU of CPT code 13150 proportionate to the other services in the family, so that the value of CPT code 13150 maintains appropriate proportionate rank order for CY 2013. For CY 2013, the work RVUs

for the 12 other CPT codes in this family are being reduced, on average, to 93 percent of their CY 2012 value. Applying that reduction to CPT code 13150 results in a CY 2013 work RVU of 3.58, which we believe appropriately reflects the work associated with this procedure. Therefore, on an interim final basis for CY 2013, we are assigning a work RVU of 3.58 to CPT code 13150. In addition to these work RVU changes, we made small refinements to the AMA RUC-recommended times for many of the CPT codes in this family to ensure consistency between congruent services. A list of the interim final times associated with these procedures is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

After reviewing the family of complex wound repair CPT codes for CY 2013, we re-reviewed the larger intermediate wound repair codes that we had been holding interim since the Fourth Five-Year Review of Work. We reviewed CPT codes 12035 through 12037, 12045 through 12047, and 12055 through 12057 in relation to each other, the other intermediate wound repair CPT codes (12031 through 12034, 12041 through 12044, and 12051 through 12054), the complex wound repair CPT codes, and other PFS services, and we continue to believe that the current interim values are appropriate relative to the other services. Therefore, on an interim final basis for CY 2013, are maintaining the following current (CY 2012) work values: A work RVU of 3.50 for CPT code 12035; a work RVU of 4.23 for CPT code 12036; a work RVU of 5.00 for CPT code 12037; a work RVU of 3.75 for CPT code 12045; a work RVU of 4.30 for CPT code 12046; a work RVU of 4.95 for CPT code 12047; a work RVU of 4.50 for CPT code 12055; a work RVU of 5.30 for CPT code 12056, and a work RVU of 6.00 for CPT code 12057.

We also believe that it is appropriate to maintain the current (CY 2012) times for these procedures, as we believe that they reflect the time involved in furnishing these procedures and that they are well-aligned with each other and with the simple and complex wound repair CPT codes. One exception to this is CPT code 12045 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 12.6 cm to 20.0 cm), which includes 10 minutes of pre-service evaluation time, while CPT codes 12046 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 20.1 cm to 30.0 cm) and 12047 (Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; over 30.0 cm) both include 9 minutes of pre-service evaluation time. We believe it is appropriate to reduce the pre-service evaluation time of CPT code 12045 to match the pre-service evaluation time of CPT codes 12046 and 12047. Therefore, for CY 2013, we are assigning an interim final pre-service evaluation time of 9 minutes to CPT 12045. A complete list of the interim final times associated with these procedures is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(3) Musculoskeletal System: Spine (Vertebral Column)

TABLE 33—MUSCULOSKELETAL SYSTEM: SPINE (VERTEBRAL COLUMN)

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 Interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
22586	Prescrl fuse w/instr l5/s1	New	N/A	28.12	N/A	N/A.

For CY 2013, the CPT Editorial Panel created CPT code 22586 (Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace). The specialty societies related to this CPT code that participate in the AMA RUC declined to survey this new CPT code and the AMA RUC issued no work RVU recommendation to us for this service for CY 2013. A related specialty society that does not participate in the AMA RUC conducted a survey of its members regarding the physician work and time associated with this procedure and submitted a recommendation to CMS. In determining the appropriate value for this CPT code, we reviewed the survey results and recommendations submitted to us, literature on the procedure, and the Medicare claims data. Ultimately, we used a building block approach based on Medicare 2011 same day billing combinations to develop the interim final value for this procedure.

New CPT code 22586 is a bundled lumbar arthrodesis procedure that includes grafting, posterior instrumentation, and fixation. To value this service we used CPT code 22558 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar) as a reference service, as it is a similar procedure but it does not include additional grafting, instrumentation, and fixation. To assess the appropriate relative work increase from unbundled CPT code 22558 to the new bundled CPT code 22586, we used Medicare claims data to assess which grafting, instrumentation, and fixation services are commonly billed with CPT code 22558 and how often. We used those data to create a utilization weighted work RVU for the grafting component of CPT code 22586, the instrumentation component of the 22586, and the fixation component of 22586. We added those components to the base service of CPT code 22558 to create a work RVU of 28.12. We believe this work RVU reflects the appropriate incremental difference in work between the base reference CPT code 22558 and new CPT code 22586. For CY 2013 we are assigning a work RVU of 28.12 to CPT code 22586 for CY 2013, and we request additional public input on the appropriate valuation of this service.

We assigned CPT code 22586 a global period of 90 days, which is consistent with similar service. Regarding physician time for CPT code 22586, after reviewing the physician time and post-operative visits for similar services, we believe this service includes 40 minutes of pre-service evaluation time, 20 minutes of pre-service positioning time, 20 minutes of pre-service scrub, dress and wait time, 180 minutes of intra-service time, and 30 minutes of immediate post-service time. In the post-operative period, we believe the typical case for this service includes 2 CPT code 99231 visits, 1 CPT code

99323 visit, 1 CPT code 99238 visit, and 4 CPT code 99213 visits. A list of the interim final times associated with this procedure is available on the CMS Web site at *www.cms.gov/physicianfeesched/.*

(4) Musculoskeletal System: Shoulder

TABLE 34—MUSCULOSKELETAL SYSTEM: SHOULDER

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
23350	Injection for shoulder x-ray	1.00	1.00	1.00	Agree	No.
23331	Remove shoulder foreign body	7.63	7.63	7.63	Interim	No.
23332	Remove shoulder foreign body	12.37	12.37	12.37	Interim	No.
23472	Reconstruct shoulder joint	22.65	22.13	22.13	Interim	No.
23473	Revis reconst shoulder joint	New	25.00	25.00	Interim	No.
23474	Revis reconst shoulder joint	New	27.21	27.21	Interim	No.
23600	Treat humerus fracture	3.11	3.00	3.00	Agree	No.

For CY 2013, the CPT Editorial Panel created two new CPT codes for total shoulder revision, CPT code 23473 (Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component) and 23474 (Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component). The specialty society surveyed these codes along with the other codes in this family, which include CPT codes 23331 (Removal of foreign body, shoulder; deep (eg, neer hemiarthroplasty removal)), 23332 (Removal of foreign body, shoulder; complicated (eg, total shoulder)), and 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))). After reviewing the survey responses, the AMA RUC concluded that the descriptors for CPT codes 23331 and 23332 needed revision. The AMA RUC referred CPT codes 23331 and 23332 to the CPT Editorial Panel for further clarification and recommended that we maintain the current (CY 2012) work RVUs of 7.63 for CPT code 23331, and 12.37 for CPT code 23332 for CY 2013. The AMA RUC recommended the survey 25th percentile work RVU for the three other services in this family: A work RVU of 22.13 for CPT code 23472; a work RVU of 25.00 for CPT code 23473; and a work RVU of 27.21 for CPT code 23474. We are accepting these work RVUs on an interim basis for CY 2013, and will review CPT codes 23472, 23473, and 23474 alongside CPT codes 23331 and 23332 after the codes descriptors are changed, to ensure consistency within this family of CPT codes.

(5) Musculoskeletal System: Humerus (Upper Arm) and Elbow

TABLE 35—MUSCULOSKELETAL SYSTEM: HUMERUS (UPPER ARM) AND ELBOW

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
24160	Remove elbow joint implant	8.00	8.00	8.00	Interim	No.
24363	Replace elbow joint	22.65	22.00	22.00	Interim	Yes.
24370	Revise reconst elbow joint	New	23.55	23.55	Interim	No.
24371	Revise reconst elbow joint	New	27.50	27.50	Interim	No.

For CY 2013, the CPT Editorial Panel created two new CPT codes for revision of a total elbow arthroplasty, 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). The specialty society surveyed these CPT codes along with component CPT codes 24160 (Implant removal; elbow joint) and 24363 (Arthroplasty, elbow; with distal humerus and proximal ulnar prosthetic replacement (eg, total elbow)). After reviewing the survey responses, the AMA RUC concluded that the descriptor for CPT code 24160 needs revision. The AMA RUC referred CPT code 24160 to the CPT Editorial Panel for revision of the descriptor and recommended that we maintain the current (CY 2012) work RVU of 8.00 for CPT code 24160 for CY 2013. The AMA RUC recommended the survey 25th percentile work RVU for the three other services in this family: a work RVU of 22.00 for CPT code 24363; a work RVU of 23.55 for CPT code 24370; and a work RVU of 27.50 for CPT code 24371. We are accepting these work RVUs on an interim basis for CY 2013, and will review CPT codes 24363, 24370, and 24371 alongside CPT code 24160 after the code descriptor is changed, to ensure consistency within this family of CPT codes. For CY 2013, we are refining the AMA RUC-recommended post-service time of CPT code 24363 to 20 minutes, from 30 minutes, to match the post-service times of CPT code 24370 and 24371. A complete list of the interim final times associated with these procedures is available on the CMS Web site at *www.cms.gov/physicianfeesched/.*

(6) Musculoskeletal System: Application of Casts and Strapping

TABLE 36—MUSCULOSKELETAL SYSTEM: APPLICATION OF CASTS AND STRAPPING

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
29075	Application of forearm cast	0.77	0.77	0.77	Agree	No.
29581	Apply multlay comprs lwr leg	0.25	0.60	0.25	Disagree	No.
29582	Apply multlay comprs upr leg	0.35	0.35	0.35	Agree	No.
29583	Apply multlay comprs upr arm	0.25	0.25	0.25	Agree	No.
29584	Appl multlay comprs arm/hand	0.35	0.35	0.35	Agree	No.

For CY 2013, the CPT Editorial Panel revised the descriptor of CPT code 29581, and created CPT codes 29582, 29583, and 29584 to describe the application of multi-layer compression to the upper and lower extremities. The CPT Editorial Panel and AMA RUC concluded that the revisions to the descriptor for CPT code 29581 were editorial only, and the AMA RUC related specialty society (Society for Vascular Surgery) believed that resurveying CPT code 29581 was not necessary. As such, the AMA RUC recommended ''No Change'' for CPT code 29581. For CY 2012, CPT codes 29582, 29583, and 29584 were surveyed through the American Physical Therapy Association (the expected dominant providers of the services), and the HCPAC reviewed the results and issued recommendations to CMS for these three CPT codes.

We discussed CPT codes 29581 (Application of multi-layer compression system; leg (below knee), including ankle and foot), 29582 (Application of multi-layer compression system; thigh and leg, including ankle and foot, when performed), 29583 (Application of multi-layer compression system; upper arm and forearm), and 29584 (Application of multi-layer compression system; upper arm, forearm, hand, and fingers) in the CY 2012 final rule with comment period (76 FR 73192 through 73193). In the CY 2012 PFS final rule with comment period, we stated that after clinical review, we believed that CPT code 29581, in relation to CPT codes 29582 through 29584, described a similar service from a resource perspective and should be valued similarly to those codes. We stated that we believed a work RVU of 0.60 for CPT code 29581 is inappropriately high in relation to the HCPAC-reviewed codes 29582, 29583, and 29584. We believed that the HCPAC-recommended work RVUs of 0.35 for CPT code 29682, 0.25 for CPT code 29583, and 0.35 for CPT code 29584 accurately reflected the work associated with these services. Additionally, we stated that we believed that the clinical conditions treated by CPT codes 29581 and 29583 are essentially the same, namely the treatment of venous ulcers and lymphedema. We stated that we recognized that there would be mild differences and variation in the application of a multi-layer compression system to the upper extremity versus the lower extremity, which is accounted for in the intra-service times of the codes. As such, we believed that a work RVU of 0.25 appropriately accounts for the work associated with CPT code 29581.

Ultimately, we stated that we believed that a survey that addressed all 4 CPT codes together as a family and gathers responses from all clinicians who furnish the services described by CPT codes 29581 through 29584 would help us to further consider the appropriate gradation in valuation of these 4 services. We assigned a work RVU of 0.25 to CPT code 29581 on an interim basis for CY 2012, and anticipated reviewing CPT code 29581 along with CPT codes 29582, 29583, and 29584 with new survey data for CY 2013.

In response to the CY 2012 PFS final rule with comment period, commenters stated that they believe the CPT Editorial Panel revisions to CPT code 29581 were editorial only and resurveying CPT code 29581 was unnecessary, and no changes should be made to the work RVU for this code. Commenters disagreed with our methodology to value CPT code 29581 similar to HCPAC-reviewed codes 29582, 29583, and 29584, stating that the beneficiaries who receive services under CPT code 29581 are more complex. Commenters noted that the work descriptor for CPT code 29581 includes evaluation and cleansing of the venous ulcer, while there is no such parallel service for CPT codes 29582, 29583, and 29584. Commenters argued that CPT code 29581 was reviewed by the AMA RUC in April 2009 and those survey results should not be invalided by crosswalking CPT code 29581 to HCPAC-reviewed codes 29582, 29583, and 29584. Commenters noted that no completed RUC survey data was submitted to the HCPAC for CPT codes 29582, 29583 or 29584—a single specialty presented crosswalk values to the HCPAC, and they were accepted. Commenters recommended we maintain the 2009 valued AMA RUC work RVU of 0.60 for CPT code 29581.

In response to our assertion that a survey that addressed all 4 CPT codes together as a family and gathers responses from all clinicians who furnish the services described by CPT codes 29581 through 29584 would help assure the appropriate gradation in valuation of these 4 services, the AMA RUC noted that when CPT codes 29582, 29583, and 29584 were created no physician (MD/DO) specialty societies had an interest in surveying the codes, so they were surveyed and reviewed by only the HCPAC. The AMA RUC noted that another survey process would not mean that these codes would be surveyed together as we had requested.

In response to comments received, we referred CPT code 29581 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 29581 was 0.50. Typically, we finalize the work values for CPT codes after reviewing the results of the refinement panel. However, for CY 2012 we assigned interim RVUs for CPT codes 29581, 29582, 29583, and 29584 and requested additional information, with the intention of re-reviewing the services for CY 2013 with the new information we had received, and setting interim final values at that time. We recognize that CPT code 29581 received only editorial changes; however, we continue to believe the HCPAC-reviewed codes 29582, 29583, and 29584 describe similar services. While the services are performed by different specialties, they do involve similar work. For example, prior to the application of the compression bandage, CPT code 29581 includes the work furnishing a physical exam to assesses adequate arterial flow, the presence of infection, the degree of swelling, and the size/depth of the lower extremity ulcer, while CPT code 29583 includes

the work of furnishing a physical exam to assesses skin integrity, cardiopulmonary status, and peripheral vascular status. We believe these services involve the same amount of physician work. Therefore, after consideration of the public comments, refinement panel results, and our clinical review we continue to believe that the crosswalk methodology is appropriate to value CPT code 29581 and the resulting work RVU accurately reflects the work associated with this service. Accordingly, on an interim final basis for CY 2012, we are assigning a work RVU of 0.25 to CPT code 29581; a work RVU of 0.35 to CPT code 29582; a work RVU of 0.25 to CPT code 29583; and a work RVU of 0.35 to CPT code 29584.

(7) Musculoskeletal System: Endoscopy/Arthroscopy

TABLE 37—MUSCULOSKELETAL SYSTEM: ENDOSCOPY/ARTHROSCOPY

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
29824	Shoulder arthroscopy/surgery	8.98	8.98	8.98	Interim	No.
29826	Shoulder arthroscopy/surgery	3.00	3.00	3.00	Interim	No.
29827	Arthroscop rotator cuff repr	15.59	15.59	15.59	Interim	No.
29828	Arthroscopy biceps tenodesis	13.16	13.16	13.16	Interim	No.

CPT codes 29824, 29826, 29827, and 29828 were identified as potentially misvalued through the Codes Reported Together 75 percent or More screen. CPT code 29826 was also identified as potentially misvalued through the Harvard-valued—Utilization over 30,000 screen, and CPT code 29828 was also identified for additional review because it was on the New Technology list.

We reviewed CPT code 29826 (Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (ie, arch) release, when performed (list separately in addition to code for primary procedure)) for CY 2012 and agreed with the AMA RUC recommended work RVU of 3.00, which was the specialty society survey 25th percentile work RVU (76 FR 73193). For CY 2013, the AMA RUC reviewed CPT codes 29824 (Arthroscopy, shoulder, surgical; distal claviculectomy including distal articular surface (mumford procedure)) and 29827 (Arthroscopy, shoulder, surgical; with rotator cuff repair), however the specialty society did not survey these CPT codes. Without survey information, the AMA RUC affirmed that the current work RVU of 8.82 for CPT code 29824 and the current work RVU of 15.59 for CPT code 29827 are correct and not overlapping with CPT code 29826. For CY 2013, the AMA RUC also reviewed CPT code 29828 (Arthroscopy, shoulder, surgical; biceps tenodesis), which, as stated above, was on the New Technology list. The specialty society surveyed CPT code 29828, and the AMA RUC recommended the current a work RVU of 13.16, which was between the survey 25th percentile and median work RVU. As we have stated many times, we believe families of services should be reviewed together to ensure relativity between the services and consistency in inputs. We do not find the AMA RUC's affirmation that the work RVUs of CPT codes 29824 and 29827 have not changed to be sufficient evidence that the current RVUs continue to accurately reflect the work associated with furnishing those services. We request additional information from commenters on the appropriate values for these services. To clarify, we do not believe the specialty society needs to resurvey CPT codes 29826 and 29828, however we would welcome data on the valuation of CPT codes 29824 and 29827. We anticipate re-reviewing this family of services together for CY 2014. On an interim basis for CY 2013, we are assigning the current (CY 2012) work RVUs to these four services: A work RVU of 8.98 to CPT code 29824; a work RVU of 3.00 to CPT code 29826; a work RVU of 15.59 to CPT code 29827; and a work RVU of 13.16 to CPT code 29828.

(8) Respiratory System: Accessory Sinuses

TABLE 38—RESPIRATORY SYSTEM: ACCESSORY SINUSES

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
31231	Nasal endoscopy dx	1.10	1.10	1.10	Agree	Yes.

CPT code 31231 was identified for review because it is on the MPC list. After clinical review of CPT code 31231 (Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)) we believe that the current work RVU of 1.10, the survey 25th percentile value and the AMA RUC recommendation accurately reflects the work associated with this procedure. Medicare claims data from 2011 indicate that this service is typically furnished to the beneficiary on the same day as an E/M visit. We believe that some of the activities furnished during the pre- and post-service period of the procedure code and the E/M visit overlap. After review, we believe that the AMA RUC appropriately accounted for this overlap in its recommendation of pre-service time, but failed to account for the overlap in post-service time. To account for this overlap, we reduced the AMA RUC-recommended post-service time for this procedure by one-third, from 5 minutes to 3 minutes. We believe 3 minutes accurately reflects the post-service time involved in furnishing this procedure, and is more in line with similar services. A complete list of the

interim final times associated with this procedure is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(9) Respiratory System: Trachea and Bronchi

TABLE 39—RESPIRATORY SYSTEM: TRACHEA AND BRONCHI

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
31647	Bronchial valve init insert	New	4.40	4.40	Agree	No.
31648	Bronchial valve addl insert	New	4.20	4.20	Agree	No.
31649	Bronchial valve remov init	New	2.00	1.44	Disagree	No.
31651	Bronchial valve remov addl	New	1.58	1.58	Agree	No.
31660	Bronch thermoplsty 1 lobe	New	4.50	4.25	Disagree	No.
31661	Bronch thermoplsty 2/> lobes	New	5.00	4.50	Disagree	No.

For CY 2013, the CPT Editorial Panel created CPT codes 31647, 31648, 31649, and 31651 to replace 0250T, 0251T and 0252T; as well as CPT codes 31660 and 31661 to replace 0276T and 0277T.

After clinical review, we agree with the AMA RUC-recommended work RVU of 4.40 for CPT code 31647 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe) and the AMA RUC recommended work RVU of 1.58 for CPT code 31651 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure[s])) which is the associated add-on code for CPT code 31647. We also agree with the AMA RUC-recommended RVU of 4.20 for CPT code 31648 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe), which is somewhat less work than CPT code 31647. We do not agree with the AMA RUC-recommended work RVU of 2.00 for CPT code 31649 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)). CPT code 31647 has a higher work RVU than CPT code 31648, so to maintain the appropriate relativity between these services, we believe that the add-on code associated with CPT code 31647 (which is CPT code 31651) should have a higher RVU than the add-on code associated with CPT code 31648 (which is CPT code 31649). As such, we believe that the survey 25th percentile work RVU of 1.44 for CPT code 31649 places these services in the appropriate rank-order. On an interim final basis for CY 2013 we are assigning a work RVU of 4.40 to CPT code 31647; a work RVU of 4.20 to CPT code 31648; a work RVU of 1.44 to CPT code 31649; and a work RVU of 1.58 to CPT code 31651.

After reviewing CPT codes 31660 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe) and 31661 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes) we believe that the specialty society survey 25th percentile work RVUs of 4.25 for CPT code 31660 and 4.50 for CPT code 31661 appropriately reflect the relativity of these services to each other and to other fee schedule services. The AMA RUC recommended the specialty society survey median work RVUs of 4.50 for CPT code 31660 and 5.00 for CPT code 31661. On an interim final basis for CY 2013, we are assigning a work RVU of 4.25 for CPT code 31660 and a work RVU of 4.50 to CPT code 31661.

(10a) Respiratory System: Lungs and Pleura

TABLE 40—RESPIRATORY SYSTEM: LUNGS AND PLEURA

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
32551	Insertion of chest tube	3.29	3.50	3.29	Disagree	No.
32554	Aspirate pleura w/o imaging	New	1.82	1.82	Agree	No.
32555	Aspirate pleura w/imaging	New	2.27	2.27	Agree	Yes.
32556	Insert cath pleura w/o image	New	2.50	2.50	Agree	No.
32557	Insert cath pleura w/image	New	3.62	3.12	Disagree	Yes.
32701	Thorax stereo rad targetw/tx	New	4.18	4.18	Agree	No.

CPT codes 32420, 32421, 32422, and 32551 were identified as potentially misvalued through the Harvard-valued—Utilization over 30,000 screen. For CY 2013, the CPT Editorial Panel deleted CPT codes 32420, 32421, and 32422 and replaced them with CPT codes 32554, 32555, 32556, and 32557.

After clinical review of CPT code 32551 (Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)), we believe that the current work RVU of 3.29 appropriately reflects the work associated with service. The AMA RUC recommended the specialty society survey 25th percentile work RVU of 3.50, however we believe that an increase in work RVU is not warranted for this service, especially considering

the substantial drops in recommended physician time. Additionally, we believe that a work RVU of 3.29 places this service in the appropriate rank order with the other similar CPT codes reviewed for CY 2013. On an interim final basis for CY 2013, we are assigning a work RVU of 3.29 for CPT code 32551.

After clinical review of CPT codes 32554 (Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance), 32555 (Thoracentesis, needle or catheter, aspiration of the pleural space; with imaging guidance), and 32556 (Pleural drainage, percutaneous, with insertion of indwelling catheter; without imaging guidance) we agree with the AMA RUC-recommended work RVUs. On an interim final basis for CY 2013, we are assigning a work RVU of 1.82 to CPT code 32554; a work RVU of 2.27 to CPT code 32555, and a work RVU of 2.50 to CPT code 32556.

After clinical review of CPT code 32557 (Pleural drainage, percutaneous, with insertion of indwelling catheter; with imaging guidance), we believe that a work RVU of 3.12 appropriately reflects the work of this service. The AMA RUC recommended a work RVU of 2.50 for CPT code 32556 and a work RVU of 3.62 for CPT code 32557. We believe the AMA RUC-recommended work RVU of 3.62 overstates the difference between CPT codes 32556 and 32557. The specialty societies that surveyed CPT code 32556 recommended to the AMA RUC a work RVU of 3.00 for CPT code 32556 and a work RVU of 3.62 for CPT code 32557. We believe this difference in work RVU of 0.62 more accurately captures the relative difference between these two services. Therefore, since we assigned CPT code 32556 an interim final work RVU of 2.50, we believe a work RVU of 3.12 appropriately reflects the work of CPT code 32557. On an interim final basis for CY 2013, we are assigning a work RVU of 3.12 to CPT code 32557.

Additionally, on an interim final basis for CY 2013, we are refining the AMA RUC recommended pre-service evaluation time to 13 minutes from 15 minutes for CPT codes 32555 and 32557 to match the pre-service evaluation times of CPT codes 32554 and 32556. A complete list of the times associated with these procedures is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(10b) Respiratory System: Lungs and Pleura

TABLE 41—RESPIRATORY SYSTEM: LUNGS AND PLEURA

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
32440	Remove lung pneumonectomy	27.28	N/A	27.28	Interim	N/A.
32480	Partial removal of lung	25.82	N/A	25.82	Interim	N/A.
32482	Bilobectomy	27.44	N/A	27.44	Interim	N/A.
32491	Lung volume reduction	25.24	N/A	25.24	Interim	N/A.
32663	Thoracoscopy w/lobectomy	24.64	24.64	24.64	Interim	No.
32668	Thoracoscopy w/w resect diag	3.00	4.00	3.00	Interim	No.
32669	Thoracoscopy remove segment	23.53	23.53	23.53	Interim	No.
32670	Thoracoscopy bilobectomy	28.52	28.52	28.52	Interim	No.
32671	Thoracoscopy pneumonectomy	31.92	31.92	31.92	Interim	No.
32672	Thoracoscopy for lvrs	27.00	27.00	27.00	Interim	No.
32673	Thoracoscopy w/thymus resect	21.13	21.13	21.13	Interim	No.
60520	Removal of thymus gland	17.16	N/A	17.16	Interim	N/A.
60521	Removal of thymus gland	19.18	N/A	19.18	Interim	N/A.
60522	Removal of thymus gland	23.48	N/A	23.48	Interim	N/A.

The CPT Editorial Panel reviewed the lung resection family of codes and deleted 8 codes, revised 5 codes, and created 18 new codes for CY 2012. During our clinical review for the CY 2012 PFS final rule with comment period, we were concerned with the varying differentials in the AMA RUC-recommended work RVUs and times between some of the open surgery lung resection codes and their endoscopic analogs. Rather than assign alternate interim final RVUs and times in this large restructured family of codes, we accepted the AMA RUC recommendations on an interim basis and requested that the AMA RUC re-review the surgical services along with their endoscopic analogs.

In the CY 2012 PFS final rule with comment period we made this request on a code-by-code basis. However, there was an inadvertent typographical error in our request—we referred to ''open heart surgery analogs'', instead of just ''open surgery analogs''. For example, we stated, ''For CPT code 32663 (Thoracoscopy, surgical; with lobectomy (single lobe)), the AMA RUC recommended a work RVU of 24.64. Upon clinical review, we have determined that it is most appropriate to accept the AMA RUC recommended work RVU of 24.64 on a provisional basis, pending review of the open heart surgery analogs, in this case CPT code 32480. We are requesting the AMA RUC look at the incremental difference in RVUs and times between the open and laparoscopic surgeries and recommend a consistent valuation of RVUs and time for CPT code 32663 and other services within this family with this same issue. Accordingly, we are assigning a work RVU of 24.64 for CPT code 32663 on an interim basis for CY 2012'' (76 FR 73195).

In response to this request, the specialty society noted that these are not open heart surgery codes and therefore are not relevant. The AMA RUC requested further information from CMS on why these services should be reviewed as part of a family. We understand that our request would have been more clear if we had referred to ''open surgery codes'' instead of ''open heart surgery codes'' and if we had written ''endoscopic procedures'' instead of ''laparoscopic surgeries''. With this clarification, we re-request public comment on the appropriate work RVU and time values for the interim codes in the table above. These codes are discussed in greater detail in the CY 2012 PFS final rule with comment period, pages 73193 through 73195. For CY 2013, we are maintaining the current (CY 2012) values for these services on an interim basis. We intend

to review these CPT codes in CY 2013 and set interim final values for CY 2014.

(11) Cardiovascular System: Heart and Pericardium

TABLE 42—CARDIOVASCULAR SYSTEM: HEART AND PERICARDIUM

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
33361	Replace aortic valve perq	New	29.50	25.13	Disagree	Yes.
33362	Replace aortic valve open	New	32.00	27.52	Disagree	Yes.
33363	Replace aortic valve open	New	33.00	28.50	Disagree	Yes.
33364	Replace aortic valve open	New	34.87	30.00	Disagree	Yes.
33365	Replace aortic valve open	New	37.50	33.12	Disagree	No.
33367	Replace aortic valve w/byp	New	11.88	11.88	Agree	No.
33368	Replace aortic valve w/byp	New	14.39	14.39	Agree	No.
33369	Replace aortic valve w/byp	New	19.00	19.00	Agree	No.
33405	Replacement of aortic valve	41.32	41.32	41.32	Interim	No.
33430	Replacement of mitral valve	50.93	50.93	50.93	Interim	No.
33533	Cabg arterial single	33.75	34.98	33.75	Interim	No.
33990	Insert vad artery access	New	8.15	8.15	Agree	No.
33991	Insert vad art&vein access	New	11.88	11.88	Agree	No.
33992	Remove vad different session	New	4.00	4.00	Agree	No.
33993	Reposition vad diff session	New	4.17	3.51	Disagree	No.

The CPT Editorial Panel deleted four Category III codes (0256T through 0259T) and approved nine CPT codes (33361 through 33369) to report transcatheter aortic valve replacement (TAVR) procedures for CY 2012.

On May 1, 2012, CMS issued a National Coverage Determination (NCD) covering TAVR under Coverage with Evidence Development (CED). The NCD identifies numerous detailed requirements, including that covered TAVR requires a cardiothoracic surgeon and an interventional cardiologist. Under this CED, coverage is limited to services furnished under specific conditions targeted to developing data on the safety and efficacy of the service for Medicare beneficiaries. Like their predecessor Category III codes (0256T through 0259T), the new Category I CPT codes 33361 through 33365 require the work of an interventional cardiologist and cardiothoracic surgeon to jointly participate in the intra-operative technical aspects of TAVR as co-surgeons. Claims processing instructions for the CED (CR 7897 transmittal 2552) require each physician to bill with modifier-62 indicating that co-surgery payment applies. Medicare pays each co-surgeon 62.5 percent of the fee schedule amount. The three add-on cardiopulmonary bypass support services (CPT codes 33367 through 33369) are only reported by the cardiothoracic surgeon; therefore the AMA RUC-recommended work RVUs for those services reflect only the work of one physician. The AMA RUC-recommended work RVUs for each of the co-surgery CPT codes (33361 through 33365) reflect the combined work of both physicians, irrespective of the co-surgery payment policy. We debated whether it was appropriate to continue our co-surgery payment policy at 62.5 percent of the physician fee schedule amount for each physician for these codes if the work value reflected 100 percent of the work for two physicians. Ultimately, we decided to set work RVU values to reflect the total physician work of the procedures, and to continue to follow our co-surgery payment policy allowing the services to be billed by two physicians, in part because co-surgery is a requirement under Medicare policy for these services. We are not sure this is the appropriate long-term payment policy. We intend to reassess payment for this family of codes when we review national coverage for TAVR. For the time package, the AMA RUC accounted for the time each physician separately spends obtaining consent and reviewing the procedure with the patient. We are concerned that time for each physician to obtain consent and review the procedure with the patient is inconsistent with a framework for valuing the service as a single service.

After clinical review of CPT code 33361 (Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach), we believe that the specialty society survey 25th percentile work RVU of 25.13 appropriately captures the total work of the service. The AMA RUC recommended the survey median work RVU of 29.50. Regarding physician time, for CPT 33361, as well as CPT codes 33362 through 33364, we believe 45 minutes of pre-service evaluation time, which is the survey median time, is more consistent with the work of this service than the AMA RUC-recommended pre-service evaluation time of 50 minutes. Accordingly, we are assigning a work RVU of 25.13 to CPT code 33361, with a refinement of 45 minutes of pre-service evaluation time, on an interim basis for CY 2013. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

After clinical review of CPT code 33362 (Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach), we believe that the specialty society survey 25th percentile work RVU of 27.52 appropriately captures the total work of the service. The AMA RUC recommended the survey median work RVU of 32.00. Like CPT code 33361, we also believe 45 minutes of pre-service evaluation time is more appropriate for this service than the AMA RUC-recommended pre-service evaluation time of 50 minutes. Accordingly, we are assigning a work RVU of 27.52 to CPT code 33362, with a refinement to 45 minutes of pre-service evaluation time, on an interim basis for CY 2013. A complete listing of the times associated with this code is available on the CMS Web site at *www.cms.gov/PhysicianFeeSched/*.

After clinical review of CPT code 33363 (Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach), we believe that the specialty society survey 25th percentile work RVU of 28.50 appropriately captures the

total work of the service. The AMA RUC reviewed the survey results and recommended the survey median work RVU of 33.00. Like CPT codes 33361 and 33362, we also believe 45 minutes of pre-service evaluation time is more appropriate for this service than the AMA RUC-recommended time of 50 minutes. Accordingly, we are assigning a work RVU of 28.50 to CPT code 33363, with a refinement to 45 minutes of pre-service evaluation time, on an interim basis for CY 2013. A complete listing of the times associated with this code is available on the CMS Web site at *www.cms.gov/PhysicianFeeSched/*.

After clinical review of CPT code 33364 (Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach), we believe that the specialty society survey 25th percentile work RVU of 30.00 more appropriately captures the total work of the service. The AMA RUC reviewed the survey results and recommended the survey median work RVU of 34.87. Like CPT codes 33361 through 33363, we also believe 45 minutes of pre-service evaluation time is more appropriate for this service than the AMA RUC-recommended time of 50 minutes. Accordingly, we are assigning a work RVU of 30.00 to CPT code 33364, with a refinement to 45 minutes of pre-service evaluation time, on an interim basis for CY 2013. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

After clinical review of CPT code 33365 (Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy), we believe a work RVU of 33.12 accurately reflects the work associated with this service. The AMA RUC reviewed the survey results and recommended the survey median work RVU of 37.50. After clinical review, we determined that the work associated with this service is very similar to reference CPT code 33410 (Replacement, aortic valve, with cardiopulmonary bypass; with stentless tissue valve) (work RVU = 46.41), which has a 90-day global period that includes inpatient hospital and office visits. Because CPT code 33365 has a 0-day global period that does not include post-operative visits, we calculated the value of the pre-operative and post-operative visits in the global period of CPT code 33410, which totaled 13.29 work RVUs, and subtracted that from the total work RVU of 46.41 for CPT code 33410 to determine the appropriate work RVU for CPT code 33365. With regard to time, we decided to maintain the 50 minutes of pre-service evaluation time because we believe that the procedure described by CPT code 33365 involves more pre-service evaluation time since it is performed by surgically opening the chest via median sternotomy. Accordingly, we are assigning a work RVU of 33.12 for CPT code 33365 on an interim basis for CY 2013.

CPT codes 33405, 33430, and 33533 were identified as potentially misvalued through the High Expenditure Procedure Code screen.

When reviewing these services, the specialty society utilized data from the Society of Thoracic Surgeons (STS) National Adult Cardiac Database in developing recommended times and RVUs for CPT codes 33405 (Replacement, aortic valve, with cardiopulmonary bypass; with prosthetic valve other than homograft or stentless valve), 33430 (Replacement, mitral valve, with cardiopulmonary bypass), and 33533 (Coronary artery bypass, using arterial graft(s); single arterial graft), and did not conduct a survey of physician work and time. After reviewing the mean procedure times for these services in the STS database alongside other information relating to the value of these services, the specialty society and AMA RUC concluded that CPT codes 33405 and 33430 are valued appropriately and that the current work RVUs of 41.32 for CPT code 33405, and 50.93 for CPT code 33430 should be maintained. After reviewing the mean procedure time for CPT code 33533 in the STS database alongside other information relating to the value of the service, the specialty society and AMA RUC concluded that the work associated with CPT code 33553 had increased since this service was last reviewed. The AMA RUC recommended a work RVU of 34.98 for CPT code 33533, which is a direct crosswalk to CPT code 33510 (Coronary artery bypass, vein only; single coronary venous graft).

We believe the STS database, which captures outcome data in addition to time and visit data, is a useful resource in the valuation of PFS services. However, the AMA RUC recommendations on these services show only the STS database mean time for CPT codes 33405, 33430, and 33533. We are interested in seeing the distribution of times, including the 25th percentile, median, and 75th percentile values (which are the data points reported on the specialty society surveys), in addition to any other information STS believes would be relevant to the valuation of the services, such as case-mix, or time data for similar services. The STS database is a robust source of information and we believe it would be helpful to review additional data points for these three services beyond the mean time provided by the AMA RUC. In order to complete our clinical review of these services, we would like to see the distribution of procedure times for CPT codes 33405, 33430, and 33533. We are also interested in more information on the methodology used to develop the recommended work RVUs based on the time data, and, using that methodology, the different RVUs that correspond to the 25th percentile, median, and 75th percentile time data. We previously have expressed our concerns regarding the manner in which data derived from the STS database was used (71 FR 37224 through 37225). We are committed to reviewing and evaluating all services using an approach that maintains the appropriate relativity among fee schedule services. For CY 2013 we are maintaining the current work RVUs for these services on an interim basis. We will consider additional time and other data submitted in response to comments on this final rule with comment period in the CY 2014 PFS final rule with comment period. Specifically, we are maintaining a work RVU of 41.32 for CPT code 33405; a work RVU of 50.93 for CPT code 33430; and a work RVU of 33.75 for CPT code 33533.

(12) Cardiovascular System: Arteries and Veins

TABLE 43—CARDIOVASCULAR SYSTEM: ARTERIES AND VEINS

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC time
35475	Repair arterial blockage	9.48	6.60	5.75	Disgaree	No.

TABLE 43—CARDIOVASCULAR SYSTEM: ARTERIES AND VEINS—Continued

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC time
35476	Repair venous blockage	6.03	5.10	4.71	Disagree	No.
36221	Place cath thoracic aorta	New	4.51	4.17	Disagree	Yes.
36222	Place cath carotid/inom art	New	6.00	5.53	Disagree	Yes.
36223	Place cath carotid/inom art	New	6.50	6.00	Disagree	Yes.
36224	Place cath carotd art	New	7.55	6.50	Disagree	Yes.
36225	Place cath subclavian art	New	6.50	6.00	Disagree	Yes.
36226	Place cath vertebral art	New	7.55	6.50	Disagree	Yes.
36227	Place cath xtrnl carotid	New	2.32	2.09	Disagree	No.
36228	Place cath intracranial art	New	4.25	4.25	Agree	No.
37197	Remove intrvas foreign body	New	6.72	6.29	Disagree	No.
37211	Thrombolytic art therapy	New	8.00	8.00	Agree	No.
37212	Thrombolytic venous therapy	New	7.06	7.06	Agree	No.
37213	Thromblytic art/ven therapy	New	5.00	5.00	Agree	No.
37214	Cessj therapy cath removal	New	3.04	2.74	Disagree	No.

In CY 2011, CPT codes 35475 and 35476 were identified in the CMS High Expenditure Procedure Codes Screen.

After clinical review of CPT code 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), we believe a work RVU of 5.75 appropriately captures the work of the service. To develop a recommended value for this service, the AMA RUC started with the work RVU of CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) (work RVU of 9.00), which the AMA RUC believed was a comperable service to CPT code 35475, then removed RVUs to account for overlap in work resulting from same day billing with CPT codes 36147 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report (includes access of shunt, injection[s] of contrast, and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava)) and 75962 (Transluminal balloon angioplasty, peripheral artery other than renal, or other visceral artery, iliac or lower extremity, radiological supervision and interpretation). Using these calculations, the AMA RUC recommended a work RVU of 6.60 for CPT code 35475. We agree with this approach, but believe that CPT code 37220 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty) (work RVU 8.15) is more similar to CPT code 35475 and therefore a better starting point for the reductions. After accounting for overlap with other services typically reported with CPT code 35475, we determined that a work RVU of 5.75 is appropriate for this service. Accordingly, we are assigning a work RVU of 5.75 to CPT code 35475 on an interim final basis for CY 2013.

After clinical review of CPT code 35476 (Transluminal balloon angioplasty, percutaneous; venous), we believe a work RVU of 4.71 more appropriately captures the work of the service. The AMA RUC reviewed the survey results and recommended a work RVU of 5.50, the survey 25th percentile value. We determined that the work associated with CPT code 35476 was similar in terms of physician time and intensity to CPT code 37191 (Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed), which has a work RVU of 4.71. We believe the work RVU of 4.71 appropriately captures the relative difference between this service and CPT code 35475. Therefore, we are assigning a work RVU of 4.71 for CPT code 35476 on an interim final basis for CY 2013.

CPT codes 36221 through 32668 were identified as potentially misvalued through the Codes Reported Together 75 percent or More screen. For CY 2012, the AMA RUC requested that CPT Editorial Panel create eight new codes to bundle selective catheter placement with radiological supervision and interpretation, including angiography. Additionally, the specialty society recognized that non-invasive vascular imaging has replaced diagnostic angiography as a screening test.

After clinical review of CPT code 36221(Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed), we believe a work RVU of 4.17 more appropriately captures the work of the service, with refinement of 30 minutes to the post-service time. The AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a value of 4.51 work RVUs and a post-service time of 40 minutes. The AMA RUC used a direct crosswalk to the two component codes being bundled, CPT code 32600 (Introduction of catheter, aorta) (work RVU = 3.02) and CPT code 75650 (Angiography, cerviocerebral, catheter, including vessel origin, radiological supervision and interpretation) (work RVU = 1.49) and the recommended value of 4.51 is the sum of the RVUs for these component codes. We believe that that there are efficiencies gained when services are bundled. We believe crosswalking to the work RVU of CPT code 32550 (Insertion of indwelling tunneled pleural catheter with cuff), which has a work RVU of 4.17, appropriately accounts for the physician time and intensity with CPT code 36221. Additionally, we believe that the survey post-service time of 30 minutes more accurately accounts for the time involved in furnishing this service than the AMA RUC-recommended post-service time of 40 minutes. Therefore, we are assigning a work RVU of 4.17 with refinement to time for CPT code

36221 on an interim final basis for CY 2013. A complete listing of the times associated with this code is available on the CMS Web site at *www.cms.gov/PhysicianFeeSched/*.

After clinical review of CPT code 36222 ((Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed).), we believe the survey 25th percentile work RVU of 5.53 appropriately captures the work of this service, particularly the efficiencies when two services are bundled together. The AMA RUC recommended the survey median work RVU of 6.00. Like CPT code 36221, we believe the survey post-service time of 30 minutes is more appropriate than the AMA RUC-recommended post-service time of 40 minutes. We are assigning a work RVU of 5.53 with refinement to time for CPT code 36222 as interim final for CY 2013. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

After clinical review of CPT code 36223 (Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed), we believe a work RVU value of 6.00, the survey 25th percentile value, appropriately captures the work of the service, particularly efficiencies when two services are bundled together. The AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a work RVU of 6.50. Like many of the other CPT codes in this family, we believe the survey post-service time of 30 minutes is more appropriate than the AMA RUC-recommended time of 40 minutes. We are assigning a work RVU of 6.00 with refinement to time for CPT code 36223 as interim final for CY 2013. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

After clinical review of CPT code 36224 (Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed), we believe a work RVU of 6.50, the survey 25th percentile value, appropriately captures the work of the service, particularly efficiencies when two services are bundled together. We believe 30 minutes of post-service times more appropriately accounts for the work of this service. The AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a value of 7.55 and a post-service time of 40 minutes for CPPT code 36224. Accordingly, we are assigning a work RVU of 6.50 with refinement to time for CPT code 36224 as interim final for CY 2013. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

After clinical review of CPT code 36225 (Selective catheter placement, subclavian or innominate artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed), we believe that this code should be valued the same as the CPT code 36223, to which we are assigning a work RVU of 6.00. Comparable to CPT code 36223, we also believe 30 minutes of post-service times more appropriately accounts for the work of this service. The AMA RUC reviewed the survey results and recommended the survey median work RVU of 6.50 and a post-service time of 40 minutes for CPT code 36225. We are assigning a work RVU of 6.00 with refinement to time for CPT code 36225 as interim final for CY 2013. A complete listing of the times associated with this code is available on the CMS Web site at: *www.cms.gov/PhysicianFeeSched/*.

After clinical review of CPT code 36226 (Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed), we believe that this CPT code should be valued the same as CPT code 36224, which has a work RVU as 6.50. Comparable to CPT code 36224, we also believe 30 minutes of post-service times more appropriately accounts for the work of this service. The AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a value of 7.55 and a post-service time of 40 minutes for CPT code 36226. We are assigning a work RVU of 6.50 with refinement to time for CPT code 36226 as interim final for CY 2013.

After clinical review of CPT code 36227 (Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (list separately in addition to code for primary procedure)), we determined that there are efficiencies gained when services are bundled, and identified a work RVU of 2.09 for this service. This work RVU reflects the application of a very conservative estimate of 10 percent for the work efficiencies that we would expect to occur when multiple component codes are bundled together to the sum of the work RVUs for the component codes. The AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a value of 2.32 for CPT code 36227. The AMA RUC used a direct crosswalk to the two component codes being bundled, CPT code 36218 (Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family (list in addition to code for initial second or third order vessel as appropriate) (work RVU= 1.01) and CPT code 75660 (Angiography, external carotid, unilateral, selective, radiological supervision and interpretation) (work RVU = 1.31). We are assigning a work RVU of 2.09 as the interim final value of CPT code 36227 for CY 2013.

(13) Hemic and Lymphatic System: General

TABLE 44—HEMIC AND LYMPHATIC SYSTEM: GENERAL

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
38240	Transplt allo hct/donor	2.24	4.00	3.00	Disagree	No.
38241	Transplt autol hct/donor	2.24	3.00	3.00	Agree	No.
38242	Transplt allo lymphocytes	1.71	2.11	2.11	Agree	No.
38243	Transplj hematopoietic boost	New	2.13	2.13	Agree	No.

CPT codes 38240, 38241, 38242, and 38243 were revised by the CPT Editorial Panel for CY 2013.

After clinical review, we agree with the AMA RUC-recommended work RVUs for CPT codes 38241 (Hematopoietic progenitor cell (hpc); autologous transplantation), 38242 (Allogeneic lymphocyte infusions), and 38243 (Hematopoietic progenitor cell (hpc); hpc boost). On an interim final basis for CY 2013 we are assigning a work RVU of 3.00 to CPT code 38241; a work RVU of 2.11 to CPT code 38242; and a work RVU of 2.13 to CPT code 38243.

After clinical review, we believe CPT code 38240 should have the same work RVU as CPT code 38241, because we believe the two services involve the same amount of work. The AMA RUC recommended a work RVU of 4.00 for CPT code 38240. On an interim final basis for CY 2013 we are assigning CPT code 38240 a work RVU of 3.00.

(14) Digestive System: Intestines (Except Rectum)

TABLE 45—DIGESTIVE SYSTEM: INTESTINES (EXCEPT RECTUM)

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
44705	Prepare fecal microbiota	New	1.42	Invalid	N/A	N/A.
G0455	Fecal microbiota prep instill	New	N/A	0.97	N/A	N/A.

The CPT Editorial Panel created CPT code 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen) for CY 2013. The AMA RUC recommended a work RVU of 1.42, which is a direct crosswalk to CPT code 99203 (Level 3 office or other outpatient visit, new patient). This service is currently (CY 2012) reported under CPT code 44799 (Unlisted procedure, intestine), as is the instillation of the microbiota. Within Medicare, payment for the preparation of the donor specimen would only be made if the specimen is ultimately used for the treatment of a beneficiary as Medicare is not authorized to pay for any costs not directly related to the diagnosis and treatment of a beneficiary. Because of this policy, we believe it is appropriate to bundle the preparation and instillation into one payable HCPCS code. For CY 2013, we have created HCPCS code G0455 (Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen). HCPCS code G0455 will replace new CPT code 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen) which will have a PFS procedure status indicator of I (Not valid for Medicare purposes), and includes both the work of preparation and instillation of the microbiota.

After reviewing the preparation and instillation work associated with this procedure, we believe that CPT code 99213 (Level 3 office or other outpatient visit, established patient) is an appropriate crosswalk for the work and time of HCPCS code G0455. Therefore, on an interim final basis for CY 2013, we are assigning a work RVU of 0.97 to HCPCS code G0455. A list of the interim final times associated with this procedure is available on the CMS Web site at *www.cms.gov/physicianfeesched/.*

(15) Digestive System: Biliary Tract

TABLE 46—DIGESTIVE SYSTEM: BILIARY TRACT

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
47562	Laparoscopic cholecystectomy	11.76	11.76	10.47	Disagree	Yes.
47563	Laparo cholecystectomy/graph	11.47	11.47	11.47	Agree	No.
47600	Removal of gallbladder	17.48	20.00	17.48	Disagree	No.
47605	Removal of gallbladder	15.98	21.00	18.48	Disagree	No.

In CY 2011, we received comments regarding a potential relativity problem between CPT codes 47600 (Cholecystectomy;) and 47605 (Cholecystectomy; with cholangiography), as CPT code 47600

has a higher work RVU and more post-operative visits than CPT code 47605. In the CY 2012 PFS proposed rule, we requested that the AMA RUC review these two CPT codes and thanked commenters for bringing this to our attention (76 FR 42796). Currently (CY 2012), CPT code 47600 has a work RVU of 17.48, and CPT code 47605 has a work RVU of 15.98, which is clearly an anomalous relationship. For CY 2013, the related specialty societies resurveyed these two CPT codes. After review, we believe that the work RVU of 17.48 appropriately reflects the work of CPT code 47600, and that the work RVU of CPT code 47605 should be increased to reflect the increase in work related to the addition of cholangiography. After clinical review, we agree with the AMA RUC and specialty societies that a work RVU of 1.00 is the correct difference between CPT code 47600 and 47605. Therefore, we believe a work RVU of 18.48 accurately accounts for the work associated with CPT code 47605. We do not believe that the work of CPT code 47600 has increased over time. The AMA RUC recommended a work RVU of 20.00 for CPT code 47600 and a work RVU of 21.00 for CPT code 47605. Both values are the specialty society survey median work RVUs. On an interim final basis for CY 2013, we are assigning a work RVU of 17.48 to CPT code 47600 and a work RVU of 18.48 to CPT code 47605.

In their review of these CPT codes, the specialty societies indicated and the AMA RUC agreed that the typical patient undergoing an open cholecystectomy is scheduled and started with a laparoscopic approach and is then converted to the open procedure. We are concerned that the vignettes associated with these procedures imply that the work of the failed laparoscopic approach is included in the work of the cholecystectomy. We request that the AMA RUC review the vignettes for these services.

CPT codes 47562 and 47563 were identified as potentially misvalued through the High Expenditure Procedure Code screen.

Though these service were identified by CMS as potentially misvalued, the related specialty societies declined to survey CPT codes 47562 (Laparoscopy, surgical; cholecystectomy) and 47563 (Laparoscopy, surgical; cholecystectomy with cholangiography), because, they said, the codes had been resurveyed many times, with CPT code 47563 last surveyed and reviewed as recently as the Fourth Five-Year Review (CY 2011). The AMA RUC Relativity Assessment Workgroup concluded that these services have not changed since last reviewed and that resurveying the codes would not produce different values. The AMA RUC reaffirmed the current (CY 2012) work RVU of 11.76 for CPT code 47562 and the current (CY 2012) work RVU of 11.47 for CPT code 47563.

After clinical review, we noticed a rank-order anomaly in these services similar to the rank-order problem discussed above for CPT codes 47600 and 47605. CPT code 47563, which includes cholangiography, is currently (CY 2012) valued lower than CPT code 47562 which describes the same procedure without cholangiography. After reviewing these two services, we agree with the AMA RUC that the recently-reviewed current work RVU of 11.47 for CPT code 47563 continues to accurately reflect the work of this service. As discussed above, we believe that a work RVU of 1.00 reflects the incremental difference between cholecystectomy with cholangiography and cholecystectomy alone. Therefore, we believe that CPT code 47562 should be valued 1.00 RVU lower than CPT code 47563. On an interim final basis for CY 2013, we are assigning a work RVU of 10.47 to CPT code 47562 and a work RVU of 11.47 to CPT code 47563.

Regarding physician time, we changed the pre-service time of CPT code 47562 to match the pre-service time of CPT code 47563, leading to small increase in pre-service time for the service. A complete listing of the interim final times assigned to these services is available on the CMS Web site at *www.cms.gov/physicianfeesched/.*

(16) Urinary System: Bladder

TABLE 47—URINARY SYSTEM: BLADDER

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
52214	Cystoscopy and treatment	3.70	3.50	3.50	Agree	No.
52224	Cystoscopy and treatment	3.14	4.05	4.05	Agree	Yes.
52234	Cystoscopy and treatment	4.62	4.62	4.62	Agree	No.
52235	Cystoscopy and treatment	5.44	5.44	5.44	Agree	No.
52240	Cystoscopy and treatment	9.71	8.75	7.50	Disagree	No.
52287	Cystoscopy chemodenervation	New	3.20	3.20	Agree	No.
52351	Cystouretero & or pyeloscope	5.85	5.75	5.75	Agree	No.
52352	Cystouretero w/stone remove	6.87	6.75	6.75	Agree	No.
52353	Cystouretero w/lithotripsy	7.96	7.88	7.50	Disagree	No.
52354	Cystouretero w/biopsy	7.33	8.58	8.00	Disagree	No.
52355	Cystouretero w/excise tumor	8.81	10.00	9.00	Disagree	No.

CPT code 52235 was identified as potentially misvalued under the Harvard-valued—Utilization over 30,000 screen. CPT codes 52234, 52240, and 52351 through 52355 were identified as a part of this family for review.

After clinical review, we agreed with the AMA RUC-recommended work RVUs for the majority of codes in this family. However, we disagreed with the AMA RUC-recommended work RVUs for CPT codes 52353 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)), 52354 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with biopsy and/or fulguration of ureteral or renal pelvic lesion), 52355 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with resection of ureteral or renal pelvic tumor), and 52240 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; large bladder tumor(s)). For CPT codes,

52353, 52354, and 52355, we believe that the survey 25th percentile work RVUs represent a more appropriate incremental difference over the base code, CPT code 52351 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic), to which we are assigning an interim final work RVU of 5.75, than the AMA RUC recommended work RVUs of 7.88, 8.58, 10.00, respectively. Additionally, we believe the survey 25th percentile work RVUs more appropriately account for the significant reduction in intra-service time of these three CPT codes. Therefore, on an interim final basis for CY 2013, we are assigning a work RVU of 7.50 for CPT 52353; a work RVU of 8.00 for CPT code 52354; and a work RVU of 9.00 for CPT code 52355.

After reviewing CPT code 52240, we believe this service should be valued the same as CPT code 52353, as the services have the same times and describe very similar procedures. Therefore, on an interim final basis for CY 2013, we are assigning a work RVU of 7.50 to CPT code 52240.

Regarding physician time, we refined the AMA RUC-recommended pre-service time for CPT code 52224 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of minor (less than 0.5 cm) lesion(s) with or without biopsy) from 32 minutes to 29 minutes to match the pre-service time of CPT code 52214 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands) which has very similar pre-service work. A complete list of the interim final times associated with these procedures is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(17) Nervous System: Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System

TABLE 48—NERVOUS SYSTEM: EXTRACRANIAL NERVES, PERIPHERAL NERVES, AND AUTONOMIC NERVOUS SYSTEM

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
64450	N block other peripheral	1.27	0.75	0.75	Agree	No.
64612	Destroy nerve face muscle	2.01	1.41	1.41	Interim	No.
64613	Destroy nerve neck muscle	2.01	N/A	2.01	Interim	N/A.
64614	Destroy nerve extrem musc	2.20	N/A	2.20	Interim	N/A.
64615	Chemodenerv musc migraine	New	1.85	1.85	Interim	No.
64640	Injection treatment of nerve	2.81	1.23	1.23	Agree	No.

The CPT Editorial Panel created CPT code 64615 and revised CPT codes 64612, 64613, and 64614 for CY 2013.

When the AMA RUC and related specialty societies reviewed CPT codes 64613 (Chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)) and 64614 (Chemodenervation of muscle(s); extremity and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)), they determined that both CPT codes should be divided into additional codes, and referred CPT codes 64613 and 64614 to the CPT Editorial Panel. The AMA RUC recommended the survey median work RVU of 1.41 for CPT code 64612 (Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)), a decrease from the current work RVU of 2.01, and recommended the survey median work RVU of 1.85 for new CPT code 64615 (Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)). We are accepting the AMA RUC-recommended work RVUs for CPT codes 64612 and 64615 on an interim basis, and will review these services alongside CPT codes 64613 and 64614 (or their successor CPT codes) after they are reviewed by the CPT Editorial Panel.

The AMA RUC requested a change in the global period of CPT code 64615 from 10 days to 0 days. We believe that a global period of 10 days is most appropriate for this service, and maintains consistency within this family of CPT codes, as the other services in this family also have 10-day global periods.

(18) Eye and Ocular Adnexa: Eyeball

TABLE 49—EYE AND OCULAR ADNEXA: EYEBALL

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
65222	Remove foreign body from eye	0.93	0.93	0.84	Disagree	Yes.

CPT code 65222 was identified as potentially misvalued under the Harvard-valued—Utilization over 30,000 screen.

Medicare claims data from 2011 indicate that CPT code 65222 (Removal of foreign body, external eye; corneal, with slit lamp) is typically furnished to the beneficiary on the same day as an E/M visit. We believe that some of the activities furnished during the pre- and post-service period of the procedure code and the E/M visit overlap. After review, we do not believe that the AMA RUC appropriately accounted for this overlap in its recommendation of pre- and post-service time. To account for this overlap, we reduced the AMA RUC-recommended pre-service evaluation time by one-third, from 7 minutes to 5 minutes, and the AMA RUC-recommended post-service time by one-third, from 5 minutes to 3 minutes. We believe that 5 minutes of pre-service evaluation time and 3 minutes of post-service time accurately reflect the time involved in furnishing the pre- and

post-service work of this procedure, and that these times are well-aligned with similar services. Because we reduced the AMA RUC-recommended procedure time for this code by 4 minutes, at a standard work intensity of .0224 RVUs per minute, we believe that it is also appropriate to remove 0.09 RVUs from the current/AMA RUC-recommended RVU of 0.93. In sum, on an interim final basis for CY 2013, we are assigning a work RVU of 0.84 to CPT code 65222, with a refinement to the AMA RUC recommended time. A complete list of the interim final times associated with this procedure is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(19) Eye and Ocular Adnexa: Ocular Adnexa

TABLE 50—EYE AND OCULAR ADNEXA: OCULAR ADNEXA

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
67810	Biopsy eyelid & lid margin	1.48	1.18	1.18	Agree	Yes.

CPT code 67810 was identified as potentially misvalued under the Harvard-valued—Utilization over 30,000 screen.

Medicare claims data from 2011 indicate that CPT code 67810 (Incisional biopsy of eyelid skin including lid margin) is typically furnished to the beneficiary on the same day as an E/M visit. We believe that some of the activities furnished during the pre- and post-service period of the procedure code and the E/M visit overlap. After review, we believe that the AMA RUC appropriately accounted for this overlap in its recommendation of pre-service time, but that the AMA RUC-recommended post-service time, while reduced from the survey time, is still high relative to similar services performed on the same day as an E/M service. To better account for this overlap, and to value this service relative to similar services, we reduced the AMA RUC-recommended post-service time for this procedure by one-third, from 5 minutes to 3 minutes.

After reviewing CPT code 67810 and assessing the overlap in time and work, we agree with the AMA RUC-recommended work RVU of 1.18 for this service, which is a decrease from the CY 2012 work RVU of 1.48. In sum, on an interim final basis for CY 2013, we are assigning a work RVU of 1.18 to CPT code 67810, with a refinement to the AMA RUC recommended time. A complete list of the interim final times associated with this procedure is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(20) Eye and Ocular Adnexa: Conjunctiva

TABLE 51—EYE AND OCULAR ADNEXA: CONJUNCTIVA

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
68200	Treat eyelid by injection	0.49	0.49	0.49	Agree	Yes.

CPT code 68200 was identified as potentially misvalued under the Harvard-valued—Utilization over 30,000 screen.

Medicare claims data from 2011 indicate that CPT code 68200 (Subconjunctival injection) is typically furnished to the beneficiary on the same day as an E/M visit. We believe that some of the activities furnished during the pre- and post-service period of the procedure code and the E/M visit overlap. After review, we believe that the AMA RUC appropriately accounted for this overlap in its recommendation of pre-service time, but that the AMA RUC did not adequately account for the overlap in the post-service time. To better account for the overlap in post-service time, we reduced the AMA RUC-recommended post-service time for this procedure by one-third, from 5 minutes to 3 minutes.

After reviewing CPT code 68200 and assessing the overlap in time and work, we agree with the AMA RUC-recommended work RVU of 0.49 for this service. In sum, on an interim final basis for CY 2013, we are assigning a work RVU of 0.49 to CPT code 68200, with a refinement to the AMA RUC recommended time. A complete list of the interim final times associated with this procedure is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(21) Auditory System: External Ear

TABLE 52—AUDITORY SYSTEM: EXTERNAL EAR

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
69200	Clear outer ear canal	0.77	0.77	0.77	Agree	Yes.

CPT code 69200 was identified as potentially misvalued under the Harvard-valued—Utilization over 30,000 screen.

Medicare claims data from 2011 indicate that CPT code 69200 (Removal foreign body from external auditory canal; without general anesthesia) is typically furnished to the beneficiary on the same day as an E/M visit. We believe that some of the activities furnished during the pre- and post-service period of the procedure code and the E/M visit overlap. To account for this overlap, we removed one-third of the pre-service evaluation time from the pre-service time package, reducing the pre-service evaluation time from 7 minutes to 5 minutes. Additionally, we reduced the AMA RUC-recommended post-service time for this procedure by one-third, from 5 minutes to 3 minutes.

After reviewing CPT code 69200 and assessing the overlap in time and work, we agree with the AMA RUC-recommended work RVU of 0.77 for this service. In sum, on an interim final basis for CY 2013, we are assigning a work RVU of 0.77 to CPT code 69200, with a refinement to the AMA RUC recommended time. A complete list of the interim final times associated with this procedure is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(22) Diagnostic Radiology (Diagnostic Imaging)

TABLE 53—DIAGNOSTIC RADIOLOGY (DIAGNOSTIC IMAGING)

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
72040	X-ray exam neck spine 3<vws	0.22	0.22	0.22	Agree	No.
72050	X-ray exam neck spine 4/5vws	0.31	0.31	0.31	Agree	No.
72052	X-ray exam neck spine 6/<vws	0.36	0.36	0.36	Agree	No.
72191	Ct angiograph pelv w/o&w/dye	1.81	N/A	1.81	Interim	N/A.
73221	Mri joint upr extrem w/o dye	1.35	1.35	1.35	Agree	No.
73721	Mri jnt of lwr extre w/o dye	1.35	1.35	1.35	Agree	No.
74170	Ct abdomen w/o & w/dye	1.40	1.40	1.40	Agree	No.
74174	Ct angio abd&pelv w/o&w/dye	2.20	2.20	2.20	Interim	No.
74175	Ct angio abdom w/o & w/dye	1.90	N/A	1.90	Interim	N/A.
74247	Contrst x-ray uppr gi tract	0.69	0.69	0.69	Agree	No.
74280	Contrast x-ray exam of colon	0.99	0.99	0.99	Agree	No.
74400	Contrst x-ray urinary tract	0.49	0.49	0.49	Agree	No.
75896	X-rays transcath therapy	1.31 (PC), Contractor Priced (TC).	Contractor Priced.	1.31 (PC), Contractor Priced (TC).	Interim	N/A.
75898	Follow-up angiography	1.65 (PC), Contractor Priced (TC).	Contractor Priced.	1.65 (PC), Contractor Priced (TC).	Interim	N/A.

CPT codes 74175 and 72191 were identified as potentially misvalued through the Codes Reported Together 75 percent or More screen. The CPT Editorial Panel created CPT code 74174, which bundles the work of CPT codes 74175 and 72191, for CY 2012.

We reviewed CPT code 74174 (Computed tomographic angiography, abdomen and pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing) for CY 2012. We stated in the CY 2012 PFS final rule with comment period that we are accepting the AMA RUC-recommended work RVU of 2.20 for CPT code 74174 on an interim basis, and request that the AMA RUC review the component CPT codes: 74175 (Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing) and 72191 (Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing) (76 FR 73200).

In response to this request, some commenters stated that the AMA RUC operates under the premise that the values assigned to all the service paid under the PFS are assumed to be accurate and therefore, our request to review the physician work component of CPT codes 74175 and 72191 is unnecessary. Commenters noted that CPT codes 74175 and 72191 were used as important building blocks in the work valuation of CPT code 74174, and that the AMA RUC considered their individual values, which in many ways equates to an AMA RUC review. Commenters stated that to review individual codes solely because they are bundled to create a new code, risks rank-order anomalies within families, which could threaten the relativity of the values for services on the PFS. Therefore, commenters stated that they believe an AMA RUC review of CPT codes 74175 and 72191 is unnecessary.

The AMA RUC Relativity Assessment Workgroup referred component CPT codes 74175 and 72191 to the PE Subcommittee of the AMA RUC to review the direct practice expense inputs, but the AMA RUC did not review the physician work or time.

We have stated many times our belief that when codes are bundled, the new codes should be reviewed along with their component codes to ensure consistency in RVUs and inputs. Therefore, we reviewed CPT codes 74174, 72191, and 74175 for CY 2013. During this review, we saw an anomalous relationship between the physician times assigned to these services. CPT code 74174 describes computed tomographic angiography (CTA) of both the abdomen and pelvis together. This CPT code includes 5 minutes of pre-service time, 30 minutes of intra-service time, and 5 minutes of post-service time, which is in line with several other similar bundled CPT codes. CPT code 74175 describes CTA of the abdomen only, and includes 10 minutes of pre-service time, 30 minutes of intra-service time, and 10 minutes of post-service time. Similarly, CPT code 72191 describes CTA of the pelvis only, and includes 9 minutes of pre-service time, 30 minutes of intra-service time, and 10 minutes of post-service time. We

do not believe that CTA of just the abdomen or just the pelvis should include more pre- and post-service time than the combined code. Also, while we believe furnishing the bundled code does not involve much more time than furnishing the stand-alone codes, we find it unlikely that the bundled service requires exactly the same intra-service time as the component services. We request recommendations from the AMA RUC and other pubic commenters on the appropriate work and time values for these services. We are maintaining the current (CY 2012) work RVUs and times for CPT codes 74174, 72191, and 74175 on an interim basis for CY 2013, and anticipate re-reviewing these services for CY 2014 considering any recommendations that we receive.

CPT code 75896 was identified as potentially misvalued through the Codes Reported Together 75 percent or More screen.

The associated specialty societies and the AMA RUC intend to survey and review CPT code 75896 (Transcatheter therapy, infusion, other than for thrombolysis, radiological supervision and interpretation) and related CPT code 75898 (Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis) for CY 2014. The AMA RUC recommended carrier pricing these two services for CY 2014. Currently (CY 2012) both codes have a national payment rate for the professional component of the service, and the technical component of the service is contractor priced. We believe it is appropriate to maintain the current national price on the professional component, and to contractor price the technical component until we are able to establish a national price that appropriately values the practice expenses associated with this service. Therefore, on an interim basis for CY 2013, we are assigning a work RVU of 1.31 to the professional component of CPT code 75896, and a work RVU of 1.65 to the professional component of CPT code 75898. The technical component and global billing for both CPT codes will be contractor priced. We anticipate reviewing these services again after reviewing the AMA RUC recommendations for these services in CY 2014.

(23) Diagnostic Ultrasound: Pelvis

TABLE 54—DIAGNOSTIC ULTRASOUND: PELVIS

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
76830	Transvaginal us non-ob	0.69	0.69	0.69	Agree	Yes.

CPT code 76830 was identified as potentially misvalued through the High Expenditure Procedure Code screen.

We reviewed CPT code 76830 (Ultrasound, transvaginal) and believe that the current work RVU of 0.69 continues to accurately reflect the work of this services. The AMA RUC also recommended maintaining the current work RVU of this service. We are refining the AMA RUC-recommended post-service time for this procedure from 10 minutes to 8 minutes to match the post-service time of CPT code 76817 (Ultrasound, pregnant uterus, real time with image documentation, transvaginal), which, we believe, involves very similar post-service work. In sum, on an interim final basis for CY 2013, we are assigning a work RVU of 0.69 to CPT code 76830, with a refinement to the AMA RUC recommended time. A complete list of the interim final times associated with this procedure is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(24) Radiologic Guidance: Fluoroscopic Guidance

TABLE 55—RADIOLOGIC GUIDANCE: FLUOROSCOPIC GUIDANCE

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/ interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
77001	Fluoroguide for vein device	0.38	N/A	0.38	Interim	N/A.
77002	Needle localization by xray	0.54	N/A	0.54	Interim	N/A.
77003	Fluoroguide for spine inject	0.60	0.60	0.60	Interim	No.

CPT code 77003 was identified as potentially misvalued through the High Expenditure Procedure Code screen.

We reviewed CPT code 77003 (Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)), and believe it is necessary to review this service alongside very similar CPT codes 77001 (Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (list separately in addition to code for primary procedure)) and 77002 (Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)) to determine the appropriate relative value for this high volume, high expenditure procedure code. The AMA RUC reviewed CPT code 77003 for CY 2013 and concluded that the current work RVU of 0.60 is appropriate for this service. It is our understanding that the AMA RUC does not intend to review CPT codes 77001 and 77002. We anticipate reviewing CPT codes 77001, 77002, and 77003 together in CY 2013 for CY 2014 and request public

comments on the appropriate work and time values for these services. On an interim basis for CY 2013, we are maintaining the current work RVU of 0.60 for CPT code 77003.

(25) Radiation Oncology: Medical Radiation Physics, Dosimetry, Treatment Devices, and Special Services

TABLE 56—RADIATION ONCOLOGY: MEDICAL RADIATION PHYSICS, DOSIMETRY, TREATMENT DEVICES, AND SPECIAL SERVICES

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
77301	Radiotherapy dose plan imrt	7.99	7.99	7.99	Agree	Yes.

CPT code 77301 was identified as potentially misvalued through the High Expenditure Procedure Code screen.

We reviewed CPT code 77301 (Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications) and do not believe the work associated with this procedure has changed. The AMA RUC also recommended the current work RVU of 7.99 for this service. On an interim final basis for CY 2013 we are assigning a work RVU of 7.99 to CPT code 77301. Regarding the physician time for this service, CPT code 77301 currently (CY 2012) includes 30 minutes of pre-service time, 131 minutes of intra-service time, and 35 minutes of post-service time. The AMA RUC recommended moving the pre-service time associated with this procedure into the intra-service period. We do not believe this is appropriate, as we think the physician work associated with those 30 minutes is pre-service work and should remain in the pre-service period. Therefore, we are assigning an interim final pre-service evaluation time of 30 minutes, intra-service time of 130 minutes, and post-service time of 35 minutes to CPT code 77301 for CY 2013.

(26) Molecular Pathology

TABLE 57—MOLECULAR PATHOLOGY

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
G0452	Molecular pathology interpr	New	N/A	0.37	N/A	N/A.

The AMA CPT Editorial Panel has created new CPT codes to replace the codes used to bill for molecular pathology services that will be deleted at the end of CY 2012. The new codes describe distinct molecular pathology tests and test methods. The CPT Editorial Panel created 101 new molecular pathology CPT codes for CY 2012 and another 14 new molecular pathology codes for CY 2013. As discussed in detail in section III.I. of this CY 2013 PFS final rule with comment period, these new molecular pathology CPT codes will be paid on the CLFS for CY 2013.

One of the molecular pathology CPT codes that is being deleted for CY 2012 is payable on the PFS: CPT code 83912–26 (Molecular diagnostics; interpretation and report). To replace this CPT code, we have created HCPCS code G0452 (molecular pathology procedure; physician interpretation and report) to describe medically necessary interpretation and written report of a molecular pathology test, above and beyond the report of laboratory results. This professional component-only HCPCS G-code will be considered a ''clinical laboratory interpretation service,'' which is one of the current categories of PFS pathology services under the definition of physician pathology services at § 415.130(b)(4). Section § 415.130(b)(4) of the regulations and section 60 of the Claims Processing Manual (IOM 100–04, Ch. 12, section 60.E.) specify certain requirements for billing the professional component of certain clinical laboratory services including that the interpretation (1) Must be requested by the patient's attending physician, (2) must result in a written narrative report included in the patient's medical record, and (3) requires the exercise of medical judgment by the consultant physician. We note that a hospital's standing order policy can be used as a substitute for the individual request by a patient's attending physician. The current CPT code for interpretation and report, 83912–26, is included on the current list of clinical laboratory interpretation services but will be deleted at the end of CY 2012.

As discussed in section III.I. of this CY 2013 PFS final rule with comment period, we reviewed the work associated with this procedure, and we believe it is appropriate to directly crosswalk the work RVUs and times of CPT code 83912–26 to HCPCS code G0452, because we do not believe this coding change reflects a change in the service or in the resources involved in furnishing the service. Accordingly, we are assigning a work RVU of 0.37, with 5 minutes of pre-service time, 10 minutes of intra-service time, and 5 minutes of post-service time to HCPCS code G0452 on an interim final basis for CY 2013.

(27) Immunology

TABLE 58—IMMUNOLOGY

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
86153	Cell enumeration phys interp	New	0.69	0.69	Agree	Yes.

The CPT Editorial Panel created CPT codes 86152 and 86153 to replace CPT Category III codes 0279T and 0280T.

CPT code 86153 (Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required) will be payable on the PFS for the physician interpretation and report of CPT code 86152 (Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)) which will be payable on the Clinical Laboratory Fee Schedule (CLFS). Like HCPCS code G0452 discussed above, CPT code 86153 is a professional component-only CPT code that will be considered a ''clinical laboratory interpretation service,'' which is one of the current categories of PFS pathology services under the definition of physician pathology services at § 415.130(b)(4). This code must be billed with the ''26'' modifier to be paid under the PFS.

After reviewing CPT code 86153, we believe that the AMA RUC-recommended work RVU of 0.69 appropriately accounts for the work of this service. Accordingly, we are assigning a work RVU of 0.69 to CPT code 86153 on an interim final basis for CY 2013. Regarding physician time, the AMA RUC recommended 20 minutes of intra-service time and 5 minutes of post-service time for CPT code 86153. We believe that all the work of this service belongs in the intra-service period, and that 20 minutes accurately captures the time involved in furnishing this service. Therefore, we are assigning 0 minutes pre-service time, 20 minutes intra-service time, and 0 minutes post-service time to CPT code 86153 on an interim final basis for CY 2013.

(28) Cytopathology and Surgical Pathology

TABLE 59—CYTOPATHOLOGY AND SURGICAL PATHOLOGY

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
88120	Cytp urne 3–5 probes ea spec	1.20	1.20	1.20	Interim	No.
88121	Cytp urine 3–5 probes cmptr	1.00	1.00	1.00	Interim	No.
88312	Special stains group 1	0.54	0.54	0.54	Agree	No.
88365	Insitu hybridization (fish)	1.20	N/A	1.20	Interim	N/A.
88367	Insitu hybridization auto	1.30	N/A	1.30	Interim	N/A.
88368	Insitu hybridization manual	1.40	N/A	1.40	Interim	N/A.
88375	Optical endomicroscpy interp	New	Contractor Priced.	Contractor Priced.	N/A	N/A.
G0416	Sat biopsy 10–20	3.09	N/A	3.09	N/A	N/A.

The CPT Editorial Panel created CPT codes 88120 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; manual) and 88121 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology) to describe in situ hybridization testing using urine samples, effective for CY 2011. Prior to CY 2011, all in situ hybridization testing was billed using CPT codes 88365 (In situ hybridization (eg, FISH), each probe), 88367 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; using computer-assisted technology), and 88368 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual). The appropriate code would be billed one time for each probe used in the performance of the test, regardless of the medium of the specimen (that is, blood, tissue, tumor, bone marrow, or urine). We stated in the CY 2012 PFS proposed rule that because the descriptors for the new CPT codes 88120 and 88121 include the use of approximately 4 probes, and existing CPT codes 88367 and 88368 include only 1 probe, we were concerned about potential payment discrepancies between the new and existing codes (76 FR 42795 through 42796). Unlike the new codes for urinary tract specimens, the existing codes (for all other specimens) allow for multiple units of each code to be billed. We asked the AMA RUC to review the work and PE for existing CPT codes 88365, 88367, and 88368 alongside CPT codes 88120 and 88121 to ensure the appropriate relativity between these two sets of services (76 FR 73153 through 73154).

In response to that request, the College of American Pathologists (CAP) indicated that they would develop a CPT Assistant article clarifying the appropriate usage of each code. The AMA RUC stated that it intends to review these services in CY 2013 for CY 2014, after CY 2012 utilization data are available to assess how these services are being billed. We agree with this approach, and are maintaining the current (CY 2012) work RVUs of 1.20 for CPT code 88120, and 1.00 for CPT code 88121, as interim until we review CPT codes 88120 and 88121 alongside CPT codes 88365, 88367, and 88368 for CY 2014.

We have received information from stakeholders that the current (CY 2012) descriptor for HCPCS code G0416 (Surgical pathology, gross and

microscopic examination for prostate needle saturation biopsy sampling, 1–20 specimens) should be revised to better reflect the interaction of this service, and associated RVUs, with billing for surgical pathology. After reviewing the service, we agree with stakeholders. For CY 2013, we are revising the descriptor for HCPCS code G0416 to the following: Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 10–20 specimens. HCPCS code G0416 will be interim final, and open for public comment for CY 2013.

(29) Psychiatry

TABLE 60—PSYCHIATRY

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
90785	Psytx complex interactive	New	Contractor Priced.	0.11	Interim	N/A.
90791	Psych diagnostic evaluation	New	3.00	2.80	Interim	No.
90792	Psych diag eval w/med srvcs	New	3.25	2.96	Interim	No.
90832	Psytx pt&/family 30 minutes	New	1.50	1.25	Interim	No.
90833	Psytx pt&/fam w/e&m 30 min	New	1.50	0.98	Interim	No.
90834	Psytx pt&/family 45 minutes	New	2.00	1.89	Interim	No.
90836	Psytx pt&/fam w/e&m 45 min	New	1.90	1.60	Interim	No.
90837	Psytx pt&/family 60 minutes	New	3.00	2.83	Interim	No.
90838	Psytx pt&/fam w/e&m 60 min	New	2.50	2.56	Interim	No.
90839	Psytx crisis initial 60 min	New	Contractor Priced.	Contractor Priced.	N/A	N/A.
90840	Psytx crisis ea addl 30 min	New	Contractor Priced.	Contractor Priced.	N/A	N/A.
90845	Psychoanalysis	1.79	2.10	1.79	Interim	Yes.
90846	Family psytx w/o patient	1.83	2.40	1.83	Interim	Yes.
90847	Family psytx w/patient	2.21	2.50	2.21	Interim	Yes.
90853	Group psychotherapy	0.59	0.59	0.59	Interim	Yes.
90863	Pharmacologic mgmt w/psytx	New	Contractor Priced.	Invalid	N/A	N/A.

In preparation for the Fourth Five-Year Review of Work, we received comments indicating that psychiatry/psychotherapy CPT codes 90801 through 90880 may be potentially misvalued. In response to these comments, we requested that the AMA RUC review these services. Ultimately, the AMA RUC concluded that the entire section of psychiatry/psychotherapy services would benefit from re-structuring within CPT. After a year of analysis, the CPT Editorial Panel replaced the current psychiatry/psychotherapy CPT codes with a new structure that allows for the separate reporting of E/M codes, eliminates the site-of-service differential, establishes CPT codes for crisis, and creates a series of add-on CPT codes to psychotherapy to describe interactive complexity and medication management.

We appreciate all the work that has been completed to date by the CPT Editorial Panel, AMA RUC, and involved specialty societies in revising this family of CPT codes. Below we discuss the specific CY 2013 work RVUs for the new psychotherapy family of CPT codes. We note that related specialty societies have not yet surveyed some of the new CPT codes, namely, the new CPT codes for psychotherapy for crisis, interactive complexity, and pharmacologic management. The AMA RUC and HCPAC have recommended contractor pricing for these services until the surveys are complete. After the specialty societies have completed the survey process for all the codes in the new code set, we intend to review the values for all codes in the family again. It is our policy to value a family of codes together to ensure more accurate valuation and proper relativity. We will take into consideration the AMA RUC and HCPAC recommendations, specialty society recommendations, public comments, Medicare utilization data, and other available information. For CY 2013, our general approach was to maintain the current CPT code values, or adopt values that approximate the values for the current CPT codes after adjusting for differences in code structure between CY 2012 and 2013, for all psychiatry services on an interim basis, pending a final review of the values for the entire family of CPT codes.

The first major change in the new coding framework involves changes to the CPT codes for initial psychiatric evaluation. For CY 2013, the CPT Editorial Panel is deleting CPT codes 90801 (Psychiatric diagnostic interview examination) (work RVU = 2.80) and 90802 (Interactive psychiatric diagnostic interview examination using play equipment, physical devices, language interpreter, or other mechanisms of communication) (work RVU = 3.01), and replacing them with new CPT codes 90791 (Psychiatric diagnostic evaluation) and 90792 (Psychiatric diagnostic evaluation with medical service). CPT code 90791 describes psychiatric diagnostic evaluation without medical work. We are assigning an interim work RVU of 2.80, the work RVU of deleted CPT code 90801, to this service for CY 2013. CPT code 90792 describes psychiatric diagnostic evaluation involving medical work. We are assigning an interim work RVU of 2.96 to this service for CY 2013. Currently (CY 2012) the psychotherapy with E/M services are valued on average 0.16 work RVUs higher than the psychotherapy without E/M services. We believe this is the appropriate differential between the diagnostic evaluation with medical services and diagnostic evaluation without medical services CPT codes. Therefore, to assign a work RVU to CPT code 90792, which includes medical services, we added 0.16 work RVUs to the work RVU of CPT code 90791, which does not include medical services.

Regarding coding and payment for these CPT codes, we note that CPT

prefatory language for these new psychiatric diagnosis codes allows for reporting of these codes more than once when an informant is ''seen in lieu of the patient.'' Medicare only pays for services provided to diagnose or treat a Medicare beneficiary. Obtaining information from relatives or close associates is appropriate in some circumstances, but should not substitute entirely for an evaluation of the patient.

We previously have addressed the delivery of mental health services to caregivers in Chapter 1, section 70.1 of the Medicare National Coverage Determinations Manual, Pub. 100–03, which provides guidance specifically for current CPT code 90846 (family psychotherapy without the patient present). It states that, ''In certain types of medical conditions, including when a patient is withdrawn and uncommunicative due to a mental disorder or comatose, the physician may contact relatives and close associates to secure background information to assist in diagnosis and treatment planning. When a physician contacts their patient's relatives or associates for this purpose, expenses of such interviews are properly chargeable as physician's services to the patient on whose behalf the information was secured. A physician may also have contacts with a patient's family and associates for purposes other than securing background information. In some cases, the physician will provide counseling to members of the household. Family counseling services are covered only where the primary purpose of such counseling is the treatment of the patient's condition. For example, two situations where family counseling services would be appropriate are as follows: (1) Where there is a need to observe the patient's interaction with family members; and/or (2) where there is a need to assess the capability of and assist the family members in aiding in the management of the patient. Counseling principally concerned with the effects of the patient's condition on the individual being interviewed would not be reimbursable as part of the physician's personal services to the patient.'' Therefore, we believe that CPT codes 90791 and 90792 may be used for diagnosis through a relative or close associate providing direct care for the patient when the focus of the service is gathering additional information about the beneficiary, and cannot substitute for an evaluation of the beneficiary. We are concerned that multiple diagnostic evaluations with family members should not replace a detailed evaluation of the beneficiary, and we intend to monitor the frequency of billing for diagnostic evaluations per patient.

The second major change in the new coding framework involves psychotherapy procedure codes without medical services, which we typically expect will be billed by clinical psychologists and licensed clinical social workers. For CY 2013, the CPT Editorial Panel created stand-alone psychotherapy CPT codes 90832 (Psychotherapy, 30 minutes with patient and/or family member), 90834 (Psychotherapy, 45 minutes with patient and/or family member), and 90837 (Psychotherapy, 60 minutes with patient and/or family member), that are not site-of-service specific. These services are currently reported using outpatient and interactive outpatient, and inpatient and interactive inpatient psychotherapy CPT codes. To assign interim work RVUs to these services that approximate the current values for these services under the current CPT coding structure, we assigned each new stand-alone psychotherapy CPT code the work RVU of the current corresponding inpatient psychotherapy code. Specifically, we are assigning an interim work RVU of 1.25 to CPT code 90832, which is the current work RVU of CPT code 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;); an interim work RVU of 1.89 to CPT code 90834, which is the current work RVU of CPT code 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;); and an interim work RVU of 2.83 to CPT code 90837, which is the current work RVU of CPT code 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;). For CY 2013, the additional work involved in psychotherapy with higher interactive complexity will be captured using an interactive complexity add-on CPT code, discussed below.

Regarding coding and payment for these psychotherapy CPT codes, we note that the CY 2012 CPT codes describe time spent face-to-face with the patient, while the CY 2013 CPT codes describe time spent with the patient and/or family member. As discussed above in relation to CPT codes 90791 and 90792, Medicare only pays for services provided to diagnose or treat a Medicare beneficiary. Obtaining information from relatives or close associates is appropriate in some circumstances, but should not substitute for direct treatment of the beneficiary. We would expect psychotherapy to be billed only when the beneficiary is present for a significant portion of the service.

The third major change in the new coding framework involves psychotherapy services furnish alongside an E/M service. For CY 2013, the CPT Editorial Panel created CPT codes 90833 (Psychotherapy, 30 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)), 90836 (Psychotherapy, 45 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)) and 90838 (Psychotherapy, 60 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)). These services are currently reported using outpatient and interactive outpatient, and inpatient and interactive inpatient psychotherapy with E/M CPT codes. For CY 2013, physicians and qualified nonphysician practitioners that can bill for E/M services will now bill for psychotherapy with evaluation and management using the existing E/M structure and a choice of one add-on psychotherapy time-based code, 30, 45 or 60 minutes. At this time, we believe that the work involved in furnishing the psychotherapy add-on CPT codes is very similar to the work of furnishing the stand-alone psychotherapy CPT codes (CPT codes 90832, 90834, and 90837). We believe the difference in work between the psychotherapy add-on codes and stand-alone psychotherapy CPT codes is not in the intensity of the services; rather, it is in amount of time involved in furnishing them. The AMA RUC has recommended, and we agree, that the psychotherapy add-on CPT codes include 12 minutes less time than the stand-alone psychotherapy CPT codes. The psychotherapy add-on CPT codes are furnished alongside an E/M service, so some of the activities in the stand-alone psychotherapy CPT codes should not be included in the psychotherapy add-on CPT codes because those activities (reviewing the record, coordinating care, and some documentation and reporting activities)

are included in the E/M service with which the add-on codes will be billed. Accordingly, to assign interim work RVUs to each of the new psychotherapy add-on CPT codes, we started with the interim work RVU of the corresponding new stand-alone psychotherapy CPT code, and then reduced that RVU by 0.27 RVUs, to capture the 12 minutes less time assigned to these services (12 minutes at an intensity of 0.0224 RVUs per minute= 0.27 RVUs). Specifically, we are assigning an interim work RVU of 0.98 to CPT code 90833; an interim work RVU of 1.60 for CPT code 90836; and an interim work RVU of 2.56 for CPT code 90838.

Like the stand-alone psychotherapy services, we note that the CY 2012 CPT codes describe time spent face-to-face with the patient, while the CY 2013 CPT codes describe time spent with the patient and/or family member. As discussed above, Medicare only pays for services provided to diagnose or treat a Medicare beneficiary. Obtaining information from relatives or close associates is appropriate in some circumstances, but should not substitute for direct treatment of the beneficiary. We would expect psychotherapy to be billed only when the beneficiary is present for a significant portion of the service.

Additionally, the CY 2013 coding structure includes a new add-on CPT code for interactive complexity, CPT code 90785 (Interactive complexity (list separately in addition to the code for primary procedure)). The interactive complexity add-on CPT code, when billed with a psychotherapy service, replaces the CY 2012 CPT codes for interactive psychotherapy. As stated above, this service has not yet been surveyed by the related specialty societies, and the AMA RUC recommended contractor pricing this service for CY 2013. However, given that services involving interactive complexity are nationally priced in the CY 2012 coding structure, we believe we have enough information to assign interim work RVUs for CPT code 90785 for CY 2013. In the 2012 coding structure, there are CPT codes for outpatient and inpatient psychotherapy services and corresponding CPT codes for outpatient and inpatient interactive psychotherapy services. For both the outpatient and inpatient services, the interactive service has a work RVU that is 0.11 RVUs higher than the corresponding service that is not interactive. We believe this reflects the current value of interactive services. Therefore, we are assigning an interim work RVU of 0.11 to CPT code 90785 for CY 2013. We are assigning this service 0 minutes of physician time because the work RVU of 0.11 reflects only the incremental difference in intensity of the base procedure; the time of this service is captured in the time of the procedure with which it is billed.

Regarding coding and payment for CPT code 90785, the CPT prefatory language for this service states that psychiatric procedures may be reported with interactive complexity for ''* * * Use of play equipment, other physical devices, interpreter or translator to communicate with the patient to overcome barriers to therapeutic or diagnostic interaction between the physician or other qualified health care professional and a patient who is not fluent in the same language as the physician or other qualified health care professional, or has not developed, or has lost, either the expressive language communication skills to explain his/her symptoms and response to treatment, or the receptive communication skills to understand the physician or other qualified health care professional if he/she were to use typical language for communication.'' Given this language, we would like to clarify that CPT code 90785 generally should not be billed solely for the purpose of translation or interpretation services. Federal laws prohibit discrimination, which in this case would take the form of higher beneficiary payments and copayments for the same service, based on disability or ethnicity. Billing for this service solely for translation or interpretation related to a beneficiary's disability could implicate section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, and billing for this service solely for translation or interpretation related to foreign language could implicate Title VI of the Civil Rights Act of 1964.

The CPT Editorial Panel has created two new CPT codes for psychotherapy when a patient is in crisis, CPT codes 90839 (Psychotherapy for crisis; first 60 minutes) and 90840 (Psychotherapy for crisis; each additional 30 minutes (list separately in addition to code for primary service)). As these CPT codes have not yet been surveyed, the AMA RUC has recommended contractor pricing for CPT codes 90839 and 90840 for CY 2013. We agree and are assigning CPT codes 90839 and 90840 a PFS procedure status of C (Contractors price the code. Contractors establish RVUs and payment amounts for these services on an interim basis for CY 2013.

Additionally, for CY 2013, the CPT Editorial Panel has deleted CPT code 90862 (Pharmacologic management, including prescription, use, and review of medication with no more than minimal medical psychotherapy). For CY 2013, psychiatrists will now bill the appropriate E/M code when furnishing pharmacologic management services. The CPT Editorial Panel also created CPT add-on code 90863 (Pharmacologic management, including prescription and review of medication, when performed with psychotherapy services (list separately in addition to the code for primary procedure) to describe medication management by a nonphysician when furnished with psychotherapy. We understand from our past meetings with stakeholders that the ability to prescribe medicine is predicated upon first providing evaluation and management (E/M) services. We have discussed in previous rulemaking that Medicare does not recognize clinical psychologists to bill E/M services because they are not authorized to furnish those services under their state scope of practice (62 FR 59057). While clinical psychologists have been granted prescribing privileges in Louisiana and New Mexico, they are not licensed or authorized under their State scope of practice to furnish the full range of traditional E/M services. CPT code 90862 describes pharmacologic management, including prescription, use, and review of medication with no more than minimal medical psychotherapy. This descriptor reference to ''medical psychotherapy'' implies that the service furnished under CPT code 90862 is an E/M service, and therefore, clinical psychologists cannot bill Medicare for CPT code 90862. We also believe that clinical psychologists would continue to be precluded from billing Medicare for pharmacologic management services under new CPT code 90863, even in the absence of the reference to ''medical psychotherapy'' because pharmacologic management services require some knowledge and ability to perform evaluation and management services. Even though clinical psychologists in Louisiana and New Mexico have been granted prescribing privileges, clinical psychologists in those and other states are not licensed or authorized to furnish E/M services. Accordingly, on an interim basis for CY 2013, we are assigning CPT code 90863 a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services.). We invite public comment on our interim assignment of this procedure status.

Finally, under the new coding structure, existing psychotherapy CPT codes 90845 (Psychoanalysis), 90846 (Family psychotherapy (without the

patient present)), 90847 (Family psychotherapy (conjoint psychotherapy) (with patient present)), and 90853 (Group psychotherapy (other than of a multiple-family group)) remain essentially unchanged for CY 2013. We are maintaining the current (CY 2012) work RVUs and times for these services on an interim basis for CY 2013. Specifically, we are assigning an interim work RVU of 1.79 for CPT code 90845; an interim work RVU of 1.83 for CPT code 90846; and interim work RVU of 2.21 for CPT code 90847; and an interim work RVU of 0.59 for CPT code 90853.

The AMA RUC and HCPAC-recommended RVUs are listed in the table at the start of this section. Regarding physician time, we accepted the AMA RUC-recommended times for all the new CPT codes in this family. We are maintaining the current work RVUs and times for existing CPT codes 90845, 90846, 90847, and 90853 on an interim basis until we are able to review all the recommended values for this family of CPT codes. Regarding the utilization crosswalk, we made some refinements to the AMA RUC-recommended utilization crosswalks for the new psychotherapy CPT codes, based on our understanding of how these services will be billed for CY 2013. We will re-review these assumptions when we review all recommended values for this family of CPT codes. The CY 2013 physician time file and utilization crosswalk are available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(30) Cardiovascular: Therapeutic Services and Procedures

TABLE 61—CARDIOVASCULAR: THERAPEUTIC SERVICES AND PROCEDURES

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
92920	Prq cardiac angioplast 1 art	New	9.00	10.10	Disagree	Yes.
92921	Prq cardiac angio addl art	New	4.00	Bundled	N/A	N/A.
92924	Prq card angio/athrect 1 art	New	11.00	11.99	Disagree	Yes.
92925	Prq card angio/athrect addl	New	5.00	Bundled	N/A	N/A.
92928	Prq card stent w/angio 1 vsl	New	10.49	11.21	Disagree	Yes.
92929	Prq card stent w/angio addl	New	4.44	Bundled	N/A	N/A.
92933	Prq card stent/ath/angio	New	12.32	12.54	Disagree	Yes.
92934	Prq card stent/ath/angio	New	5.50	Bundled	N/A	N/A.
92937	Prq revasc byp graft 1 vsl	New	10.49	11.20	Disagree	Yes.
92938	Prq revasc byp graft addl	New	6.00	Bundled	N/A	N/A.
92941	Prq card revasc mi 1 vsl	New	12.32	12.56	Disagree	No.
92943	Prq card revasc chronic 1vsl	New	12.32	12.56	Disagree	Yes.
92944	Prq card revasc chronic addl	New	6.00	Bundled	N/A	N/A.

CPT code 92980 (Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel) was identified for review because it is on the MPC list. After reviewing CPT code 92980, the related specialty societies believed that the family of percutaneous coronary intervention (PCI) codes should be revised to better reflect current practice, and referred the family of codes to the CPT Editorial Panel for review.

The CPT Editorial Panel approved 13 new PCI CPT codes for CY 2013 to replace the 6 existing codes. In the current (CY 2012) coding structure, CPT code 92980 describes the placement of a coronary stent in a single vessel, and add-on CPT code 92981 describes placement of a stent in each additional vessel. As currently described, a single vessel includes one artery and all its branches. Under this coding convention, if a physician placed a stent in one artery and one branch to that artery, the physician would bill only CPT code 92980. If that physician placed a stent in one artery and one branch of that artery, then went on to place a stent in a second artery and one branch of that artery, the physician would bill CPT code 92980 along with add-on CPT code 92981.

The CY 2013 coding structure creates more codes and more granular coding. For CY 2013, the placement of a stent in an artery is billed using a base code, and the placement of a stent in a branch of that artery is billed using an add-on code. Stenting each new artery is billed using a new base code and stenting each branch is billed using an add-on to that base code. If a physician placed a stent in one artery and one branch of that artery, and then went on to place a stent in a second artery and one branch of that second artery, the physician would bill two base code/add-on pairs.

The CPT Panel made similar changes to the current codes for angioplasty and atherectomy and added new codes for atherectomy with stenting, any revascularization of a coronary artery bypass graft, and any revascularization procedure through a chronic total occlusion of any coronary artery or graft. The CPT Panel created a separate base code for each procedure for each new artery and an add-on code for each branch within that artery. Finally, the CPT Panel created a new code for any revascularization procedure for an acute coronary artery occlusion during an acute myocardial infarction. This final code does not have an add-on code.

We believe that this revised coding structure represents a CPT trend toward identifying greater granularity in codes describing the most intense and difficult work. As we discuss in section III.B.1. of this final rule with comment period, the agency has an interest in pursuing additional bundling in the PFS payment structure. Bundling is one method for structuring payment that can improve payment accuracy and efficiency. We believe that unbundling the placement of branch-level stents in a fee-for-service system may encourage increased placement of stents. To eliminate that incentive, on an interim final basis for CY 2013, we are rebundling the work associated with the placement of a stent in an arterial branch into the base code for the placement of a stent in an artery.

Specifically, we are bundling the work of CPT code 92921 (Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)) into CPT code 92920 (Percutaneous transluminal coronary angioplasty; single major coronary artery or branch); we are bundling the work of CPT code 92925

(Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)) into CPT code 92924 (Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch); we are bundling with work of CPT code 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)) into CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch); we are bundling the work of 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)) into CPT code 92933 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch); we are bundling the work of 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)) into 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); and we are bundling the work of 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)) into 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).

To bundle the work of each new add-on code into its respective base code, we used the AMA RUC-recommended utilization crosswalk to determine what percentage of the base code utilization would be billed with the add-on code, and added that percentage of the add-on code AMA RUC-recommended work RVU to the base code AMA RUC-recommended work RVU. For example, the AMA RUC estimated that CPT code 92920 would have 26,848 Medicare allowed services in CY 2013, and that corresponding add-on CPT code 92921 would have 7,368 Medicare allowed services in CY 2013. Therefore, the AMA RUC estimates that CPT code 92920 will be billed without add-on CPT code 92921 for 73 percent of the Medicare allowed services, and that CPT code 92920 will be billed with add-on CPT code 92921 for 27 percent of the allowed services (7,368/26,848). To account for the additional work involved in 27 percent of the allowed services, we added a work RVU of 1.10 (27.44 percent of a work RVU of 4.00 for CPT code 92921) to the work RVU of 9.00 for CPT code 92920, to get to a work RVU of 10.10 for the combined service. We followed this methodology to establish the combined work RVUs for all the new base code/add-on code pairs. Based this methodology, we are assigning the following interim final work RVUs for CY 2013: a work RVU of 10.10 to CPT code 92920; a work RVU of 11.99 to CPT code 92924; a work RVU of 11.21 to CPT code 92928; a work RVU of 12.54 to CPT code 92933; a work RVU of 11.20 to CPT code 92937; and a work RVU of 12.56 to CPT code 92943. On an interim final basis for CY 2013, add-on CPT codes 92921, 92925, 92929, 92934, 92938, and 92944 will have a PFS procedure status indicator of B (Bundled code. Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled) and will not be separately payable.

We did not use this methodology directly to establish a work RVU for 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), which does not have a specific corresponding add-on code. After reviewing this service alongside the other services in this family, like the AMA RUC, we believe CPT code 92941 should have the same work RVU as CPT code 92943 to preserve the appropriate rank order of the services in this family. As we stated above, we are assigning a work RVU of 12.56 to CPT code 92943. Therefore, on an interim final basis for CY 2013 we are assigning a work RVU of 12.56 to CPT code 92941, with the AMA RUC-recommended intra-service time of 70 minutes.

The AMA RUC recommended RVUs for these services are listed in the table above. The CY 2013 physician time file and utilization crosswalk are available on the CMS Web site at *www.cms.gov/physicianfeesched/.*

(31) Cardiovascular: Intracardiac Electrophysiological Procedures/Studies

TABLE 62—CARDIOVASCULAR: INTRACARDIAC ELECTROPHYSIOLOGICAL PROCEDURES/STUDIES

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
93653	Ep & ablate supravent arrhyt	New	15.00	15.00	Agree	No.
93654	Ep & ablate ventric tachy	New	20.00	20.00	Agree	No.
93655	Ablate arrhythmia add on	New	9.00	7.50	Disagree	No.
93656	Tx atrial fib pulm vein isol	New	20.02	20.02	Agree	No.
93657	Tx l/r atrial fib addl	New	10.00	7.50	Disagree	No.

CPT codes 93651 and 93652 were identified as potentially misvalued through the Codes Reported Together 75 percent or More screen. The CPT Editorial Panel deleted CPT codes 93651 and 93652, and replaced them with new CPT codes 93653 through 93657 for CY 2013.

We reviewed new CPT codes 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), 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), and 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). We believe that the survey 25th percentile work RVUs of 15.00 for CPT code 93653, 20.00 for CPT code 93654, and 20.02 for CPT code 93656 accurately account for the work involved in furnishing these services. The AMA RUC recommended these values as well, with 180 minutes of intra-service time for CPT code 93653, and 240 minutes of intra-service time for CPT codes 93654 and 93656. We agree with these values. Accordingly, we are assigning a work RVU of 15.00 for CPT code 93653, a work RVU of 20.00 for 93654, and a work RVU of 20.02 for CPT code 93656, with no refinements to the AMA RUC-recommended time, on an interim final basis for CY 2013.

After reviewing CPT codes 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)) and 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)), we believe these CPT codes have a very similar level of intensity as their related base codes: CPT codes 93653, 93654, and 93656. CPT codes 93653, 93654, and 93656 are all valued at 5.00 RVUs per 1 hour of intra-service time. We believe this is the appropriate increment for CPT codes 93655 and 93657 as well, which include 90 minutes of intra-service time. Therefore, we believe that a work RVU of 7.50 accurately accounts for the work of these services and reflects the appropriate relativity within this family of CPT codes. The AMA RUC recommended a work RVU of 9.00 for CPT code 93655 and a work RVU of 10.00 for CPT code 93657. We are assigning a work RVU of 7.50 to CPT codes 93655 and 93657 with no refinements to the AMA RUC-recommended time, on an interim final basis for CY 2013.

(32) Noninvasive Vascular Diagnostic Studies: Extremity Arterial Studies (Including Digits)

TABLE 63—NONINVASIVE VASCULAR DIAGNOSTIC STUDIES: EXTREMITY ARTERIAL STUDIES

[Including digits]

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
93925	Lower extremity study	0.58	0.90	0.80	Disagree	Yes.
93926	Lower extremity study	0.39	0.70	0.50	Disagree	Yes.
93970	Extremity study	0.68	0.70	0.70	Agree	No.
93971	Extremity study	0.45	0.45	0.45	Agree	No.

CPT codes 93925 and 93926 were identified by the AMA RUC as potentially misvalued because the time and PE inputs for these services had never been reviewed by the AMA RUC and these services have utilization of 500,00 service per year.

After reviewing CPT codes 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study) and 93926 (Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study), we believe that the specialty society survey 25th percentile work RVUs of 0.80 for CPT code 93925, and 0.50 for CPT code 93926 accurately account for the work involved in furnishing these services and appropriately captures the increase in work since these services were last valued. We believe that the AMA RUC-recommended the survey median work RVUs of 0.90 for CPT code 93925 and 0.70 for 93926 overstate the increase in value for these services and that those values are too high relative to similar services. Regarding physician time, we have refined the AMA RUC-recommended pre-service and post-service times from 5 minutes to 3 minutes to align with similar CPT codes 93922 (Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries, (e.g., for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, doppler waveform recording and analysis at 1–2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1–2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with, transcutaneous oxygen tension measurement at 1–2 levels)) and 93923

(Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels (e.g., for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional doppler waveform recording and analysis, at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension measurements at 3 or more levels), or single level study with provocative functional maneuvers (e.g., measurements with postural provocative tests, or measurements with reactive hyperemia). In sum, we are assigning a work RVU of 0.80 to CPT code 93925 and a work RVU of 0.50 to CPT code 93926, with refinements to the AMA RUC-recommended times, on an interim final basis for CY 2013. A complete list of the interim final times assigned to these procedures is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(33) Neurology and Neuromuscular Procedures: Sleep Medicine Testing

TABLE 64—NEUROLOGY AND NEUROMUSCULAR PROCEDURES: SLEEP MEDICINE TESTING

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
95782	Polysom <6 yrs 4/> paramtrs	New	3.00	2.60	Disagree	No.
95783	Polysom <6 yrs cpap/bilvl	New	3.20	2.83	Disagree	No.

The CPT Editorial Panel created CPT codes 95782 and 95783 for CY 2013 to describe the physician work involved in pediatric polysomnography for children 5 years of age or younger.

We reviewed CPT codes 95782 and 95783 and determined that the specialty society survey 25th percentile work RVUs of 2.60 for CPT code 95782 (Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist) and 2.83 for CPT code 95783 (Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist) appropriately reflect the work involved in furnishing these services. CPT codes 95782 and 95783 were previously reported under CPT codes 95810 (Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist) and 95811 (Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist). These CPT codes (95810 and 95811) have revised descriptors for CY 2013 indicating age 6 years and older. CPT code 95810 has a CY 2012 work RVU of 2.50, and CPT code 95811 has a CY 2012 work RVU of 2.60. We believe the increase from these current work RVUs to the CY 2013 work RVUs of 2.60 for CPT code 95782 and 2.83 for CPT code 95783 reflect the incremental difference in work between the existing services for ages 6 years and older and new services for younger than 6 years. The AMA RUC recommended the specialty society survey median work RVUs of 3.00 for CPT code 95782 and 3.20 for CPT code 95783. We are assigning a work RVU of 2.60 to CPT code 95782 and a work RVU of 2.83 to CPT code 95783 on an interim final basis for CY 2013.

(34) Neurology and Neuromuscular Procedures: Electromyography and Nerve Conduction Tests

TABLE 65—NEUROLOGY AND NEUROMUSCULAR PROCEDURES: ELECTROMYOGRAPHY AND NERVE

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
95860	Muscle test one limb	0.96	0.96	0.96	Agree	No.
95861	Muscle test 2 limbs	1.54	1.54	1.54	Agree	No.
95863	Muscle test 3 limbs	1.87	1.87	1.87	Agree	No.
95864	Muscle test 4 limbs	1.99	1.99	1.99	Agree	No.
95865	Muscle test larynx	1.57	1.57	1.57	Agree	No.
95866	Muscle test hemidiaphragm	1.25	1.25	1.25	Agree	No.
95867	Muscle test cran nerv unilat	0.79	0.79	0.79	Agree	No.
95868	Muscle test cran nerve bilat	1.18	1.18	1.18	Agree	No.
95869	Muscle test thor paraspinal	0.37	0.37	0.37	Agree	No.
95870	Muscle test nonparaspinal	0.37	0.37	0.37	Agree	No.
95885	Musc tst done w/nerv tst lim	0.35	0.35	0.35	Agree	No.
95886	Musc test done w/n test comp	0.92	0.92	0.70	Disagree	No.
95887	Musc tst done w/n tst nonext	0.73	0.73	0.47	Disagree	No.
95905	Motor &/sens nrve cndj test	0.05	0.05	0.05	Agree	No.
95907	Motor&/sens 1–2 nrv cndj tst	New	1.00	1.00	Agree	No.
95908	Motor&/sens 3–4 nrv cndj tst	New	1.37	1.25	Disagree	Yes.
95909	Motor&/sens 5–6 nrv cndj tst	New	1.77	1.50	Disagree	Yes.
95910	Motor&sens 7–8 nrv cndj test	New	2.80	2.00	Disagree	No.
95911	Motor&sen 9–10 nrv cndj test	New	3.34	2.50	Disagree	No.
95912	Motor&sen 11–12 nrv cnd test	New	4.00	3.00	Disagree	No.

TABLE 65—NEUROLOGY AND NEUROMUSCULAR PROCEDURES: ELECTROMYOGRAPHY AND NERVE—Continued

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
95913	Motor&sens 13/> nrv cnd test	New	4.20	3.56	Disagree	No.

CPT codes 95860, 95861, 95863, and 95864 were identified as potentially misvalued through the Codes Reported Together 75 percent or More screen. The related specialty societies submitted a code change proposal to the CPT Editorial Panel to bundle the services commonly reported together. In response, for CY 2012, the CPT Panel created three add-on codes (CPT codes 95885 through 95887), and for CY 2013, the Panel created seven new codes (CPT codes 95907 through 95913) that bundle the work of multiple nerve conduction studies into each individual code.

We first reviewed CPT codes 95885 (Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; limited (list separately in addition to code for primary procedure)), 95886 (Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; complete, five or more muscles studied, innervated by three or more nerves or four or more spinal levels (list separately in addition to code for primary procedure)), and 95887 (Needle electromyography, non-extremity (cranial nerve supplied or axial) muscle(s) done with nerve conduction, amplitude and latency/velocity study (list separately in addition to code for primary procedure)) for the CY 2012 PFS final rule with comment period. We stated that we were accepting the AMA RUC-recommended work RVUs and times on an interim basis, pending review of the other electromyography services (76 FR 73207). For CY 2013 we were able to review these services alongside the related electromyography services and nerve conduction tests. After reviewing these services, we agree with the AMA RUC-recommended times and RVUs for needle electromyography CPT codes 95860 through 95870 (all listed in the table above). We also agree with the AMA RUC-recommendations for the CY 2012 needle electromyography add-on CPT code 95885, however we do not agree with the AMA RUC recommendations for the other two CY 2012 needle electromyography add-on CPT codes 95886 and 95887.

After review, we determined that the AMA RUC-recommended work RVU of 0.35 for CPT code 95885 was appropriate and was well-aligned with CPT code 95870 (Needle electromyography; limited study of muscles in 1 extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters), to which we are assigning a work RVU of 0.37; the services involve similar work and both include 15 minutes of intra-service time. We believe that CPT codes 95886 and 95887 involve the same level of work intensity as CPT code 95885. To determine the appropriate RVU for CPT codes 95886 and 95887 relative to 95885, we increased the work RVU in proportion to the increase in time for the services. Under this methodology, because we are assigning a work RVU of 0.35 and 15 minutes of intra-service time to CPT code 95885, we believe it is appropriate to assign a work RVU of 0.70 to CPT code 95886, which has an intra-service time of 30 minutes; and a work RVU of 0.47 to CPT code 95887, which has an intra-service time of 20 minutes. The AMA RUC recommended a work RVU of 0.92 for CPT code 95886 and a work RVU of 0.73 for CPT code 95887. We are assigning a work RVU of 0.70 to CPT code 95886 and a work RVU of 0.47 to CPT code 95887 on an interim final basis for CY 2013.

We reviewed new CPT codes 95907 (Nerve conduction studies; 1–2 studies), 95908 (Nerve conduction studies; 3–4 studies), 95909 (Nerve conduction studies; 5–6 studies), 95910 (Nerve conduction studies; 7–8 studies), 95911 (Nerve conduction studies; 9–10 studies), 95912 (Nerve conduction studies; 11–12 studies), and 95913 (Nerve conduction studies; 13 or more studies) and found that the progression of the survey 25th percentile work RVUs and survey median times appropriately reflect the relativity of these services. The two CPT codes in the nerve conduction studies series that describe the fewest nerve conduction studies, 95907 and 95908, are the exception to this trend, as the survey 25th percentile work RVUs are too low relative to other fee schedule services. For CPT code 95907, the survey 25th percentile work RVU is 0.48, but we believe that the survey median and AMA RUC recommended work RVU of 1.00 is more appropriate for this service. For CPT code 95908, the survey 25th percentile work RVU is 1.00, however CPT code 95908 should be valued between CPT code 95907 and 95909, which has a survey 25th percentile work RVU of 1.50. We believe a work RVU of 1.25, half-way between the work RVU of CPT codes 95907 and 95909, accurately reflects the work of this service relative to other services in this series. The AMA RUC recommended the survey median values for most of the services in the series, and used a crosswalk methodology to develop a work RVU recommendation for CPT codes 95908 and 95909. In sum, on an interim final basis for CY 2013, we are assigning a work RVU of 1.00 to CPT code 95907; a work RVU of 1.25 to CPT code 95908; a work RVU of 1.50 to CPT codes 95909; a work RVU of 2.00 to CPT codes 95910; a work RVU of 2.50 to CPT code 95911; a work RVU of 3.00 to CPT code 95912; and a work RVU of 3.56 to CPT code 95913. We are refining the AMA RUC-recommended intra-service time for CPT code 95908 from 25 minutes to the survey median time of 22 minutes, and for CPT code 95909 from 35 minutes to the survey median time of 30 minutes, so that all the CPT codes in this series are valued using the survey median intra-service time. A complete list of the interim final times assigned to these procedures is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

(35) Neurology and Neuromuscular Procedures: Evoked Potentials and Reflex Tests

TABLE 66—NEUROLOGY AND NEUROMUSCULAR PROCEDURES: EVOKED POTENTIALS AND REFLEX TESTS

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
95925	Somatosensory testing	0.54	N/A	0.54	Interim	N/A.
95926	Somatosensory testing	0.54	N/A	0.54	Interim	N/A.
95928	C motor evoked uppr limbs	1.50	N/A	1.50	Interim	N/A.
95929	C motor evoked lwr limbs	1.50	N/A	1.50	Interim	N/A.
95938	Somatosensory testing	0.86	0.86	0.86	Interim	No.
95939	C motor evoked upr&lwr limbs	2.25	2.25	2.25	Interim	No.

CPT code pairs 95925 with 95926, and 95928 with 95929, were identified as potentially misvalued through the Codes Reported Together 75 percent or More screen. For CY 2012, the CPT Editorial Panel created CPT code 95938 to capture the reporting of CPT codes 95925 and 95926 together, and CPT codes 95939 to capture the reporting of CPT codes 95928 with 95929. The related specialty societies surveyed CPT codes 95938 and 95939 and the AMA RUC sent us recommendations on those services for the CY 2012 PFS final rule with comment period.

We reviewed CPT codes 95938 (Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs) and 95939 (Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs) for the CY 2012 PFS final rule with comment period. In that rule, we stated that we were accepting the AMA RUC-recommended values on an interim basis, and requested that the AMA RUC review the component CPT codes 95925 (Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs), 95926 (Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs), 95928 (Central motor evoked potential study (transcranial motor stimulation); upper limbs), and 95929 (Central motor evoked potential study (transcranial motor stimulation); lower limbs) (76 FR 73207 through 73208).

In response to this request, the AMA RUC Relativity Assessment Workgroup referred component CPT codes 95925, 95926, 95928, and 95929 to the PE Subcommittee of the AMA RUC to review the direct practice expense inputs, but the AMA RUC decided not to review the physician work or time.

When reviewing the physician work and time for the two new bundled CPT codes and their component codes, we saw unlikely relationships between the physician times assigned to these services, especially CPT codes 95928, 95929, and 95939. Given these time anomalies, we are also concerned the current (CY 2012) work RVUs do not reflect the appropriate relativity of the services. CPT code 95939 describes an evoked potential study in both the upper and lower limbs together, and is assigned 30 minutes of intra-service time. CPT code 95928 describes an evoked potential study in the upper limbs only, and is assigned 60 minutes of intra-service time. CPT code 95929 describes an evoked potential study in the lower limbs, and is assigned 55 minutes of intra-service time. We do not believe that an evoked potential study on the upper or lower limbs alone takes twice as long as an evoked potential study on both the upper and lower limbs.

Additionally, CPT code 95938 describes an evoked potential study in both the upper and lower limbs together, and is assigned 30 minutes of intra-service time. CPT code 95925 describes an evoked potential study in the upper limbs only and is assigned 15 minutes of intra-service time. CPT code 95926 describes an evoked potential study in the lower limbs and is assigned 15 minutes of intra-service time. We note that the intra-service times of CPT codes 95925 and 95926 are significantly different from the intra-service times of CPT codes 95928 and 95929 for very similar procedures, but somehow the new bundled procedure codes for both have 30 minutes of intra-service time. We conclude that there are valuation and time inaccuracies, both across the evoked potential study codes and relative to the new bundled codes. For example, for CPT codes 95925 and 95926, we do not believe that the correct intra-service time for CPT code 95938 can be the sum of the intra-service times of CPT codes 95925 and 95926, as we are confident that there efficiencies to be recognized when performing these services together.

Given these anomalous relationships, we request public comments on the appropriate work and time values for these services. We are maintaining the current (CY 2012) work RVUs and times for CPT codes 95925, 95926, 95928, 95929, 95938, and 95939 on an interim basis for CY 2013, and anticipate re-reviewing these services for CY 2014.

(36) Neurology and Neuromuscular Procedures: Intraoperative Neurophysiology

TABLE 67—NEUROLOGY AND NEUROMUSCULAR PROCEDURES: INTRAOPERATIVE NEUROPHYSIOLOGY

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
95940	Ionm in operatng room 15 min	New	0.60	0.60	Agree	No.
95941	Ionm remote/>1 pt or per hr	New	2.00	Invalid	N/A	N/A.
G0453	Cont intraop neuro monitor	New	N/A	0.50	N/A	N/A.

Effective January 1, 2013, the CPT Editorial Panel is deleting CPT code 95920 (Intraoperative neurophysiology testing, per hour (List separately in addition to code for primary procedure)), and is replacing it with CPT codes 95940 (Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes) and CPT code 95941 (Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour). Currently remote monitoring is billed under the PFS using CPT code 95920, though the code does not specify whether the physician is present in the same room with a patient or monitoring from a remote location, nor does the code descriptor indicate whether the code may be billed for the monitoring of one patient or more than one simultaneously. Some carriers have established local coverage determinations (LCDs) to address these issues and more tightly define the circumstances under which CPT code 95920 may be billed.

The CPT prefatory language for CPT code 95941 states: ''* * * One or more simultaneous cases may be reported * * * Report 95941 for all remote or non-one on one monitoring time connected to each case regardless of overlap with other cases.'' Given this language, we are concerned that CPT code 95941 allows a practitioner to bill individual beneficiaries for monitoring more than one beneficiary for the same work during the same time interval. To resolve this concern, we have created HCPCS code G0453 (Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure)), effective January 1, 2013. HCPCS code G0453 may be billed only for undivided attention by the monitoring physician to a single beneficiary, not for simultaneous attention by the monitoring physician to more than one patient. HCPCS code G0453 may be billed in multiple units to account for the cumulative time spent monitoring, that is, 15 minutes of continuous attendance followed by another 15 minutes later in the procedure would constitute one half hour of monitoring, and CPT code G0453 would be billed with a unit of 2. HCPCS code G0453 will replace CPT code 95941, which will have a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services) for CY 2013. CPT code 95940, which describes continuous intraoperative neurophysiology monitoring in the operating room for one patient at a time, will be payable on the PFS for CY 2013, with a PFS procedure status indicator of A (Active).

After reviewing CPT code 95940, we agree with the AMA RUC that a work RVU of 0.60 accurately accounts for the work involved in furnishing this procedure. We are assigning a work RVU of 0.60 to CPT code 95940 on an interim final basis for CY 2013. Also, we agree with the AMA RUC that a work RVU of 2.00 accurately accounts for the work for involved in furnishing 60 minutes of continuous intraoperative neurophysiology monitoring from outside the operating room. Accordingly, we are assigning a work RVU of 0.50 to HCPCS code G0453, which describes 15 minutes of monitoring from outside the operating room, on an interim final basis for CY 2013.

(37) Physical Medicine and Rehabilitation: Active Wound Care Management

TABLE 68—PHYSICAL MEDICINE AND REHABILITATION: ACTIVE WOUND CARE MANAGEMENT

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
G0456	Neg pre wound <=50 sq cm	New	N/A	Contractor Priced.	N/A	N/A.
G0457	Neg pres wound >50 sq cm	New	N/A	Contractor Priced.	N/A	N/A.

For CY 2013, we are creating two HCPCS codes in order to provide a payment mechanism for negative pressure wound therapy services furnished to beneficiaries through means unrelated to the durable medical equipment benefit: G0456 (Negative pressure wound therapy. (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters) and G0457 (Negative pressure wound therapy. (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 sq cm). The two new codes will be contractor priced on an interim basis for CY 2013. We request comments on the appropriate value for this service.

(38) Inpatient Neonatal Intensive Care Services and Pediatric and Neonatal Critical Care Services: Pediatric Critical Care Patient Transport

TABLE 69—INPATIENT NEONATAL INTENSIVE CARE SERVICES AND PEDIATRIC AND NEONATAL CRITICAL CARE SERVICES: PEDIATRIC CRITICAL CARE PATIENT TRANSPORT

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
99485	Suprv interfacilty transport	New	1.50	Bundled	N/A	N/A.
99486	Suprv interfac trnsport addl	New	1.30	Bundled	N/A	N/A.

The CPT editorial panel created CPT codes 99485 and 99486 for CY 2013, to describe the non-face-to-face services provided by physician to supervise interfacility care of critically ill or critically injured pediatric patients.

We reviewed CPT codes 99485 (Supervision by a control physician of interfacility transport care of the critically ill or critically injured pediatric patient, 24 months of age or younger, includes two-way communication with transport team before transport, at the referring facility and during the transport, including data interpretation and report; first 30 minutes) and 99486 (Supervision by a control physician of interfacility transport care of the critically ill or critically injured pediatric patient, 24 months of age or younger, includes two-way communication with transport team before transport, at the referring facility and during the transport, including data interpretation and report; each additional 30 minutes (list separately in addition to code for primary procedure)), and we believe these services are bundled into other services and are not separately payable. We believe these services are similar to CPT codes 99288 (Physician or other qualified health care professional direction of emergency medical systems (ems) emergency care, advanced life support), which is also bundled on the PFS. The AMA RUC recommended a work RVU of 1.50 for CPT code 99485 and a work RVU of 1.30 for CPT code 99486. On an interim final basis for CY 2013, we are assigning CPT codes 99485 and 99486 a PFS procedure status indicator of B (Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled.

(39) Complex Chronic Care Coordination Services

TABLE 70—COMPLEX CHRONIC CARE COORDINATION SERVICES

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
99487	Cmplx chron care w/o pt vsit	New	1.00	Bundled	N/A	N/A.
99488	Cmplx chron care w/pt vsit	New	2.50	Bundled	N/A	N/A.
99489	Complx chron care addl30 min	New	0.50	Bundled	N/A	N/A.

The CPT Editorial Panel created CPT codes 99487, 99488, and 99489 for CY 2013 to describe complex chronic care coordination services that are patient-centered management and support services.

In section II.H. of this CY 2013 PFS final rule with comment period, we discuss our broader HHS and CMS multi-year strategy to recognize and support primary care and care management under the PFS and commitment to exploring payment approaches and developing proposals to promote primary care within a fee-for-service payment structure. We intend to consider CPT codes 99487 (Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with no face-to-face visit, per calendar month), 99488 (Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with one face-to-face visit, per calendar month), and 99489 (Complex chronic care coordination services; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (list separately in addition to code for primary procedure)) as part of that larger discussion. At this time, we believe these services are bundled into the services to which they are incident and are not separately payable. The AMA RUC recommended a work RVU of 1.00 for CPT code 99487, a work RVU of 2.50 for CPT code 99488, and a work RVU of 0.50 for CPT code 99489. On an interim final basis for CY 2013, we are assigning CPT codes 99487, 99488, and 99489 a PFS procedure status indicator of B (Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled).

(40) Transitional Care Management Services

TABLE 71—TRANSITIONAL CARE MANAGEMENT SERVICES

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
99495	Trans care mgmt 14 day disch	New	2.11	2.11	Agree	No.
99496	Trans care mgmt 7 day disch	New	3.05	3.05	Agree	Yes.

The CPT Editorial Panel created CPT codes 99495 and 99496 for CY 2013 to describe transitional care provided to patients from an inpatient setting to a home setting over a 30-day period.

CPT codes 99495 (Transitional care management services with 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 face-to-face visit, within 14 calendar days of discharge) and 99496 (Transitional care management services with 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 face-to-face Visit, within 7 calendar days of discharge) are discussed in detail in section III.H of this CY 2013 PFS final rule with comment period. In sum, after clinical review, we are assigning a work RVU of 2.11 with 40 minutes of intra-service time to CPT code 99495, and a work RVU of 3.05 with 50 minutes of intra-service time to CPT codes 99496 on an interim final basis for CY 2013.

(41) Physician Documentation of Face-to-Face visit for Durable Medical Equipment (DME)

TABLE 72—PHYSICIAN DOCUMENTATION OF FACE-TO-FACE VISIT FOR DURABLE MEDICAL EQUIPMENT (DME)

HCPCS code	Short descriptor	CY 2012 work RVU	AMA RUC/ HCPAC recommended work RVU	CY 2013 interim/interim final work RVU	Agree/disagree with AMA RUC/ HCPAC recommended work RVU	CMS refinement to AMA/HCPAC recommended time
G0454	MD document visit by NPP	New	N/A	0.18	N/A	N/A.

Effective January 1, 2013, we have created HCPCS code G0454 (Physician documentation of face-to-face visit for Durable Medical Equipment determination performed by Nurse Practitioner, Physician Assistant or Clinical Nurse Specialist) for payment to a physician who documents that a PA, NP, or CNS practitioner has performed a face-to-face encounter for the list of specified DME covered items. As discussed in section IV.C. of this CY 2013 PFS final rule with comment period, for HCPCS code G0454, we are finalizing a work RVU of 0.18, with 5 minutes of intra-service time and 2 minutes of post-service time, which is a crosswalk to CPT code 99211 (Level 1 office or other outpatient visit, established patient). We believe these values appropriately capture the work and time involved in furnishing this service.

(42) Other CY 2013 New, Revised, and Potentially Misvalued CPT Codes Not Specifically Discussed Previously

For all other CY 2013 new, revised and potentially misvalued CPT codes not specifically discussed previously, we agree with the AMA RUC/HCPAC recommended work RVUs and times and are setting as interim final the work RVUs listed in Table 30.

3. Establishing Interim and Interim Final Direct PE RVUs for CY 2013

b. Establishing Interim Final Direct PE RVUs for CY 2013

i. Background

The AMA RUC provides CMS with recommendations regarding direct PE inputs, including clinical labor, supplies, and equipment, for new, revised, and potentially misvalued codes. We review the AMA RUC-recommended direct PE inputs on a code-by-code basis, including the recommended facility PE inputs and/or nonfacility PE inputs, as clinically appropriate for the code. We determine whether we agree with the AMA RUC's recommended direct PE inputs for a service or, if we disagree, we refine the PE inputs to represent inputs that better reflect our estimate of the PE resources required to furnish the service in the facility and/or nonfacility settings. We also confirm that CPT codes should have facility and/or nonfacility direct PE inputs and make changes based on our clinical judgment and any PFS payment policies that would apply to the code.

ii. Methodology

We have accepted for CY 2013, as interim and without refinement, the direct PE inputs based on the recommendations submitted by the AMA RUC for the codes listed in Table KK6. For the remainder of the AMA RUC's direct PE recommendations, we have accepted the PE recommendations submitted by the AMA RUC as interim, but with refinements. These codes and the refinements to their direct PE inputs are listed in Table KK7. In some cases, we have maintained the interim status of direct PE inputs for certain code beyond the year of the initial recommendation. In those cases, we address the associated direct PE inputs in this section, along with the interim direct PE inputs, established through our review of AMA RUC recommendations.

We note that the final CY 2013 PFS direct PE input database reflects the refined direct PE inputs that we are adopting on an interim basis for CY 2013. That database is available under downloads for the CY 2013 PFS final rule with comment period on the CMS Web site at: *http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage*. We also note that the PE RVUs displayed in Addenda B and C reflect the interim values and policies described in this section. All codes adopted on an interim basis are

included in Addenda C and are open for comment.

iii. Common and Code-Specific Refinements

While Table KK7 details the CY 2013 refinements of the AMA RUC's direct PE recommendations at the code-specific level, we discuss the general nature of some common refinements and the reasons for particular refinements in the following section.

(a) Changes in Physician Time

Some direct PE inputs are directly affected by revisions in physician time described in section III.B.3. and III.M.3.a. of this final rule with comment period. Specifically, changes in the intra-service portions of the physician time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs.

Changes in Intra-service Physician Time in the Nonfacility Setting. For most codes valued in the nonfacility setting, a portion of the clinical labor time allocated to the intra-service period reflects minutes assigned for assisting the physician with the procedure. To the extent that we are refining the times associated with the intra-service portion of such procedures, we have adjusted the corresponding intra-service clinical labor minutes in the nonfacility setting.

For equipment associated with the intra-service period in the nonfacility setting, we generally allocate time based on the typical number of minutes a piece of equipment is being used and, therefore, not available for use with another patient during that period. In general, we allocate these minutes based on the description of typical clinical labor activities. To the extent that we are making changes in the clinical labor times associated with the intra-service portion of procedures, we have adjusted the corresponding equipment minutes associated with the codes.

Changes in the Number or Level of Postoperative Office Visits in the Global Period. For codes valued with post-service physician office visits during a global period, most of the clinical labor time allocated to the post-service period reflects a standard number of minutes allocated for each of those visits. To the extent that we are refining the number or level of postoperative visits, we have modified the clinical staff time in the post-service period to reflect the change. For codes valued with post-service physician office visits during a global period, we allocate standard equipment for each of those visits. To the extent that we are making a change in the number or level of postoperative visits associated with a code, we have adjusted the corresponding equipment minutes. For codes valued with post-service physician office visits during a global period, a certain number of supply items are allocated for each of those office visits. To the extent that we are making a change in the number of postoperative visits, we have adjusted the corresponding supply item quantities associated with the codes. We note that many supply items associated with post-service physician office visits are allocated for each office visit (for example, a minimum multi-specialty visit pack (SA048) in the CY 2012 direct PE database). For these supply items, the quantities in the direct PE database should reflect the number of office visits associated with the code's global period. However, some supply items are associated with post-service physician office visits but are only allocated once during the global period because they are typically used during only one of the post-service office visits (for example, pack, post-op incision care (suture) (SA054) in the direct PE database). For these supply items, the quantities in the proposed notice direct PE database reflect that single quantity.

These refinements are reflected in the final CY 2013 PFS direct PE input database and detailed in Table 73.

(b) Equipment Minutes

In general, the equipment time inputs reflect the sum of the times within the intra-service period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. While some services include equipment that is typically unavailable during the entire clinical labor service period, certain highly technical pieces of equipment and equipment rooms are less likely to be used by a clinician for all tasks associated with a service and therefore are typically available for other patients during the pre-service and post-service components of the service period. We adjust those equipment times accordingly. We refer interested stakeholders to our extensive discussion of these policies in the CY 2012 PFS final rule (76 FR 73182–73183). We are refining the CY 2013 AMA RUC direct PE recommendations to conform to these equipment time policies. These refinements are reflected in the final CY 2013 PFS direct PE database and detailed in Table 73.

(c) Moderate Sedation Inputs

In the CY 2012 PFS final rule (76 FR 73043–73049), we finalized a standard package of direct PE inputs for services where moderate sedation is considered inherent in the procedure. We are refining the CY 2013 AMA RUC direct PE recommendations to conform to these policies. These refinements are reflected in the final CY 2013 PFS direct PE database and detailed in Table 73.

(d) Standard Minutes for Clinical Labor Tasks

In general, the minutes associated with certain clinical labor tasks are standardized depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. In the case of some services, the RUC has recommended a numbers of minutes either greater or less than time typically allotted for certain tasks. In those cases, CMS clinical staff has reviewed the deviations from the standards to determine their clinical appropriateness. Where CMS clinical judgment considers that the standard number of minutes generally accommodates the range of minutes likely to be typical for such activities, the recommended exceptions have not been accepted, and we have refined the interim final direct PE inputs to match the standard times for those tasks. Each of those refinements appears in Table 73.

(e) Digestive System (CPT Code 44705 and HCPCS Code G0455)

The CPT Editorial Panel created CPT code 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen) and the AMA RUC recommended nonfacility direct PE inputs for this service for CY 2013. As discussed in section III.M.3.a. of this final rule, Medicare payment for the preparation of the donor specimen would only be made if the specimen is ultimately used for the treatment of a beneficiary. Because of this policy, we believe it is appropriate to bundle the preparation and instillation into one payable HCPCS code. For CY 2013, we have created HCPCS code G0455 (Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen). HCPCS code G0455 will replace new CPT code 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen) which will have a PFS procedure status indicator of I (Not valid for Medicare purposes), and includes both the work of preparation and instillation of the microbiota.

In order to establish direct PE inputs for this service that includes both the preparation and instillation, we examined the AMA RUC recommendations for CPT code 44705 and incorporated an additional 17 minutes of clinical labor time in the service period to account for pre-service activities like greeting and gowning the beneficiary, obtaining the vital signs, providing pre-education/obtaining consent, preparing the room and equipment, and preparing the patient and post-service activities like cleaning the room and providing home care instructions to the beneficiary, based on the amount of time allocated for those services in the direct PE inputs for evaluation and management services. We note that we have also included a minimum multi-specialty visit pack (SA048) as a supply input for the code and otherwise crosswalked the AMA RUC-recommended supply and equipment inputs from CPT code 44705.

(f) Diagnostic Radiology: Abdomen (CPT Codes 72191, 72192, 72193, 72194, 74150, 74160, 74170, 74174, 74175, 74176, 74177, 74178)

Generally, we only establish interim final direct PE inputs for services when the RUC has provided a new recommendation. However, in some cases, we believe it is necessary to establish new interim final direct PE inputs for codes not recently reviewed by the RUC in order to maintain appropriate relativity between the PE and work components of PFS payment or among those codes and other related codes. For example, this situation can occur when either the physician work of particular codes has been reviewed without parallel review of the direct PE inputs or when the direct PE inputs of certain codes have been reviewed without parallel review of the direct PE inputs of closely related codes. We addressed the issue in detail in the CY 2012 PFS final rule (76 FR 73212).

Over the past several years, AMA CPT has created codes for diagnostic radiology services that describe CT and computed tomographic angiography (CTA) of the abdomen and pelvis combined while maintaining the current component codes that describe CT and CTA of each region separately. In reviewing both the physician work and the direct PE inputs for these services, we have consistently requested that recommendations for appropriate valuation of these services consider the whole code set at once.

In response to this request, commenters contended that the AMA RUC operates under the premise that the values of all the services paid on the PFS are assumed to be accurate and therefore, our request to review component codes is unnecessary and that reviewing and possibly revaluing individual codes solely because they are bundled to create a new code, risks rank-order anomalies within families, which could threaten the relativity of the values of the PFS services. One commenter suggested that our requests would create an endless cycle of review.

We continue to believe that code sets that include component and combined codes should be reviewed for appropriate revaluing as whole sets instead of in fragments. In fact, we believe that disjointed review, as opposed to comprehensive review, is itself the most likely cause of rank order anomalies and ''endless cycles of review.'' The Act requires CMS to conduct periodic reviews of PFS services [1848(c)(2)(B)] and make appropriate adjustments to misvalued codes [1848(c)(2)(K)]. In consideration of these obligations, we believe that the relative values for these codes must be considered as a whole set instead of in fragments. In the interest of examining the direct PE inputs of these services as a comprehensive set, we have reviewed the direct PE inputs for all of the abdomen and pelvis CT codes and all of the abdomen and pelvis CTA codes as two individual sets. We have started from the basis that the most recently developed AMA RUC recommendation represents the most current information regarding typical medical practice. For each set of codes, we have established a common set of disposable supplies and medical equipment. We established clinical labor minutes that reflect the fundamental assumption that the component codes should include a base number of minutes for particular tasks and that the number of minutes in the combined codes should reflect efficiencies that occur when the regions are examined together.

We are establishing the direct PE input for each of these services on an interim basis for CY 2013, and we have displayed particular refinements to the most recent AMA RUC recommendations or current direct PE inputs for the codes in Table 73.

Regarding the supply item called ''computer media, optical disk 2.6gb'' (SK016), we note that the most recent AMA RUC recommendation included the item with a quantity of 1 as a disposable supply. When reviewing the item in the direct PE input database, we noted that its quantity for other similar codes is 0.1. We believe that quantity better reflects the resource costs of storing digital images for these services. We also note that the item is currently priced at $68.75 in the direct PE input database, and we believe that price may be significantly higher than typical prices. Therefore, we are seeking comment on the appropriate quantity and price for the item, which will be set at a quantity of 0.1 for these services on an interim basis for CY 2013.

Finally, we note that the direct PE inputs for these services will not be finalized until the associated work RVUs are finalized, consistent with our established policies regarding the concurrent review of work and direct practice expense inputs.

(g) Nuclear Medicine: Diagnostic (CPT Code 78072)

When clinically appropriate, the AMA RUC generally recommends the use of supply and equipment items that already exist in the direct PE database for new, revised, and potentially misvalued codes. Some recommendations include supply or equipment items that are not currently in the direct PE database. In these cases, the AMA RUC has historically recommended a new item be created and has facilitated CMS' pricing of that item by working with the specialty societies to provide sales invoices to us. We appreciate the contributions of the AMA RUC in that process.

We received invoices for several new supply and equipment items for CY 2013. We have accepted the majority of these items and added them to the direct PE database. For CY 2013, we could not price the new equipment for CPT code 78072 (Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT), and concurrently acquired computed tomography (CT) for anatomical localization). We received a recommendation to create a new equipment item in the direct PE database called ''gamma camera system, single-dual head SPECT/CT'' for use in furnishing this service in the nonfacility setting. In order to facilitate pricing the new item, the AMA RUC forwarded information from the specialty society, but that information only included a letter from the device manufacturer that offered a price quote. While we recognize that the resource costs for the equipment is significant, we do not believe that a letter from the manufacturer is adequate documentation for establishing a price for a new equipment item. In many cases when we cannot adequately price a newly recommended item, we have included the item in the direct PE input database without an associated price. While doing so means that the item does not contribute to the calculation of the

PE RVU for particular services, it facilitates our ability to incorporate a price once we are able to do so. However, in the case of this new CPT code, because the cost of the item we cannot currently price is disproportionately large relative to the costs reflected by remainder of the recommended direct PE inputs, we are contractor pricing the technical component of the code for CY 2013, on an interim basis, until the newly recommended equipment item can be appropriately priced.

(h) Pathology and Laboratory: Chemistry (CPT Code 86153)

The AMA RUC submitted direct PE input recommendations for CPT code 86153 (Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required) that describes a laboratory physician interpretation code. As we discuss in section III.M.3.a. of this final rule with comment period, CPT code 86153 is a professional component-only CPT code that will be considered a ''clinical laboratory interpretation service,'' which is one of the current categories of PFS pathology services under the definition of physician pathology services at § 415.130(b)(4). This code must be billed with the ''26'' modifier to be paid under the PFS. Therefore, CPT code 86153–26 should be valued exclusively without direct practice expense inputs. Therefore, we are not accepting the recommended direct PE inputs for CPT code 86153.

(i) Pathology and Laboratory: Surgical Pathology (CPT Codes 88300, 88302, 88304, 88305, 88307, 88309)

For surgical pathology CPT codes 88300, 88302, 88304, 88305, 88307, 88309 (Surgical Pathology, Levels I through VI), the AMA RUC recommended creating several new supply and equipment items in direct PE input database that we will not incorporate for CY 2013 in addition to several new direct PE inputs that we are adopting on an interim basis. The new supply items that we will not incorporate were called ''specimen, solvent, and formalin disposal cost,'' and ''courier transportation costs.'' We do not believe that specimen and supply disposal or courier costs for transporting specimens are appropriately considered as disposable medical supplies. Instead, we believe the costs described by these recommendations are incorporated into the PE RVUs for these services through the indirect PE allocation. We note that the current direct PE inputs for these and similar services across the PFS do not include these kinds of costs as disposable supplies.

In addition to the recommendation to include these new supply items, the AMA RUC recommended that we create new equipment items called ''equipment maintenance cost,'' ''Copath System with maintenance contract,'' and ''Copath software'' as direct PE inputs for these codes. Our standard equipment cost per minute calculation includes a maintenance factor to incorporate costs related to maintenance in amortizing the cost of the equipment itself. Therefore, we will not incorporate separate maintenance costs for particular items. Regarding the ''Copath'' system and software equipment, the AMA RUC forwarded materials from a manufacturer that included a description of a computer system that is used to interface with other data systems to provide inbound demographic information and export laboratory results and billing information. Based on the way those functionalities were presented in this information, we believe that this computer system and associated software reflects an indirect practice expense since the clerical and other administrative functionality seem central to its purpose. We note that no similar equipment is currently included as a direct PE input for these services. All direct PE inputs for these services are interim for CY 2013 and open to comment. We would consider additional information regarding whether this computer system and associated software might be considered a direct cost as medical equipment associated with furnishing the technical component of these surgical pathology services for CY 2014 rulemaking. We are especially interested in understanding the clinical functionality of the equipment in relation to the services being furnished.

In addition to this information, we are also seeking additional public comment regarding the appropriate assumptions regarding the direct PE inputs for these services. We note that the AMA RUC recommendations for these potentially misvalued codes were developed based on an underlying assumption regarding the typical number of blocks used each time a service is reported. The number of blocks assumed to be used has significant impact on the quantity of other supplies and the number of clinical labor and equipment minutes assigned as direct PE inputs to each code. After conducting an initial clinical review of these direct PE inputs, we are concerned that the number of blocks assumed for each code may be inaccurate. For 88300, no blocks are assumed. For 88302, one block is assumed. For 88304 and 88305, the assumed number of blocks typically used is 2. For 88307, the assumed number of blocks is 12 and for 88309, the typical number of blocks is assumed to be 18. We are accepting the AMA RUC's recommended direct PE inputs that derive from these assumptions on an interim basis for CY 2013, but we are seeking independent evidence regarding the appropriate number of blocks to assume as typical for each of these services. We are requesting public comment regarding the appropriate number of blocks and urge the AMA RUC and interested medical specialty societies to provide corroborating, independent evidence that the number of blocks assumed in the current direct PE input recommendations is typical prior to finalizing the direct PE inputs for these services.

(j) Pathology and Laboratory: Cytopathology (CPT Codes 88120 and 88121)

The CPT Editorial Panel created CPT codes 88120 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; manual) and 88121 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology) to describe in situ hybridization testing using urine samples, effective for CY 2011.

As we explain in section III.M.3.a. of this final rule with comment period, we believe that the work and direct PE inputs for existing CPT codes 88365, 88367, and 88368 should be reviewed alongside CPT codes 88120 and 88121 to ensure the appropriate relativity between these two sets of services (76 FR 73153 through 73154). The AMA RUC has stated that it intends to do so after CY 2012 utilization data are available to assess how these services are being billed. We agree with this approach, and are maintaining the interim status for the direct PE inputs for CPT code 88120 and 88121 until we review CPT codes 88120 and 88121 alongside CPT codes 88365, 88367, and 88368 for CY 2014.

Distinct from that forthcoming review, stakeholders have informed us of two separate issues related to the interim direct PE inputs for these services. Two stakeholders have examined the AMA RUC recommendations and found miscalculations in the recommended equipment minutes. The information we

reviewed suggested that that the recommended times of 107 minutes for the ThemoBrite equipment (EP088) for 88120 and 26.75 minutes for 88121 were derived in error because the division for the typical batch sizes of 3 and 6, respectively, occurred twice. The stakeholders also presented information that the recommended minutes for the Olympus BX41 Fluorescent Microscope (without filters or camera) (EP092) as a direct PE input for CPT code 88120 ought to have been 73 minutes, instead of 1.33 minutes. Finally, the stakeholders provided information suggesting the minutes for the IkoniScope (EP090) and IkoniLan software (EP091) included as direct PE inputs for CPT code 88121 were intended to be 29.7 minutes, instead of 2.97. Upon clinical review of this information, we agree with the stakeholders regarding the intention of these recommendations, and have refined the CY 2013 direct PE input database accordingly.

These stakeholders also suggested that CMS should increase the price of the supply ''UroVysion test kit'' (SA105) by building in an ''efficiency factor'' to account for the kits that are purchased by practitioners and used in tests that fail. The stakeholders provided documentation suggesting that a certain failure rate is inherent in the procedure.

The prices associated with supply inputs in the direct PE input database reflect the price per unit of each supply. Since the current PE methodology relies on the inputs for each service reflecting the typical direct practice expense costs for each service, and the supply costs for the failed tests are not used in furnishing PFS services, we do not believe that the methodology accommodates a failure rate in allocating the cost of disposable medical supplies. Therefore, we are not adjusting the price input for ''UroVysion test kit'' (SA105) in the direct PE input database.

(j) Psychiatry (CPT Codes 90791, 90832, 90834, 90837)

For CY 2013, the CPT Editorial Panel has replaced the current psychiatry/psychotherapy CPT codes with a new structure that allows for the separate reporting of E/M codes, eliminates the site-of-service differential, establishes CPT codes for crisis, and creates a series of add-on CPT codes to psychotherapy to describe interactive complexity and medication management. As we note in section III.M.3.a. of this final rule with commenter period, because related specialty societies have not yet surveyed some of the new CPT codes, namely, the new CPT codes for psychotherapy for crisis, interactive complexity, and pharmacologic management, we anticipate re-reviewing the values for all the codes in the family in the near future. For CY 2013, our general approach is to maintain the current values, or as close to the current values as possible, given the consolidation of multiple CY 2012 CPT codes into a single CY 2013 CPT code, for these service on an interim basis, pending re-review.

The AMA RUC submitted direct PE input recommendations for codes in this family that included significant reductions in the direct PE costs associated with the predecessor codes. For most of the new codes, we believe that accepting these recommended reductions in direct practice expense conforms to our general approach of maintaining the current values for these services since many practitioners who furnish these services will now report concurrent medical evaluation and management services with PE values that will offset the differences in total PE values between the new and old psychotherapy codes. However, for practitioners who do not furnish medical evaluation and management services, there are no corresponding PE value increases to offset the recommended reductions in the direct PE inputs for these codes. Therefore, instead of accepting the recommended direct PE inputs for the new CPT codes that describe services primarily furnished by practitioners who do not also report medical evaluation and management services, we will crosswalk the PE RVUs from the CY 2012 codes that describe the same services. We believe this crosswalk will effectively maintain the total value of the services, pending a comprehensive review of the code family. The CPT codes with CY 2013 PE RVU crosswalks are: 90791 (Psychiatric diagnostic evaluation), 90832 (Psychotherapy, 30 minutes with patient and/or family member), 90834 (Psychotherapy, 45 minutes with patient and/or family member), and 90837 (Psychotherapy, 60 minutes with patient and/or family member). For CY 2013, we are crosswalking the PE RVUs developed for the predecessor codes for CY 2012. We note that the PE RVUs used for these services will correspond with the CY 2013 fully implemented values instead of the transition values since this interim policy is to maintain the current values relative to the new coding structure for the services, not exempt the services from the final year of the PPIS transition, as described in section III.A. of this final rule with comment period. The values in Addendum C reflect the interim PE RVUs for these codes.

(k) Medicine: Gastroenterology (CPT Code 91112)

The AMA RUC submitted direct PE input recommendations for CPT code 91112 (Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report). The recommendations reflect an assumption that the patient data receiver would be typically used for 7200 minutes, or 5 days, for each service. However, product information available on the device manufacturer's Web site specifies a 24 to 48 hour capsular passage time. Based on this information and CMS clinical review, we believe that assigning 2880 minutes to the data receiver is appropriate based on the assumption that 2 days reflects the maximum typical time for passage of the capsule. We also note that while the AMA RUC's recommendation included the capsule and standardized meal as separate disposable items, the submitted invoice priced the items together, so the new supply item created in the direct PE input database reflects the combined items as a single disposable supply.

(l) Neurology and Neuromuscular Procedures: Intraoperative Neurophysiology (CPT Codes 95940, 95941 and HCPCS Code G0453)

Effective January 1, 2013, the CPT Editorial Panel is deleting CPT code 95920 (Intraoperative neurophysiology testing, per hour (List separately in addition to code for primary procedure)), and is replacing it with CPT codes 95940 (Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes) and CPT code 95941 (Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour).

As we note in section III.M.3.a. of this final rule with comment period, we have created HCPCS code G0453 (Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure)), effective January 1, 2013 to replace CPT code 95941 for Medicare purposes. CPT code 95941 will have a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of

and the payment for these services) for CY 2013. CPT code 95940, which describes continuous intraoperative neurophysiology monitoring in the operating room for one patient at a time, will be payable on the PFS for CY 2013.

The AMA RUC provided direct PE input recommendations for CPT codes 95940 and 95941. However, we do not believe that these services are furnished to patients outside of facility settings. Medicare makes payment for technical inputs (labor, supplies, equipment, capital, and overhead) to the facility when services are performed in a facility setting. For these services, the patient would receive this service in the ASC or hospital setting and payment for any technical services, including those for remote monitoring, should be included in the facility payment. We do not believe it would be appropriate to incorporate nonfacility direct PE inputs or develop nonfacility PE RVUs for CPT code 95940 and newly created HCPCS code G0453 for CY 2013. We do not believe that these services incur PFS direct practice expense costs when furnished to patients in the facility setting. Therefore, we are developing facility PE RVUs for this service based on no direct PE inputs.

(m) Neurology and Neuromuscular Procedures: Sleep Medicine Testing CPT Codes 95782, 95783)

The AMA RUC submitted direct PE input recommendations for new CPT codes describing pediatric polysomonography: 95782 (Polysomnography, younger than 6 years, 4 or more) and 95783 (Polysomnography, younger than 6 years, w/cpap). We note that in addition to refining minutes assigned to certain labor tasks based on CMS clinical judgment, we have not accepted the AMA RUC's recommendation to create a new equipment item 'crib' for use in these services. We do not believe that a crib would typically be used in this service, and we have incorporated the bedroom furniture including a hospital bed and a reclining chair as typical equipment for this service.

(n) Special Dermatological Procedures (CPT Codes 96920, 96921, 96922)

The AMA RUC provided new direct PE input recommendations for CPT codes 96920(Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm), 96921 (Laser treatment for inflammatory skin disease, (psoriasis); between 250 sq cm to 500 sq cm), and 96922 (Laser treatment for inflammatory skin disease, (psoriasis); over 500 sq cm).

Included in the new direct PE inputs for these services was a disposable laser tip (SF028). This disposable item, priced at $290 in the direct PE input database, was not previously included as a direct PE input for these services. The recommendation did not provide a rationale as to why this highly priced disposable should be included as a direct PE input for these existing services when the codes have not previously included this item or any similarly priced disposable supply. Therefore, we are refining the RUC recommendation by removing the supply item SF028 from 96920, 96921, and 96922. We note that the direct PE inputs for these codes are interim for CY 2013, and we will consider any additional information and public comments regarding the typical use of this supply in furnishing these services prior to finalizing the direct PE inputs for CY 2014.

(o) Transitional Care Management Services (CPT Codes 99495, 99496)

The CPT Editorial Panel created CPT codes 99495 and 99496 for CY 2013 to describe transitional care provided to patients from an inpatient setting to a home setting over a 30-day period. The AMA RUC submitted direct PE input recommendations for these services that we are accepting with the following refinements.

As discussed in detail in section III.H of this CY 2013 PFS final rule with comment, we agree with the AMA RUC recommendation to include 45 minutes of RN/LPN time for CPT code 99495 for dedicated to non-face-to-face care management activities. However, for CPT code 99496, we are refining the 60 minutes of recommended clinical labor time for a RN/LPN nurse blend dedicated to non-face-to-face care management activities from 60 minutes to 70 minutes. We believe that the total clinical labor staff time and physician intra-service work time that the AMA RUC-recommended for non-face-to-face care management activities was accurate for both codes, but that the proportionality between physician work and clinical staff time should be refined to reflect greater clinical staff time in 99496.

We also note that we are refining the AMA RUC recommendation by incorporating the clinical labor inputs for dedicated to non-face-to-face care management activities as facility inputs.

TABLE 73—CPT CODES WITH ACCEPTED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES

CPT code	CPT code description
20985	Cptr-asst dir ms px.
24160	Remove elbow joint implant.
24371	Revise reconst elbow joint.
29828	Arthroscopy biceps tenodesis.
31648	Bronchial valve addl insert.
31649	Bronchial valve remov init.
31651	Bronchial valve remov addl.
31660	Bronch thermoplsty 1 lobe.
31661	Bronch thermoplsty 2/> lobes.
33430	Replacement of mitral valve.
33533	Cabg arterial single.
36227	Place cath xtrnl carotid.
37211	Thrombolytic art therapy.
37212	Thrombolytic venous therapy.
37213	Thromblytic art/ven therapy.
37214	Cessj therapy cath removal.
66982	Cataract surgery complex.
66984	Cataract surg w/iol 1 stage.
77082	Dxa bone density vert fx.
90792	Psych diag eval w/med srvcs.
90833	Psytx pt&/fam w/e&m 30 min.
90837	Psytx pt&/family 60 minutes.
90838	Psytx pt&/fam w/e&m 60 min.
90845	Psychoanalysis
90846	Family psytx w/o patient.
90847	Family psytx w/patient.
90853	Group psychotherapy.
92286	Internal eye photography.
93016	Cardiovascular stress test.
93018	Cardiovascular stress test.
95017	Perq & icut allg test venoms.
95018	Perq&ic allg test drugs/biol.
95079	Ingest challenge addl 60 min.
95860	Muscle test one limb.
95866	Muscle test hemidiaphragm.
95867	Muscle test cran nerv unilat.
95869	Muscle test thor paraspinal.
95870	Muscle test nonparaspinal.
95925	Somatosensory testing.
95926	Somatosensory testing.
95928	C motor evoked uppr limbs.
95929	C motor evoked lwr limbs.
95938	Somatosensory testing.
95939	C motor evoked upr&lwr limbs.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
11300	Shave skin lesion 0.5 cm/<.	ED004	camera, digital (6 mexapixel).	NF		29	14	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		29	14	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		29	14	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		29	14	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		29	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		29	24	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		29	14	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11301	Shave skin lesion 0.6–1.0 cm.	ED004	camera, digital (6 mexapixel).	NF		32	17	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		32	17	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		32	17	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		32	17	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		32	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		32	27	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		32	17	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11302	Shave skin lesion 1.1–2.0 cm.	ED004	camera, digital (6 mexapixel).	NF		37	20	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		37	20	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		37	20	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		37	20	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		37	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		37	30	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		37	20	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11303	Shave skin lesion >2.0 cm.	ED004	camera, digital (6 mexapixel).	NF		41	22	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		41	22	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		41	22	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EF031	table, power	NF		41	22	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		41	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		41	32	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		41	22	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11305	Shave skin lesion 0.5 cm/<.	ED004	camera, digital (6 mexapixel).	NF		29	17	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		29	17	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		29	17	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		29	17	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		29	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		29	27	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		29	17	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
11306	Shave skin lesion 0.6–1.0 cm.	ED004	camera, digital (6 mexapixel).	NF		31	17	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		31	17	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		31	17	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		31	17	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		31	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		31	27	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		31	17	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	10	18	Conforming to physician time.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11307	Shave skin lesion 1.1–2.0 cm.	ED004	camera, digital (6 mexapixel).	NF		37	21	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		37	21	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		37	21	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		37	21	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		37	0	CMS clinical review; not described as typical in work vignette.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EQ137	instrument pack, basic ($500–$1499).	NF		37	31	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		37	21	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11308	Shave skin lesion >2.0 cm.	ED004	camera, digital (6 mexapixel).	NF		42	24	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		42	24	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		42	24	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		42	24	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		42	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		42	34	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		42	24	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11310	Shave skin lesion 0.5 cm/<.	ED004	camera, digital (6 mexapixel).	NF		34	20	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		34	20	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EF015	mayo stand	NF		34	20	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		34	20	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		34	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		34	30	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		34	20	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11311	Shave skin lesion 0.6–1.0 cm.	ED004	camera, digital (6 mexapixel).	NF		34	18	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		34	18	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		34	18	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		34	18	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		34	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		34	28	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		34	18	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	11	17	Conforming to physician time.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11312	Shave skin lesion 1.1–2.0 cm.	ED004	camera, digital (6 mexapixel).	NF		43	17	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		43	17	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		43	17	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		43	17	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		43	0	CMS clinical review; not described as typical in work vignette.
		EQ137	instrument pack, basic ($500–$1499).	NF		43	37	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		43	17	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11313	Shave skin lesion >2.0 cm.	ED004	camera, digital (6 mexapixel).	NF		43	30	Refined equipment time to reflect typical use exclusive to patient.
		EF014	light, surgical	NF		43	30	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		43	30	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		43	30	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		43	0	CMS clinical review; not described as typical in work vignette.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EQ137	instrument pack, basic ($500–$1499).	NF		43	40	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		43	30	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	1	10	Standardized time input.
		SB003	cover, probe (cryosurgery).	NF		1	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB033	mask, surgical	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
11719	Trim nail(s) any number.	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available.	3	1	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Provide pre-service education/ obtain consent.	2	1	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Prepare room, equipment, supplies.	2	1	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff.	3	1	CMS clinical review.
		SJ028	hydrogen peroxide	NF		10	0	CMS clinical review.
		SJ053	swab-pad, alcohol	NF		10	0	CMS clinical review.
13100	Cmplx rpr trunk 1.1–2.5 cm.	EF014	light, surgical	NF		32	27	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		32	39	Refined equipment time to reflect typical use exclusive to patient.
		EF023	table, exam	NF		32	27	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		32	39	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		32	39	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		32	46	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		32	39	Refined equipment time to reflect typical use exclusive to patient.
		SB016	drape-cover, sterile, OR light handle.	NF		2	1	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SB027	gown, staff, impervious.	NF		2	0	Duplicative.
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		5	0	Duplicative.
13101	Cmplx rpr trunk 2.6–7.5 cm.	EF014	light, surgical	NF		45	27	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		45	47	Refined equipment time to reflect typical use exclusive to patient.
		EF023	table, exam	NF		45	27	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		45	47	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		45	47	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		45	54	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		45	47	CMS clinical review.
		SB016	drape-cover, sterile, OR light handle.	NF		2	1	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	0	Duplicative.
		SB027	gown, staff, impervious.	F		2	0	CMS clinical review.
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
		SB034	mask, surgical, with face shield.	F		2	1	CMS clinical review.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		10	0	Duplicative.
13102	Cmplx rpr trunk addl 5 cm/<.	EF015	mayo stand	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EQ114	electrosurgical generator, up to 120 watts.	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		5	0	Duplicative.
13120	Cmplx rpr s/a/l 1.1–2.5 cm.	EF014	light, surgical	NF		86	27	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		86	41	Refined equipment time to reflect typical use exclusive to patient.
		EF023	table, exam	NF		86	27	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		86	41	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		86	41	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		86	48	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		86	41	Refined equipment time to reflect typical use exclusive to patient.
		SB016	drape-cover, sterile, OR light handle.	NF		2	1	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	0	Duplicative.
		SB027	gown, staff, impervious.	F		2	0	CMS clinical review.
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
		SB034	mask, surgical, with face shield.	F		2	1	CMS clinical review.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		5	0	Duplicative.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
13121	Cmplx rpr s/a/l 2.6–7.5 cm.	EF014	light, surgical	NF		129	27	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		129	48	Refined equipment time to reflect typical use exclusive to patient.
		EF023	table, exam	NF		129	27	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		129	48	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		129	48	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		129	55	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		129	48	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	15	10	Standardized time input.
		SB016	drape-cover, sterile, OR light handle.	NF		2	1	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	0	Duplicative.
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		10	0	Duplicative.
13122	Cmplx rpr s/a/l addl 5 cm/>.	EF015	mayo stand	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		30	20	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		5	0	Duplicative.
13131	Cmplx rpr f/c/c/m/n/ax/g/h/f.	EF014	light, surgical	NF		45	27	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		45	48	Refined equipment time to reflect typical use exclusive to patient.
		EF023	table, exam	NF		45	27	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		45	48	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		45	48	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		45	55	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		45	48	Refined equipment time to reflect typical use exclusive to patient.
		SB016	drape-cover, sterile, OR light handle.	NF		2	1	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	0	Duplicative.
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		5	0	Duplicative.
13132	Cmplx rpr f/c/c/m/n/ax/g/h/f.	EF014	light, surgical	NF		50	27	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		50	51	Refined equipment time to reflect typical use exclusive to patient.
		EF023	table, exam	NF		50	27	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		50	51	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EQ114	electrosurgical generator, up to 120 watts.	NF		50	51	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		50	58	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		50	51	Refined equipment time to reflect typical use exclusive to patient.
		SB016	drape-cover, sterile, OR light handle.	NF		2	1	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	0	Duplicative.
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		10	0	Duplicative.
13133	Cmplx rpr f/c/c/m/n/ax/g/h/f.	EF015	mayo stand	NF		35	23	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		35	23	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		35	23	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		35	23	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		35	23	Refined equipment time to reflect typical use exclusive to patient.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		5	0	Duplicative.
13150	Cmplx rpr e/n/e/l 1.0 cm/<.	EF014	light, surgical	NF		30	27	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		30	44	Refined equipment time to reflect typical use exclusive to patient.
		EF023	table, exam	NF		30	27	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EF031	table, power	NF		30	44	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		30	44	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		30	51	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		30	44	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	20	26	Conforming to physician time.
		SB016	drape-cover, sterile, OR light handle.	NF		2	1	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	0	Duplicative.
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		5	0	Duplicative.
13151	Cmplx rpr e/n/e/l 1.1–2.5 cm.	EF014	light, surgical	NF		45	27	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		45	48	Refined equipment time to reflect typical use exclusive to patient.
		EF023	table, exam	NF		45	27	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		45	48	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		45	48	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		45	55	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		45	48	Refined equipment time to reflect typical use exclusive to patient.
		SB016	drape-cover, sterile, OR light handle.	NF		2	1	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	0	Duplicative.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		5	0	Duplicative.
13152	Cmplx rpr e/n/e/l 2.6–7.5 cm.	EF014	light, surgical	NF		50	27	Refined equipment time to reflect typical use exclusive to patient.
		EF015	mayo stand	NF		50	51	Refined equipment time to reflect typical use exclusive to patient.
		EF023	table, exam	NF		50	27	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		50	51	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		50	51	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		50	58	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		50	51	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF		15	10	Standardized time input.
		SB016	drape-cover, sterile, OR light handle.	NF		2	1	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	0	Duplicative.
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		10	0	Duplicative.
13153	Cmplx rpr e/n/e/l addl 5cm/<.	EF015	mayo stand	NF		45	30	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		45	30	Refined equipment time to reflect typical use exclusive to patient.
		EQ114	electrosurgical generator, up to 120 watts.	NF		45	30	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EQ137	instrument pack, basic ($500–$1499).	NF		45	30	Refined equipment time to reflect typical use exclusive to patient.
		EQ351	Smoke Evacuator (tubing, covering, etc.) with stand.	NF		45	30	Refined equipment time to reflect typical use exclusive to patient.
		SC029	needle, 18–27g	NF		2	0	CMS clinical review.
		SF016	cautery, monopolar, electrode tip.	NF		1	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		5	0	Duplicative.
20600	Drain/inject joint/ bursa.	EF023	table, exam	NF		19	16	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		19	16	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	CMS clinical review.
		L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions.	0	3	CMS clinical review.
		SC029	needle, 18–27g	NF		4	2	CMS clinical review.
		SC055	syringe 3ml	NF		2	1	CMS clinical review.
20605	Drain/inject joint/ bursa.	EF023	table, exam	NF		19	16	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		19	16	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	CMS clinical review.
		L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions.	0	3	CMS clinical review.
		SC029	needle, 18–27g	NF		4	2	CMS clinical review.
		SC055	syringe 3ml	NF		2	1	CMS clinical review.
20610	Drain/inject joint/ bursa.	EF023	table, exam	NF		19	16	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		19	16	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	CMS clinical review.
		L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions.	0	3	CMS clinical review.
		SC029	needle, 18–27g	NF		4	2	CMS clinical review.
		SC057	syringe 5–6ml	NF		2	1	CMS clinical review.
23472	Reconstruct shoulder joint.	SA052	pack, post-op incision care (staple).	F		0	1	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SA053	pack, post-op incision care (suture & staple).	F		1	0	CMS clinical review.
23473	Revis reconst shoulder joint.	SA052	pack, post-op incision care (staple).	F		0	1	CMS clinical review.
		SA053	pack, post-op incision care (suture & staple).	F		1	0	CMS clinical review.
23474	Revis reconst shoulder joint.	SA052	pack, post-op incision care (staple).	F		0	1	CMS clinical review.
		SA053	pack, post-op incision care (suture & staple).	F		1	0	CMS clinical review.
24363	Replace elbow joint.	SA052	pack, post-op incision care (staple).	F		0	1	CMS clinical review.
		SA053	pack, post-op incision care (suture & staple).	F		1	0	CMS clinical review.
24370	Revise reconst elbow joint.	SA052	pack, post-op incision care (staple).	F		0	1	CMS clinical review.
		SA052	pack, post-op incision care (staple).	F		0	1	CMS clinical review.
		SA053	pack, post-op incision care (suture & staple).	F		1	0	CMS clinical review.
		SA053	pack, post-op incision care (suture & staple).	F		1	0	CMS clinical review.
31231	Nasal endoscopy dx.	EF008	chair with headrest, exam, reclining.	NF		43	35	Refined equipment time to reflect typical use exclusive to patient.
		EQ138	instrument pack, medium ($1500 and up).	NF		0	47	Refined equipment time to reflect typical use exclusive to patient.
		EQ167	light source, xenon.	NF		43	35	Refined equipment time to reflect typical use exclusive to patient.
		EQ170	light, fiberoptic headlight w-source.	NF		43	35	Refined equipment time to reflect typical use exclusive to patient.
		EQ234	suction and pressure cabinet, ENT (SMR).	NF		43	35	Refined equipment time to reflect typical use exclusive to patient.
		ES013	endoscope, rigid, sinoscopy.	NF		63	42	Refined equipment time to reflect typical use exclusive to patient.
		ES013	endoscope, rigid, sinoscopy.	NF		63	0	CMS clinical review.
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		43	35	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		ES032	video system, stroboscopy (strobing platform, camera, digital recorder, monitor, printer, cart).	NF		43	35	Refined equipment time to reflect typical use exclusive to patient.
		ES036	Nasal Endoscopy Instrument Package.	NF		63	0	Non-standard direct practice expense input.
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available.	2	0	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	1	0	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package.	10	15	Standardized time input.
		L037D	RN/LPN/MTA	NF	Review/read X-ray, lab, and pathology reports.	5	0	CMS clinical review.
		SB027	gown, staff, impervious.	NF		2	1	Duplicative.
		SB034	mask, surgical, with face shield.	NF		2	1	Duplicative.
31647	Bronchial valve init insert.	L047C	RN/Respiratory Therapist.	F	Complete pre-service diagnostic & referral forms.	3	5	CMS clinical review.
		L047C	RN/Respiratory Therapist.	F	Coordinate pre-surgery services.	5	3	CMS clinical review.
32554	Aspirate pleura w/o imaging	EF023	table, exam	NF		56	52	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		0	52	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	1	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/ check tubes, monitors, drains.	5	10	CMS clinical review.
		SA048	pack, minimum multi-specialty visit.	NF		0	1	CMS clinical review.
		SA067	tray, shave prep	NF		0	1	CMS clinical review.
		SA077	kit, pleural catheter insertion.	NF		0	1	CMS clinical review.
		SB001	cap, surgical	NF		0	2	CMS clinical review.
		SB006	drape, non-sterile, sheet 40in x 60in.	NF		1	0	CMS clinical review.
		SB024	gloves, sterile	NF		1	2	CMS clinical review.
		SB034	mask, surgical, with face shield.	NF		0	2	CMS clinical review.
		SB039	shoe covers, surgical.	NF		0	2	CMS clinical review.
		SB044	underpad 2ft x 3ft (Chux).	NF		0	1	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SG056	gauze, sterile 4in x 4in (10 pack uou).	NF		0	1	CMS clinical review.
32555	Aspirate pleura w/ imaging.	ED024	film processor, dry, laser.	NF		58	7	Refined equipment time to reflect typical use exclusive to patient.
		EF019	stretcher chair	NF		15	10	CMS clinical review.
		EL015	room, ultrasound, general.	NF		33	35	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		58	7	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	1	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/ check tubes, monitors, drains.	15	10	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Process images, complete data sheet, present images and data to the interpreting physician.	5	2	CMS clinical review.
		SA027	kit, scissors and clamp.	NF		0	1	CMS clinical review.
		SA077	kit, pleural catheter insertion.	NF		0	1	CMS clinical review.
		SB001	cap, surgical	NF		0	3	CMS clinical review.
		SB027	gown, staff, impervious.	NF		0	1	CMS clinical review.
		SB039	shoe covers, surgical.	NF		0	3	CMS clinical review.
		SB044	underpad 2ft x 3ft (Chux).	NF		0	1	CMS clinical review.
		SG078	tape, surgical occlusive 1in (Blenderm).	NF		0	15	CMS clinical review.
		SM012	disinfectant spray (Transeptic).	NF		10	0	CMS clinical review.
		SM021	sanitizing cloth-wipe (patient).	NF		2	0	CMS clinical review.
32556	Insert cath pleura w/o image.	EQ168	light, exam	NF		0	76	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	1	CMS clinical review.
		SA044	pack, moderate sedation.	NF		0	1	CMS clinical review.
		SA048	pack, minimum multi-specialty visit.	NF		0	1	CMS clinical review.
		SA067	tray, shave prep	NF		0	1	CMS clinical review.
		SB001	cap, surgical	NF		0	2	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SB006	drape, non-sterile, sheet 40in x 60in.	NF		1	0	CMS clinical review.
		SB034	mask, surgical, with face shield.	NF		0	2	CMS clinical review.
		SB039	shoe covers, surgical.	NF		0	2	CMS clinical review.
		SB044	underpad 2ft x 3ft (Chux).	NF		0	1	CMS clinical review.
		SC010	closed flush system, angiography.	NF		0	1	CMS clinical review.
		SG056	gauze, sterile 4in x 4in (10 pack uou).	NF		1	0	CMS clinical review.
		SH065	sodium chloride 0.9% flush syringe.	NF		0	1	CMS clinical review.
		SH069	sodium chloride 0.9% irrigation (500–1000ml uou).	NF		0	1	CMS clinical review.
		SL157	cup, sterile, 8 oz	NF		0	1	CMS clinical review.
32557	Insert cath pleura w/image.	ED024	film processor, dry, laser.	NF		58	7	CMS clinical review.
		EF019	stretcher chair	NF		15	10	CMS clinical review.
		EL007	room, CT	NF		43	40	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		60	40	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		58	7	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	1	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	3	5	CMS clinical review.
		L046A	CT Technologist	NF	Assist physician in performing procedure.	28	30	Conforming to physician time.
		SA044	pack, moderate sedation.	NF		0	1	CMS clinical review.
		SA071	kit, AccuStick II Introducer System with RO Marker.	NF		1	0	CMS clinical review.
		SA077	kit, pleural catheter insertion.	NF		0	1	CMS clinical review.
		SB001	cap, surgical	NF		2	3	CMS clinical review.
		SB011	drape, sterile, fenestrated 16in x 29in.	NF		1	0	CMS clinical review.
		SB014	drape, sterile, three-quarter sheet.	NF		1	0	CMS clinical review.
		SB019	drape-towel, sterile 18in x 26in.	NF		4	0	CMS clinical review.
		SB024	gloves, sterile	NF		2	1	CMS clinical review.
		SB027	gown, staff, impervious.	NF		0	1	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SB039	shoe covers, surgical.	NF		2	3	CMS clinical review.
		SC049	stop cock, 3-way	NF		1	0	CMS clinical review.
		SC056	syringe 50–60ml	NF		2	0	CMS clinical review.
		SC058	syringe w-needle, OSHA compliant (SafetyGlide).	NF		1	0	CMS clinical review.
		SD043	dilator, vessel, angiographic.	NF		1	0	CMS clinical review.
		SD088	guidewire	NF		1	0	CMS clinical review.
		SD146	catheter percutaneous fastener (Percu-Stay).	NF		1	0	CMS clinical review.
		SD161	drainage catheter, all purpose.	NF		1	0	CMS clinical review.
		SD163	drainage pouch, nephrostomy-biliary.	NF		1	0	CMS clinical review.
		SF007	blade, surgical (Bard-Parker).	NF		1	0	CMS clinical review.
		SG009	applicator, sponge-tipped.	NF		4	0	CMS clinical review.
		SG078	tape, surgical occlusive 1in (Blenderm).	NF		0	25	CMS clinical review.
		SH047	lidocaine 1%–2% inj (Xylocaine).	NF		10	0	CMS clinical review.
		SJ041	povidone soln (Betadine).	NF		60	0	CMS clinical review.
		SL036	cup, biopsy-specimen sterile 4oz.	NF		1	0	CMS clinical review.
		SL156	cup, sterile, 12–16 oz.	NF		1	0	CMS clinical review.
33361	Replace aortic valve perq.	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	40	10	Standardized time input.
		L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	8	5	Standardized time input.
		L037D	RN/LPN/MTA	F	Provide pre-service education/ obtain consent.	20	7	Standardized time input.
		L037D	RN/LPN/MTA	F	Follow-up phone calls & prescriptions.	7	3	Standardized time input.
33362	Replace aortic valve open.	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	40	10	Standardized time input.
		L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	8	5	Standardized time input.
		L037D	RN/LPN/MTA	F	Provide pre-service education/ obtain consent.	20	7	Standardized time input.
		L037D	RN/LPN/MTA	F	Follow-up phone calls & prescriptions.	7	3	Standardized time input.
33363	Replace aortic valve open.	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	40	10	Standardized time input.
		L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	8	5	Standardized time input.
		L037D	RN/LPN/MTA	F	Provide pre-service education/ obtain consent.	20	7	Standardized time input.
		L037D	RN/LPN/MTA	F	Follow-up phone calls & prescriptions.	7	3	Standardized time input.
33364	Replace aortic valve open.	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	40	10	Standardized time input.
		L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	8	5	Standardized time input.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L037D	RN/LPN/MTA	F	Provide pre-service education/ obtain consent.	20	7	Standardized time input.
		L037D	RN/LPN/MTA	F	Follow-up phone calls & prescriptions.	7	3	Standardized time input.
33365	Replace aortic valve open.	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	40	10	Standardized time input.
		L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	8	5	Standardized time input.
		L037D	RN/LPN/MTA	F	Provide pre-service education/ obtain consent.	20	7	Standardized time input.
		L037D	RN/LPN/MTA	F	Follow-up phone calls & prescriptions.	7	3	Standardized time input.
33405	Replacement of aortic valve.	L051A	RN	F	Other Clinical Activity—specify: For reference code 33406 and codes 33405 and 33430: Additional coordination between multiple specialties for complex procedures (tests, meds, scheduling, etc) prior to patient arrival at site of service.	15	0	CMS clinical review.
		L051A	RN	F	Other Clinical Activity—specify: For reference code 33406 and codes 33405 and 33430: Additional coordination between multiple specialties for complex procedures (tests, meds, scheduling, etc) prior to patient arrival at site of service.	15	0	CMS clinical review.
35475	Repair arterial blockage.	EL011	room, angiography.	NF		51	52	Refined equipment time to reflect typical use exclusive to patient.
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		212	285	Moderate Sedation equipment—Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	IV infusion pump	NF		212	285	Moderate Sedation equipment—Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ168	light, exam	NF		120	52	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L037D	RN/LPN/MTA	F	Complete pre-service diagnostic & referral forms.	5	3	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	5	3	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Prepare room, equipment, supplies.	4	2	Standardized time input.
		SB019	drape-towel, sterile 18in x 26in.	NF		4	2	CMS clinical review.
35476	Repair venous blockage.	Ef027	table, instrument, mobile.	NF		302	277	Moderate Sedation equipment—Time includes administering anesthesia, procedure time, and monitoring patient.
		EL011	room, angiography.	NF		43	44	Refined equipment time to reflect typical use exclusive to patient.
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		137	277	Moderate Sedation equipment—Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	IV infusion pump	NF		137	277	Moderate Sedation equipment—Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ168	light, exam	NF		120	44	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	3	5	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	5	3	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Prepare room, equipment, supplies.	4	2	Standardized time input.
		SB019	drape-towel, sterile 18in x 26in.	NF		4	2	CMS clinical review.
36221	Place cath thoracic aorta.	EF018	stretcher	NF		272	0	CMS Code correction.
		EF027	table, instrument, mobile.	NF		0	272	CMS Code correction.
		EL011	room, angiography.	NF		49	39	Refined equipment time to reflect typical use exclusive to patient.
		EQ088	contrast media warmer.	NF		49	39	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		49	39	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available.	5	3	Standardized time input.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	5	3	CMS clinical review.
		L041A	Angio Technician	NF	Image Post Processing.	5	0	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Prepare room, equipment, supplies.	2	7	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Prepare and position patient/ monitor patient/ set up IV.	2	7	CMS clinical review.
		SD249	Sterile Radio-opaque ruler (le Maitre, documentation available).	NF		1	0	CMS clinical review.
36222	Place cath carotid/ inom art.	EF018	stretcher	NF		282	0	CMS Code correction.
		EF027	table, instrument, mobile.	NF		0	282	CMS Code correction.
		EL011	room, angiography.	NF		59	49	Refined equipment time to reflect typical use exclusive to patient.
		EQ088	contrast media warmer.	NF		59	49	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		59	49	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available.	5	3	Standardized time input.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	5	3	CMS clinical review.
		SD147	catheter, (Glide)	NF		1	0	CMS clinical review.
		SD249	Sterile Radio-opaque ruler (le Maitre, documentation available).	NF		1	0	CMS clinical review.
36223	Place cath carotid/ inom art.	EF018	stretcher	NF		287	0	CMS Code correction.
		EF027	table, instrument, mobile.	NF		0	287	CMS Code correction.
		EL011	room, angiography.	NF		64	54	Refined equipment time to reflect typical use exclusive to patient.
		EQ088	contrast media warmer.	NF		64	54	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		64	54	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available.	5	3	Standardized time input.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	5	3	CMS clinical review.
		SD249	Sterile Radio-opaque ruler (le Maitre, documentation available).	NF		1	0	CMS clinical review.
36224	Place cath carotd art.	EF018	stretcher	NF		292	0	CMS Code correction.
		EF027	table, instrument, mobile.	NF		0	292	CMS Code correction.
		EL011	room, angiography.	NF		69	59	Refined equipment time to reflect typical use exclusive to patient.
		EQ088	contrast media warmer.	NF		69	59	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		69	59	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available.	5	3	Standardized time input.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	5	3	CMS clinical review.
36225	Place cath subclavian art.	EF018	stretcher	NF		287	0	CMS Code correction.
		EF027	table, instrument, mobile.	NF		0	287	CMS Code correction.
		EL011	room, angiography.	NF		64	54	Refined equipment time to reflect typical use exclusive to patient.
		EQ088	contrast media warmer.	NF		64	54	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		64	54	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available.	5	3	Standardized time input.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	5	3	CMS clinical review.
36226	Place cath vertebral art.	EF018	stretcher	NF		292	0	CMS Code correction.
		EF027	table, instrument, mobile.	NF		0	292	CMS Code correction.
		EL011	room, angiography.	NF		69	59	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EQ088	contrast media warmer.	NF		69	59	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		69	59	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available.	5	3	Standardized time input.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	5	3	CMS clinical review.
36228	Place cath intracranial art.	L041B	Radiologic Technologist.	NF	Prepare room, equipment, supplies.	1	0	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Assisting with flouroscopy/ image acquisition (75%).	23	22	CMS clinical review.
		SC057	syringe 5–6ml	NF		4	0	CMS clinical review.
37197	Remove intrvas foreign body.	EF027	table, instrument, mobile.	NF		305	302	Moderate Sedation equipment—Time includes administering anesthesia, procedure time, and monitoring patient.
		EL011	room, angiography.	NF		77	72	Refined equipment time to reflect typical use exclusive to patient.
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		305	302	Moderate Sedation equipment—Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ032	IV infusion pump	NF		305	302	Moderate Sedation equipment—Time includes administering anesthesia, procedure time, and monitoring patient.
		EQ088	contrast media warmer.	NF		77	0	CMS clinical review.
		EQ250	ultrasound unit, portable.	NF		77	0	CMS clinical review.
		ER029	film alternator (motorized film viewbox).	NF		77	72	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, assure appropriate medical records are available.	5	3	Standardized time input.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	5	3	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L041B	Radiologic Technologist.	NF	Prepare room, equipment, supplies (including imaging equipment).	7	5	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Prepare and position patient/ monitor patient/ set up IV.	5	2	Standardized time input.
		SB048	sheath-cover, sterile, 96in x 6in (transducer).	NF		1	0	CMS clinical review.
		SB048	sheath-cover, sterile, 96in x 6in (transducer).	NF		1	0	CMS clinical review.
		SD147	catheter, (Glide)	NF		1	0	CMS clinical review.
		SD252	guidewire, Amplatz wire 260 cm.	NF		1	0	CMS clinical review.
		SH065	sodium chloride 0.9% flush syringe.	NF		2	0	CMS clinical review.
47600	Removal of gallbladder.	SA053	pack, post-op incision care (suture & staple).	F		1	0	CMS clinical review.
		SA054	pack, post-op incision care (suture).	F		0	1	CMS clinical review.
47605	Removal of gallbladder.	SA053	pack, post-op incision care (suture & staple).	F		1	0	CMS clinical review.
		SA054	pack, post-op incision care (suture).	F		0	1	CMS clinical review.
50590	Fragmenting of kidney stone.	EL014	room, radiographic-fluoroscopic.	NF		86	0	Consistent with the AMA RUC's CY2011 recommendation.
		EQ175	lithotriptor, with C-arm (ESWL).	NF		86	67	Refined equipment time to reflect typical use exclusive to patient.
52214	Cystoscopy and treatment.	EF027	table, instrument, mobile.	NF		100	65	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		100	65	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		100	65	Refined equipment time to reflect typical use exclusive to patient.
		EQ153	laser (gs, uro, obg, ge) (Indigo Optima).	NF		100	65	Refined equipment time to reflect typical use exclusive to patient.
		EQ167	light source, xenon.	NF		100	65	Refined equipment time to reflect typical use exclusive to patient.
		ES006	endoscope forceps, biopsy.	NF		100	65	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		ES007	endoscope forceps, grasping.	NF		100	65	Refined equipment time to reflect typical use exclusive to patient.
		ES018	fiberscope, flexible, cystoscopy.	NF		100	92	Refined equipment time to reflect typical use exclusive to patient.
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		100	65	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Review Chart	3	0	CMS clinical review.
		SB019	drape-towel, sterile 18in x 26in.	NF		1	0	Duplicative.
		SB024	gloves, sterile	NF		0	1	CMS clinical review.
		SD270	Penis clamp	NF		1	0	Not a disposable supply.
		SH047	lidocaine 1%–2% inj (Xylocaine).	NF		50	0	Duplicative.
52224	Cystoscopy and treatment.	EF027	table, instrument, mobile.	NF		105	67	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		105	67	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		105	67	Refined equipment time to reflect typical use exclusive to patient.
		EQ153	laser (gs, uro, obg, ge) (Indigo Optima).	NF		105	67	Refined equipment time to reflect typical use exclusive to patient.
		EQ167	light source, xenon.	NF		105	67	Refined equipment time to reflect typical use exclusive to patient.
		ES006	endoscope forceps, biopsy.	NF		105	67	Refined equipment time to reflect typical use exclusive to patient.
		ES007	endoscope forceps, grasping.	NF		105	67	Refined equipment time to reflect typical use exclusive to patient.
		ES018	fiberscope, flexible, cystoscopy.	NF		105	94	Refined equipment time to reflect typical use exclusive to patient.
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		105	67	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Review Chart	3	0	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Prepare biopsy Specimen.	5	2	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SB019	drape-towel, sterile 18in x 26in.	NF		1	0	Duplicative.
		SB024	gloves, sterile	NF		3	1	CMS clinical review.
		SD270	Penis clamp	NF		1	0	Not a disposable according to submitted invoice.
		SH047	lidocaine 1%–2% inj (Xylocaine).	NF		50	0	Duplicative.
		SL036	cup, biopsy-specimen sterile 4oz.	NF		6	3	CMS clinical review.
52287	Cystoscopy chemodenervation.	EF027	table, instrument, mobile.	NF		78	49	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		78	49	Refined equipment time to reflect typical use exclusive to patient.
		EQ170	light, fiberoptic headlight w-source.	NF		78	49	Refined equipment time to reflect typical use exclusive to patient.
		ES018	fiberscope, flexible, cystoscopy.	NF		78	76	Refined equipment time to reflect typical use exclusive to patient.
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		78	49	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	20	21	Conforming to physician time.
		SH048	lidocaine 2% jelly, topical (Xylocaine).	NF		10	0	Duplicative.
53850	Prostatic microwave thermotx.	EF020	stretcher, endoscopy.	NF		99	85	Refined equipment time to reflect typical use exclusive to patient.
		EF027	table, instrument, mobile.	NF		99	85	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		169	152	Refined equipment time to reflect typical use exclusive to patient.
		EQ037	TUMT system control unit.	NF		99	85	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		169	152	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	F		169	152	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EQ250	ultrasound unit, portable.	NF		99	85	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Prepare room, equipment, supplies.	2	4	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Setup ultrasound probe.	5	0	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Setup TUMT machine.	5	0	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Clean TUMT machine.	3	0	CMS clinical review.
		SB022	gloves, non-sterile	NF		3	2	CMS clinical review.
		SB024	gloves, sterile	NF		3	2	CMS clinical review.
		SH047	lidocaine 1%–2% inj (Xylocaine).	NF		3	30	CMS clinical review.
64612	Destroy nerve face muscle.	EL006	lane, screening (oph).	F		39	27	Refined equipment time to reflect typical use exclusive to patient.
		EL006	lane, screening (oph).	NF		48	45	Refined equipment time to reflect typical use exclusive to patient.
		SC031	needle, 30g	F		0	1	CMS clinical review.
64615	Chemodenerv musc migraine.	EF023	table, exam	NF		24	18	Refined equipment time to reflect typical use exclusive to patient.
65800	Drainage of eye	E7111	Lane, Screening	NF		21	22	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		21	22	Refined equipment time to reflect typical use exclusive to patient.
67810	Biopsy eyelid & lid margin.	EF014	light, surgical	NF		20	22	Refined equipment time to reflect typical use exclusive to patient.
		EF031	table, power	NF		20	22	Refined equipment time to reflect typical use exclusive to patient.
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		1	22	Refined equipment time to reflect typical use exclusive to patient.
		EQ137	instrument pack, basic ($500–$1499).	NF		1	30	Refined equipment time to reflect typical use exclusive to patient.
		SB011	drape, sterile, fenestrated 16in x 29in.	NF		0	1	CMS clinical review.
		SB019	drape-towel, sterile 18in x 26in.	NF		4	1	CMS clinical review.
		SC029	needle, 18–27g	NF		1	0	Standardized time input.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
72040	X-ray exam neck spine 3/<vws.	ED025	film processor, wet.	NF		20	4	Refined equipment time to reflect typical use exclusive to patient.
		EL012	room, basic radiology.	NF		20	13	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		20	4	Refined equipment time to reflect typical use exclusive to patient.
			Film jacket or jacket insert.	NF		1	0	Non-standard direct practice expense input.
72050	X-ray exam neck spine 4/5vws.	ED025	film processor, wet.	NF		28	6	Refined equipment time to reflect typical use exclusive to patient.
		EL012	room, basic radiology.	NF		28	19	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		28	6	Refined equipment time to reflect typical use exclusive to patient.
			Film jacket or jacket insert.	NF		1	0	Non-standard direct practice expense input.
72052	X-ray exam neck spine 6/>vws.	ED025	film processor, wet.	NF		36	8	Refined equipment time to reflect typical use exclusive to patient.
		EL012	room, basic radiology.	NF		36	25	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		36	8	Refined equipment time to reflect typical use exclusive to patient.
			Film jacket or jacket insert.	NF		1	0	Non-standard direct practice expense input.
72191	Ct angiograph pelv w/o&w/dye.	EL007	room, CT	NF		101	40	Refined equipment time to reflect typical use exclusive to patient.
		L041B	Radiologic Technologist.	NF	—Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information.	0	5	CMS Clinical Review.
		L041B	Radiologic Technologist.	NF	Greet patient, provide gowning, assure appropriate medical records are available.	0	3	CMS Clinical Review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L041B	Radiologic Technologist.	NF	Education/instruction/counseling/ obtain consent.	0	2	CMS Clinical Review.
		L041B	Radiologic Technologist.	NF	Prepare room, equipment, supplies.	0	2	Standardized time input.
		L041B	Radiologic Technologist.	NF	Prepare and position patient/ monitor patient/ set up IV.	0	7	CMS Clinical Review.
		L041B	Radiologic Technologist.	NF	Aquire images	0	28	CMS Clinical Review.
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	0	3	CMS Clinical Review.
		L046A	CT Technologist	NF	—Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information.	5	0	CMS Clinical Review.
		L046A	CT Technologist	NF	Greet patient, provide gowning, assure appropriate medical records are available.	3	0	CMS Clinical Review.
		L046A	CT Technologist	NF	Education/instruction/counseling/ obtain consent.	2	0	CMS Clinical Review.
		L046A	CT Technologist	NF	Prepare room, equipment, supplies.	5	0	CMS Clinical Review.
		L046A	CT Technologist	NF	Prepare and position patient/ monitor patient/ set up IV.	7	0	CMS Clinical Review.
		L046A	CT Technologist	NF	Aquire images	28	0	CMS Clinical Review.
		L046A	CT Technologist	NF	Clean room/equipment by physician staff.	3	0	CMS Clinical Review.
		SK016	computer media, optical disk 2.6gb.	NF		1	0.1	CMS clinical review.
72192	Ct pelvis w/o dye	ED024	film processor, dry, laser.	NF		5	0	CMS clinical review.
		ED032	printer, laser, paper.	NF		0	5	CMS clinical review.
		EL007	room, CT	NF		45	22	CMS clinical review.
		L046A	CT Technologist	NF	Pre-Service Period.	6	4	CMS clinical review.
		SK013	computer media, dvd.	NF		1	0	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		0	0.1	CMS clinical review.
		SK076	slide sleeve (photo slides).	NF		0	1	CMS clinical review.
		SK091	x-ray envelope	NF		1	0	CMS clinical review.
		SK098	film, x-ray, laser print.	NF		4	8	CMS clinical review.
72193	Ct pelvis w/dye	ED024	film processor, dry, laser.	NF		5	0	CMS clinical review.
		ED032	printer, laser, paper.	NF		0	5	CMS clinical review.
		EL007	room, CT	NF		40	32	CMS clinical review.
		L046A	CT Technologist	NF	Pre-Service Period.	7	4	CMS clinical review.
		L046A	CT Technologist	NF	Service Period	40	43	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SB006	drape, non-sterile, sheet 40in x 60in.	NF		1	0	CMS clinical review.
		SB014	drape, sterile, three-quarter sheet.	NF		0	1	CMS clinical review.
		SC001	angiocatheter 14g–24g.	NF		1	0	CMS clinical review.
		SC002	angiocatheter set	NF		0	1	CMS clinical review.
		SC025	needle, 14–20g, biopsy.	NF		0	1	CMS clinical review.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SC059	syringe, 25ml (MRI power injector).	NF		0	1	CMS clinical review.
		SG059	oto-wick	NF		0	6	CMS clinical review.
		SG068	plaster bandage (4in x 5yd uou).	NF		1	0	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		6	0	CMS clinical review.
		SH065	sodium chloride 0.9% flush syringe.	NF		0	15	CMS clinical review.
		SK013	computer media, dvd.	NF		1	0	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		0	0.1	CMS clinical review.
		SK076	slide sleeve (photo slides).	NF		0	1	CMS clinical review.
		SK091	x-ray envelope	NF		1	0	CMS clinical review.
72194	Ct pelvis w/o & w/ dye.	ED024	film processor, dry, laser.	NF		10	7	CMS clinical review.
		EL007	room, CT	NF		54	39	CMS clinical review.
		ER029	film alternator (motorized film viewbox).	NF		10	7	CMS clinical review.
		L046A	CT Technologist	NF	Pre-Service Period.	7	4	CMS clinical review.
		L046A	CT Technologist	NF	Service Period	54	52	CMS clinical review.
		SC025	needle, 14–20g, biopsy.	NF		0	1	CMS clinical review.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SK013	computer media, dvd.	NF		1	0	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		0	0.1	CMS clinical review.
		SK076	slide sleeve (photo slides).	NF		0	1	CMS clinical review.
		SK091	x-ray envelope	NF		1	0	CMS clinical review.
		SK098	film, x-ray, laser print.	NF		0	8	CMS clinical review.
73221	Mri joint upr extrem w/o dye.	ED024	film processor, dry, laser.	NF		63	33	Refined equipment time to reflect typical use exclusive to patient.
		EL008	room, MR	NF		63	33	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		63	33	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L047A	MRI Technologist	NF	Prepare room, equipment, supplies.	5	3	CMS clinical review.
		L047A	MRI Technologist	NF	Prepare and position patient/ monitor patient/ set up IV.	3	2	Standardized time input.
		L047A	MRI Technologist	NF	Escort patient from exam room due to magnetic sensitivity.	2	0	Non-standard direct practice expense input.
			Insert folder	NF		1	0	Non-standard direct practice expense input.
73721	Mri jnt of lwr extre w/o dye.	ED024	film processor, dry, laser.	NF		63	33	Refined equipment time to reflect typical use exclusive to patient.
		EL008	room, MR	NF		63	33	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		63	33	Refined equipment time to reflect typical use exclusive to patient.
		L047A	MRI Technologist	NF	Prepare room, equipment, supplies.	5	3	CMS clinical review.
		L047A	MRI Technologist	NF	Prepare and position patient/ monitor patient/ set up IV.	3	2	Standardized time input.
		L047A	MRI Technologist	NF	Escort patient from exam room due to magnetic sensitivity.	2	0	Non-standard direct practice expense input.
			Insert folder	NF		1	0	Non-standard direct practice expense input.
74150	Ct abdomen w/o dye.	ED024	film processor, dry, laser.	NF		5	0	CMS clinical review.
		ED032	printer, laser, paper.	NF		0	5	CMS clinical review.
		EL007	room, CT	NF		32	22	CMS clinical review.
		L046A	CT Technologist	NF	Pre-Service Period.	6	4	CMS clinical review.
		SK013	computer media, dvd.	NF		1	0	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		0	0.1	CMS clinical review.
		SK076	slide sleeve (photo slides).	NF		0	1	CMS clinical review.
		SK091	x-ray envelope	NF		1	0	CMS clinical review.
		SK098	film, x-ray, laser print.	NF		4	8	CMS clinical review.
74160	Ct abdomen w/ dye.	ED024	film processor, dry, laser.	NF		7	0	CMS clinical review.
		ED032	printer, laser, paper.	NF		0	5	CMS clinical review.
		EL007	room, CT	NF		47	32	CMS clinical review.
		ER029	film alternator (motorized film viewbox).	NF		7	5	CMS clinical review.
		L046A	CT Technologist	NF	Pre-Service Period.	7	4	CMS clinical review.
		L046A	CT Technologist	NF	Service Period	47	43	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SB006	drape, non-sterile, sheet 40in x 60in.	NF		1	0	CMS clinical review.
		SB014	drape, sterile, three-quarter sheet.	NF		0	1	CMS clinical review.
		SC001	angiocatheter 14g–24g.	NF		1	0	CMS clinical review.
		SC002	angiocatheter set	NF		0	1	CMS clinical review.
		SC025	needle, 14–20g, biopsy.	NF		0	1	CMS clinical review.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SC059	syringe, 25ml (MRI power injector).	NF		0	1	CMS clinical review.
		SG059	oto-wick	NF		0	1	CMS clinical review.
		SG075	tape, elastic, 1in (Elastoplast, Elasticon) (5yd uou).	NF		0	6	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		6	0	CMS clinical review.
		SH065	sodium chloride 0.9% flush syringe.	NF		0	15	CMS clinical review.
		SH068	sodium chloride 0.9% inj bacteriostatic (30ml uou).	NF		1	0	CMS clinical review.
		SK013	computer media, dvd.	NF		1	0	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		0	0.1	CMS clinical review.
		SK076	slide sleeve (photo slides).	NF		0	1	CMS clinical review.
		SK091	x-ray envelope	NF		1	0	CMS clinical review.
		SK098	film, x-ray, laser print.	NF		6	4	CMS clinical review.
74170	Ct abdomen w/o & w/dye.	ED024	film processor, dry, laser.	NF		15	7	Refined equipment time to reflect typical use exclusive to patient.
		EL007	room, CT	NF		65	39	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		15	7	Refined equipment time to reflect typical use exclusive to patient.
		L046A	CT Technologist	NF	—Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information and confirm contrast protocol with interpreting MD.	7	4	CMS clinical review.
		L046A	CT Technologist	NF	Assist physician in performing procedure.	32	27	CMS clinical review.
		L046A	CT Technologist	NF	Image Post Processing.	15	7	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SB006	drape, non-sterile, sheet 40in x 60in.	NF		1	0	CMS clinical review.
		SB014	drape, sterile, three-quarter sheet.	NF		0	1	CMS clinical review.
		SC001	angiocatheter 14g–24g.	NF		1	0	CMS clinical review.
		SC002	angiocatheter set	NF		0	1	CMS clinical review.
		SC025	needle, 14–20g, biopsy.	NF		0	1	CMS clinical review.
		SC029	needle, 18–27g	NF		1	0	CMS clinical review.
		SC059	syringe, 25ml (MRI power injector).	NF		0	1	CMS clinical review.
		SG075	tape, elastic, 1in (Elastoplast, Elasticon) (5yd uou).	NF		0	6	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		6	0	CMS clinical review.
		SH016	barium suspension (Polibar).	NF		900	0	CMS clinical review.
		SH065	sodium chloride 0.9% flush syringe.	NF		0	15	CMS clinical review.
		SH068	sodium chloride 0.9% inj bacteriostatic (30ml uou).	NF		1	0	CMS clinical review.
		SK013	computer media, dvd.	NF		1	0	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		0	0.1	CMS clinical review.
		SK050	neurobehavioral status forms, average.	NF		0	1	CMS clinical review.
		SK076	slide sleeve (photo slides).	NF		0	1	CMS clinical review.
		SK091	x-ray envelope	NF		1	0	CMS clinical review.
		SK098	film, x-ray, laser print.	NF		14	8	CMS clinical review.
74175	Ct angio abdom w/o & w/dye.	EL007	room, CT	NF		101	40	Refined equipment time to reflect typical use exclusive to patient.
		L041B	Radiologic Technologist.	NF	—Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information.	0	5	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Greet patient, provide gowning, assure appropriate medical records are available.	0	3	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Education/instruction/counseling/obtain consent.	0	2	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Prepare room, equipment, supplies.	0	2	Standardized time input.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L041B	Radiologic Technologist.	NF	Prepare and position patient/ monitor patient/ set up IV.	0	7	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Aquire images	0	28	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	0	3	CMS clinical review.
		L046A	CT Technologist	NF	—Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information.	5	0	CMS clinical review.
		L046A	CT Technologist	NF	Greet patient, provide gowning, assure appropriate medical records are available.	3	0	CMS clinical review.
		L046A	CT Technologist	NF	Education/instruction/counseling/ obtain consent.	2	0	CMS clinical review.
		L046A	CT Technologist	NF	Prepare room, equipment, supplies.	5	0	CMS clinical review.
		L046A	CT Technologist	NF	Prepare and position patient/ monitor patient/ set up IV.	7	0	CMS clinical review.
		L046A	CT Technologist	NF	Aquire images	28	0	CMS clinical review.
		L046A	CT Technologist	NF	Clean room/equipment by physician staff.	3	0	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		1	0.1	CMS clinical review.
74176	Ct abd & pelvis	ED032	printer, laser, paper.	NF		8	7	CMS clinical review.
		ER029	film alternator (motorized film viewbox).	NF		27	7	CMS clinical review.
		L046A	CT Technologist	NF	Service Period	40	39	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		0	0.1	CMS clinical review.
		SK076	slide sleeve (photo slides).	NF		0	1	CMS clinical review.
74177	Ct abd & pelv w/ contrast.	ED032	printer, laser, paper.	NF		10	7	CMS clinical review.
		EL007	room, CT	NF		42	39	CMS clinical review.
		ER029	film alternator (motorized film viewbox).	NF		42	7	CMS clinical review.
		L046A	CT Technologist	NF	Pre-Service Period.	7	6	CMS clinical review.
		L046A	CT Technologist	NF	Service Period	58	52	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		0	0.1	CMS clinical review.
		SK076	slide sleeve (photo slides).	NF		0	1	CMS clinical review.
		SK098	film, x-ray, laser print.	NF		10	8	CMS clinical review.
74178	Ct abd & pelv 1/> regns.	ED032	printer, laser, paper.	NF		20	10	CMS clinical review.
		EL007	room, CT	NF		57	48	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		ER029	film alternator (motorized film viewbox).	NF		57	10	CMS clinical review.
		L046A	CT Technologist	NF	Pre-Service Period.	7	6	CMS clinical review.
		L046A	CT Technologist	NF	Service Period	83	64	CMS clinical review.
		SK016	computer media, optical disk 2.6gb.	NF		0	0.1	CMS clinical review.
		SK076	slide sleeve (photo slides).	NF		0	1	CMS clinical review.
		SK098	film, x-ray, laser print.	NF		23	16	CMS clinical review.
76830	Transvaginal us non-ob.	ED024	film processor, dry, laser.	NF		5	0	CMS clinical review.
		ED032	printer, laser, paper.	NF		1	0	CMS clinical review.
		EF027	table, instrument, mobile.	NF		0	36	Refined equipment time to reflect typical use exclusive to patient.
		EF034	table, ultrasound	NF		0	36	Refined equipment time to reflect typical use exclusive to patient.
		EL015	room, ultrasound, general.	NF		37	0	CMS clinical review.
		EQ250	ultrasound unit, portable.	NF		0	36	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		10	0	CMS clinical review.
		ER086	ultrasound probe	NF		0	37	Refined equipment time to reflect typical use exclusive to patient.
		L051B	RN/Diagnostic Medical Sonographer.	NF	Clean room/equipment by physician staff.	3	2	CMS clinical review.
		SB026	gown, patient	NF		0	1	CMS clinical review.
		SJ033	lubricating jelly (Surgilube).	NF		1	0	CMS clinical review.
76872	Us transrectal	EF027	table, instrument, mobile.	NF		68	34	Refined equipment time to reflect typical use exclusive to patient.
		EF034	table, ultrasound	NF		68	34	Refined equipment time to reflect typical use exclusive to patient.
		EQ250	ultrasound unit, portable.	NF		68	34	Refined equipment time to reflect typical use exclusive to patient.
		ER086	ultrasound probe	NF		68	35	Refined equipment time to reflect typical use exclusive to patient.
		L051B	RN/Diagnostic Medical Sonographer.	NF	Retrieve prior images for comparison:	0	3	CMS clinical review.
		L051B	RN/Diagnostic Medical Sonographer.	NF	Review Chart	3	0	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L051B	RN/Diagnostic Medical Sonographer.	NF	Obtain vital signs	3	0	CMS clinical review.
		L051B	RN/Diagnostic Medical Sonographer.	NF	Prepare room, equipment, supplies.	2	3	CMS clinical review.
		L051B	RN/Diagnostic Medical Sonographer.	NF	Prepare ultrasound probe.	5	0	CMS clinical review.
		L051B	RN/Diagnostic Medical Sonographer.	NF	Obtain vital signs	3	0	CMS clinical review.
		L051B	RN/Diagnostic Medical Sonographer.	NF	Clean room/equipment by physician staff.	3	2	CMS clinical review.
		SB012	drape, sterile, for Mayo stand.	NF		1	0	CMS clinical review.
		SC019	iv tubing (extension).	NF		1	0	CMS clinical review.
		SH048	lidocaine 2% jelly, topical (Xylocaine).	NF		10	0	CMS clinical review.
		SJ001	alcohol isopropyl 70%.	NF		5	0	CMS clinical review.
		SJ032	lubricating jelly (K-Y) (5gm uou).	NF		2	0	CMS clinical review.
		SM018	glutaraldehyde 3.4% (Cidex, Maxicide, Wavicide).	NF		32	0	CMS clinical review.
		SM019	glutaraldehyde test strips (Cidex, Metrex).	NF		1	0	CMS clinical review.
		SM022	sanitizing cloth-wipe (surface, instruments, equipment).	NF		2	0	CMS clinical review.
77003	Fluoroguide for spine inject.	ED025	film processor, wet.	NF		3	2	Refined equipment time to reflect typical use exclusive to patient.
		EL014	room, radiographic-fluoroscopic.	NF		9	18	Refined equipment time to reflect typical use exclusive to patient.
		ER029	film alternator (motorized film viewbox).	NF		3	2	Refined equipment time to reflect typical use exclusive to patient.
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	2	1	CMS clinical review.
		L041B	Radiologic Technologist.	NF	Process films, hang films and review study with interpreting MD prior to patient discharge.	3	2	CMS clinical review.
77080	Dxa bone density axial.	ER078	phantom, spine, DXA calibration check.	NF		1	2	Refined equipment time to reflect typical use exclusive to patient.
77301	Radiotherapy dose plan imrt.	ED011	computer system, record and verify.	NF		20	0	CMS clinical review.
		ED033	treatment planning system, IMRT (Corvus w-Peregrine 3D Monte Carlo).	NF		376	330	CMS clinical review.
		ER005	IMRT CT-based simulator.	NF		58	47	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		ER014	chamber, Farmer-type.	NF		45	47	Refined equipment time to reflect typical use exclusive to patient.
		ER028	electrometer, PC-based, dual channel.	NF		45	47	Refined equipment time to reflect typical use exclusive to patient.
		ER050	phantom, solid water calibration check.	NF		45	47	Refined equipment time to reflect typical use exclusive to patient.
		ER089	IMRT accelerator	NF		45	47	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Obtain vital signs	3	0	CMS clinical review.
78012	Thyroid uptake measurement.	EF010	chair, thyroid imaging.	NF		40	30	Refined equipment time to reflect typical use exclusive to patient.
		ER063	thyroid uptake system.	NF		40	30	Refined equipment time to reflect typical use exclusive to patient.
78013	Thyroid imaging w/blood flow.	ER032	gamma camera system, single-dual head.	NF		48	38	Refined equipment time to reflect typical use exclusive to patient.
78014	Thyroid imaging w/blood flow.	EF010	chair, thyroid imaging.	NF		65	55	Refined equipment time to reflect typical use exclusive to patient.
		ER032	gamma camera system, single-dual head.	NF		65	50	Refined equipment time to reflect typical use exclusive to patient.
		ER063	thyroid uptake system.	NF		65	55	Refined equipment time to reflect typical use exclusive to patient.
78070	Parathyroid planar imaging.	ER032	gamma camera system, single-dual head.	NF		73	68	Refined equipment time to reflect typical use exclusive to patient.
78071	Parathyrd planar w/wo subtrj.	ER032	gamma camera system, single-dual head.	NF		86	81	Refined equipment time to reflect typical use exclusive to patient.
86153	Cell enumeration phys interp.	EP106	CELLSEARCH system.	NF		16	0	Laboratory Physician Interpretation Code.
		EP107	Laboratory Information System.	NF		4	0	Laboratory Physician Interpretation Code.
		L045A	Cytotechnologist	NF	Collate images and review with Pathologist.	5	0	Laboratory Physician Interpretation Code.
88120	Cytp urne 3–5 probes ea spec.	EP088	ThermoBrite	NF		107	321	CMS clinical review.
		EP092	Olympus BX41 Fluorescent Microscope (without filters or camera).	NF		1.33	73	CMS clinical review.
88121	Cytp urine 3–5 probes cmptr.	EP088	ThermoBrite	NF		26.75	160.5	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EP090	IkoniScope	NF		2.97	29.7	CMS clinical review.
		EP091	IkoniLan software	NF		2.97	29.7	CMS clinical review.
88300	Surgical path gross.		courier transportation cost.	NF		2.02	0	Indirect Practice Expense.
			Copath System with maintenance contract.	NF		3	0	Indirect Practice Expense.
			Copath software	NF		3	0	Indirect Practice Expense.
88302	Tissue exam by pathologist.		specimen, solvent, and formalin disposal cost.	NF		0.18	0	Indirect Practice Expense.
			courier transportation cost.	NF		2.02	0	Indirect Practice Expense.
			equipment maintenance cost.	NF		0.61	0	Included in equipment cost per minute calculation.
			Copath System with maintenance contract.	NF		3	0	Indirect Practice Expense.
			Copath software	NF		3	0	Indirect Practice Expense.
88304	Tissue exam by pathologist.		specimen, solvent, and formalin disposal cost.	NF		0.35	0	Indirect Practice Expense.
			courier transportation cost.	NF		2.02	0	Indirect Practice Expense.
			equipment maintenance cost.	NF		0.61	0	Included in equipment cost per minute calculation.
			Copath System with maintenance contract.	NF		5	0	Indirect Practice Expense.
			Copath software	NF		5	0	Indirect Practice Expense.
88305	Tissue exam by pathologist.		specimen, solvent, and formalin disposal cost.	NF		0.35	0	Indirect Practice Expense.
			courier transportation cost.	NF		2.02	0	Indirect Practice Expense.
			equipment maintenance cost.	NF		0.61	0	Included in equipment cost per minute calculation.
			Copath System with maintenance contract.	NF		4	0	Indirect Practice Expense.
			Copath software	NF		4	0	Indirect Practice Expense.
88307	Tissue exam by pathologist.		specimen, solvent, and formalin disposal cost.	NF		1.85	0	Indirect Practice Expense.
			courier transportation cost.	NF		2.02	0	Indirect Practice Expense.
			equipment maintenance cost.	NF		0.61	0	Included in equipment cost per minute calculation.
			Copath System with maintenance contract.	NF		10	0	Indirect Practice Expense.
			Copath software	NF		10	0	Indirect Practice Expense.
88309	Tissue exam by pathologist.		specimen, solvent, and formalin disposal cost.	NF		1.85	0	Indirect Practice Expense.
			courier transportation cost.	NF		2.02	0	Indirect Practice Expense.
			equipment maintenance cost.	NF		0.61	0	Included in equipment cost per minute calculation.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
			Copath System with maintenance contract.	NF		12	0	Indirect Practice Expense.
			Copath software	NF		12	0	Indirect Practice Expense.
90791	Psych diagnostic evaluation.			NF				2012 Fully Implemented PE RVUs maintained.
90832	Psytx pt&/family 30 minutes.			NF				2012 Fully Implemented PE RVUs maintained.
90834	Psytx pt&/family 45 minutes.			NF				2012 Fully Implemented PE RVUs maintained.
90836	Psytx pt&/fam w/ e&m 45 min.			NF				2012 Fully Implemented PE RVUs maintained.
91112	Gi wireless capsule measure.	EQ352	Data receiver	NF		7220	2880	CMS clinical review.
		SA048	pack, minimum multi-specialty visit.	NF		1	0	CMS clinical review.
		SK116	SmartBar	NF		1	0	CMS clinical review.
92081	Visual field examination(s).	EL006	lane, screening (oph).	NF		12	17	Refined equipment time to reflect typical use exclusive to patient.
92082	Visual field examination(s).	EL006	lane, screening (oph).	NF		22	27	Refined equipment time to reflect typical use exclusive to patient.
92083	Visual field examination(s).	EL006	lane, screening (oph).	NF		32	37	Refined equipment time to reflect typical use exclusive to patient.
92235	Eye exam with photos.	ED008	camera, retinal (TRC 50IX, w-ICG, filters, motor drives).	NF		60	35	Refined equipment time to reflect typical use exclusive to patient.
		EF030	table, motorized (for instruments-equipment).	NF		60	35	Refined equipment time to reflect typical use exclusive to patient.
		EL005	lane, exam (oph)	NF		60	35	Refined equipment time to reflect typical use exclusive to patient.
		L038A	COMT/COT/RN/CST.	NF	Monitor pt. following service/ check tubes, monitors, drains.	5	2	CMS clinical review.
		L039A	Certified Retinal Angio.	NF	Assist physician in performing procedure.	40	20	CMS clinical review.
93015	Cardiovascular stress test.	EF023	table, exam	NF		58	46	Refined equipment time to reflect typical use exclusive to patient.
		EQ078	cardiac monitor w-treadmill (12-lead PC-based ECG).	NF		58	46	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L051A	RN	NF	Assist physician in performing procedure.	20	14	CMS clinical review.
93017	Cardiovascular stress test.	EF023	table, exam	NF		58	46	Refined equipment time to reflect typical use exclusive to patient.
		EQ078	cardiac monitor w-treadmill (12-lead PC-based ECG).	NF		58	46	Refined equipment time to reflect typical use exclusive to patient.
		L051A	RN	NF	Assist physician in performing procedure.	20	14	CMS clinical review.
		L051A	RN	NF	Complete diagnostic forms, lab & X-ray requisitions.	0	4	CMS clinical review.
93925	Lower extremity study.	ED011	computer system, record and verify.	NF		10	0	CMS clinical review.
		ED021	computer, desktop, w-monitor.	NF		95	7	Refined equipment time to reflect typical use exclusive to patient.
		ED025	film processor, wet.	NF		10	7	Refined equipment time to reflect typical use exclusive to patient.
		ED034	video SVHS VCR (medical grade).	NF		95	0	CMS clinical review.
		EL016	room, ultrasound, vascular.	NF		95	76	Refined equipment time to reflect typical use exclusive to patient.
		ER067	x-ray view box, 4 panel.	NF		10	7	Refined equipment time to reflect typical use exclusive to patient.
		L054A	Vascular Technologist.	NF	Provide pre-service education/ obtain consent.	3	2	CMS clinical review.
		L054A	Vascular Technologist.	NF	Prepare room, equipment, supplies.	3	2	Standardized time input.
		L054A	Vascular Technologist.	NF	Prepare and position patient.	3	2	Standardized time input.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: Collate preliminary data, arrange images, archive.	10	7	CMS clinical review.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: Record patient history.	1	0	CMS clinical review.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: QA documentation.	4	0	CMS clinical review.
		SK086	video tape, VHS	NF		1	0	CMS clinical review.
93926	Lower extremity study.	ED011	computer system, record and verify.	NF		10	0	CMS clinical review.
		ED021	computer, desktop, w-monitor.	NF		59	4	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		ED025	film processor, wet.	NF		10	4	Refined equipment time to reflect typical use exclusive to patient.
		ED034	video SVHS VCR (medical grade).	NF		59	0	CMS clinical review.
		EL016	room, ultrasound, vascular.	NF		59	42	Refined equipment time to reflect typical use exclusive to patient.
		ER067	x-ray view box, 4 panel.	NF		10	4	Refined equipment time to reflect typical use exclusive to patient.
		L054A	Vascular Technologist.	NF	Provide pre-service education/ obtain consent.	3	2	CMS clinical review.
		L054A	Vascular Technologist.	NF	Prepare room, equipment, supplies.	3	2	Standardized time input.
		L054A	Vascular Technologist.	NF	Prepare and position patient.	3	2	Standardized time input.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: Collate preliminary data, arrange images, archive.	8	4	CMS clinical review.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: Record patient history.	1	0	CMS clinical review.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: QA documentation.	4	0	CMS clinical review.
		SK086	video tape, VHS	NF		1	0	CMS clinical review.
93970	Extremity study	ED011	computer system, record and verify.	NF		10	0	CMS clinical review.
		ED021	computer, desktop, w-monitor.	NF		71	7	Refined equipment time to reflect typical use exclusive to patient.
		ED025	film processor, wet.	NF		10	7	Refined equipment time to reflect typical use exclusive to patient.
		ED034	video SVHS VCR (medical grade).	NF		71	0	CMS clinical review.
		EL016	room, ultrasound, vascular.	NF		71	52	Refined equipment time to reflect typical use exclusive to patient.
		ER067	x-ray view box, 4 panel.	NF		10	7	Refined equipment time to reflect typical use exclusive to patient.
		L054A	Vascular Technologist.	NF	Provide pre-service education/ obtain consent.	3	2	CMS clinical review.
		L054A	Vascular Technologist.	NF	Prepare room, equipment, supplies.	3	2	Standardized time input.
		L054A	Vascular Technologist.	NF	Prepare and position patient.	3	2	Standardized time input.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: Collate preliminary data, arrange images, archive.	10	7	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L054A	Vascular Technologist.	NF	Other Clinical Activity: Record patient history.	1	0	CMS clinical review.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: QA documentation.	4	0	CMS clinical review.
		SK086	video tape, VHS	NF		1	0	CMS clinical review.
93971	Extremity study	ED011	computer system, record and verify.	NF		10	0	CMS clinical review.
		ED021	computer, desktop, w-monitor.	NF		45	4	Refined equipment time to reflect typical use exclusive to patient.
		ED025	film processor, wet.	NF		10	4	Refined equipment time to reflect typical use exclusive to patient.
		ED034	video SVHS VCR (medical grade).	NF		45	0	CMS clinical review.
		EL016	room, ultrasound, vascular.	NF		45	30	CMS clinical review.
		ER067	x-ray view box, 4 panel.	NF		10	4	Refined equipment time to reflect typical use exclusive to patient.
		L054A	Vascular Technologist.	NF	Provide pre-service education/ obtain consent.	3	2	CMS clinical review.
		L054A	Vascular Technologist.	NF	Prepare room, equipment, supplies.	3	2	Standardized time input.
		L054A	Vascular Technologist.	NF	Prepare and position patient.	3	2	Standardized time input.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: Collate preliminary data, arrange images, archive.	6	4	CMS clinical review.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: Record patient history.	1	0	CMS clinical review.
		L054A	Vascular Technologist.	NF	Other Clinical Activity: QA documentation.	4	0	CMS clinical review.
		SB006	drape, non-sterile, sheet 40in x 60in.	NF		2	1	CMS clinical review.
		SK086	video tape, VHS	NF		1	0	CMS clinical review.
95076	Ingest challenge ini 120 min.	EF023	table, exam	NF		141	133	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		141	133	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Prepare testing doses.	15	7	CMS clinical review.
95115	Immunotherapy one injection.	EF040	refrigerator, vaccine, commercial grade, w-alarm lock.	NF		15	0	CMS clinical review.
95117	Immunotherapy injections.	EF041	x-ray machine, portable.	NF		17	0	CMS clinical review.
95782	Polysom <6 yrs 4/ > paramtrs.	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF		660	602	Refined equipment time to reflect typical use exclusive to patient.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		EF044	Crib	NF		660	0	CMS clinical review.
		EQ134	impedance meter, 32-channel.	NF		660	602	Refined equipment time to reflect typical use exclusive to patient.
		EQ272	sleep diagnostic system, attended (w-acquisition station, review master, computer).	NF		660	662	Refined equipment time to reflect typical use exclusive to patient.
		EQ348	Capnograph	NF		660	0	CMS clinical review.
		ER088	Infrared illuminator	NF		660	602	Refined equipment time to reflect typical use exclusive to patient.
		L047B	REEGT	NF	Provide pre-service education/ obtain consent.	5	3	CMS clinical review.
		L047B	REEGT	NF	Other Clinical Activity—specify: Set up and calibrate all monitoring and recording equipment (initial), including capnograph (for child).	6	5	CMS clinical review.
		L047B	REEGT	NF	Other Clinical Activity—specify: Measure and mark head and face. Apply and secure electrodes to head and face. Check impedances. Reapply electrodes as needed. (1.5 min per electrode for child, 1 min per electrode for adult).	30	20	CMS clinical review.
		L047B	REEGT	NF	Other Clinical Activity—specify: Apply recording devices for cardio-respiratory, leg movements, body positioning and snoring.	0	15	CMS clinical review.
		L047B	REEGT	NF	Other Clinical Activity—specify: Apply recording devices for cardio-respiratory, leg movements, body positioning, snoring and capnography.	20	0	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L047B	REEGT	NF	Other Clinical Activity—specify: Daytime tech reviews and edits recording, marks artifacts, scores sleep stages, performs evaluation of physiological changes.	100	97	CMS clinical review.
95783	Polysom <6 yrs cpap/bilvl.	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF		660	647	Refined equipment time to reflect typical use exclusive to patient.
		EF044	Crib	NF		660	0	CMS clinical review.
		EQ134	impedance meter, 32-channel.	NF		660	647	Refined equipment time to reflect typical use exclusive to patient.
		EQ272	sleep diagnostic system, attended (w-acquisition station, review master, computer).	NF		660	707	Refined equipment time to reflect typical use exclusive to patient.
		EQ348	Capnograph	NF		660	0	CMS clinical review.
		ER088	Infrared illuminator	NF		660	647	Refined equipment time to reflect typical use exclusive to patient.
		L047B	REEGT	NF	Provide pre-service education/ obtain consent.	5	3	CMS clinical review.
		L047B	REEGT	NF	Other Clinical Activity—specify: Set up and calibrate all monitoring and recording equipment (initial), including capnograph (for child).	6	5	CMS clinical review.
		L047B	REEGT	NF	Other Clinical Activity—specify: Measure and mark head and face. Apply and secure electrodes to head and face. Check impedances. Reapply electrodes as needed. (1.5 min per electrode for child, 1 min per electrode for adult).	30	20	CMS clinical review.
		L047B	REEGT	NF	Other Clinical Activity—specify: Apply recording devices for cardio-respiratory, leg movements, body positioning and snoring.	0	15	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		L047B	REEGT	NF	Other Clinical Activity—specify: Apply recording devices for cardio-respiratory, leg movements, body positioning, snoring and capnography.	20	0	CMS clinical review.
		L047B	REEGT	NF	Other Clinical Activity—specify: Daytime tech reviews and edits recording, marks artifacts, scores sleep stages, performs evaluation of physiological changes.	100	97	CMS clinical review.
95861	Muscle test 2 limbs.	EF023	table, exam	NF		44	41	Refined equipment time to reflect typical use exclusive to patient.
		EQ024	EMG–NCV–EP system, 8 channel.	NF		44	41	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	19	29	Conforming to physician time.
95863	Muscle test 3 limbs.	EF023	table, exam	NF		58	52	Refined equipment time to reflect typical use exclusive to patient.
		EQ024	EMG–NCV–EP system, 8 channel.	NF		58	52	Refined equipment time to reflect typical use exclusive to patient.
95864	Muscle test 4 limbs.	EF023	table, exam	NF		71	62	Refined equipment time to reflect typical use exclusive to patient.
		EQ024	EMG–NCV–EP system, 8 channel.	NF		71	62	Refined equipment time to reflect typical use exclusive to patient.
95865	Muscle test larynx	EF023	table, exam	NF		27	22	Refined equipment time to reflect typical use exclusive to patient.
		EQ024	EMG–NCV–EP system, 8 channel.	NF		27	22	Refined equipment time to reflect typical use exclusive to patient.
95868	Muscle test cran nerve bilat.	EF023	table, exam	NF		35	32	Refined equipment time to reflect typical use exclusive to patient.
		EQ024	EMG–NCV–EP system, 8 channel.	NF		35	32	Refined equipment time to reflect typical use exclusive to patient.
95907	Motor&/sens 1–2 nrv cndj tst.	SG051	gauze, non-sterile 4in x 4in.	NF		0	4	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SG055	gauze, sterile 4in x 4in.	NF		4	0	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		12	0	CMS clinical review.
		SJ022	electrode skin prep gel (NuPrep).	NF		100	0	CMS clinical review.
95908	Motor&/sens 3–4 nrv cndj tst.	SG051	gauze, non-sterile 4in x 4in.	NF		0	8	CMS clinical review.
		SG055	gauze, sterile 4in x 4in.	NF		8	0	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		24	0	CMS clinical review.
		SJ022	electrode skin prep gel (NuPrep).	NF		100	0	CMS clinical review.
95909	Motor&/sens 5–6 nrv cndj tst.	SG051	gauze, non-sterile 4in x 4in.	NF		0	12	CMS clinical review.
		SG055	gauze, sterile 4in x 4in.	NF		12	0	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		36	0	CMS clinical review.
		SJ022	electrode skin prep gel (NuPrep).	NF		100	0	CMS clinical review.
95910	Motor&sens 7–8 nrv cndj test.	L037A	Electrodiagnostic Technologist.	NF		50	40	Conforming to physician time.
		SG051	gauze, non-sterile 4in x 4in.	NF		0	16	CMS clinical review.
		SG055	gauze, sterile 4in x 4in.	NF		16	0	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		48	0	CMS clinical review.
		SJ022	electrode skin prep gel (NuPrep).	NF		100	0	CMS clinical review.
95911	Motor&sen 9–10 nrv cndj test.	L037A	Electrodiagnostic Technologist.	NF		64	50	Conforming to physician time.
		SG051	gauze, non-sterile 4in x 4in.	NF		0	20	CMS clinical review.
		SG055	gauze, sterile 4in x 4in.	NF		20	0	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		60	0	CMS clinical review.
		SJ022	electrode skin prep gel (NuPrep).	NF		100	0	CMS clinical review.
95912	Motor&sen 11–12 nrv cnd test.	L037A	Electrodiagnostic Technologist.	NF		77	60	Conforming to physician time.
		SG051	gauze, non-sterile 4in x 4in.	NF		0	24	CMS clinical review.
		SG055	gauze, sterile 4in x 4in.	NF		24	0	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		72	0	CMS clinical review.
		SJ022	electrode skin prep gel (NuPrep).	NF		100	0	CMS clinical review.
95913	Motor&sens 13/> nrv cnd test.	L037A	Electrodiagnostic Technologist.	NF		87	70	Conforming to physician time.
		SG051	gauze, non-sterile 4in x 4in.	NF		0	26	CMS clinical review.
		SG055	gauze, sterile 4in x 4in.	NF		26	0	CMS clinical review.
		SG079	tape, surgical paper 1in (Micropore).	NF		78	0	CMS clinical review.
		SJ022	electrode skin prep gel (NuPrep).	NF		100	0	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
95921	Autonomic nrv parasym inervj.	EF032	table, tilt (w-trendelenberg).	NF		64	55	Refined equipment time to reflect typical use exclusive to patient.
		EQ051	arterial tonometry acquisition system (WR Testworks).	NF		64	55	Refined equipment time to reflect typical use exclusive to patient.
		EQ052	arterial tonometry monitor (Colin Pilot).	NF		64	55	Refined equipment time to reflect typical use exclusive to patient.
		L037A	Electrodiagnostic Technologist.	NF	Greet patient, provide gowning, assure appropriate medical records are available.	3	0	CMS clinical review.
		L037A	Electrodiagnostic Technologist.	NF	Obtain vital signs	3	0	CMS clinical review.
		L037A	Electrodiagnostic Technologist.	NF	Monitor pt. following service/ check tubes, monitors, drains.	5	2	CMS clinical review.
95922	Autonomic nrv adrenrg inervj.	EF032	table, tilt (w-trendelenberg).	NF		79	70	Refined equipment time to reflect typical use exclusive to patient.
		EQ051	arterial tonometry acquisition system (WR Testworks).	NF		79	70	Refined equipment time to reflect typical use exclusive to patient.
		EQ052	arterial tonometry monitor (Colin Pilot).	NF		79	70	Refined equipment time to reflect typical use exclusive to patient.
		L037A	Electrodiagnostic Technologist.	NF	Greet patient, provide gowning, assure appropriate medical records are available.	3	0	CMS clinical review.
		L037A	Electrodiagnostic Technologist.	NF	Obtain vital signs	3	0	CMS clinical review.
		L037A	Electrodiagnostic Technologist.	NF	Monitor pt. following service/ check tubes, monitors, drains.	5	2	CMS clinical review.
95923	Autonomic nrv syst funj test.	EQ035	QSART acquisition system (Q-Sweat).	NF		74	61	Refined equipment time to reflect typical use exclusive to patient.
		EQ124	stimulator, constant current, w-stimulating and grounding electrodes (Grass Telefactor).	NF		74	61	Refined equipment time to reflect typical use exclusive to patient.
		EQ171	light, infra-red, ceiling mount.	NF		74	61	Refined equipment time to reflect typical use exclusive to patient.
		L037A	Electrodiagnostic Technologist.	NF	Assist physician in performing procedure.	55	45	CMS clinical review.
		L037A	Electrodiagnostic Technologist.	NF	Monitor pt. following service/ check tubes, monitors, drains.	5	2	CMS clinical review.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
		SJ020	electrode conductive gel.	NF		5	0	CMS clinical review.
95924	Ans parasymp & symp w/tilt.	EF032	table, tilt (w-trendelenberg).	NF		79	76	Refined equipment time to reflect typical use exclusive to patient.
		EQ051	arterial tonometry acquisition system (WR Testworks).	NF		79	76	Refined equipment time to reflect typical use exclusive to patient.
		EQ052	arterial tonometry monitor (Colin Pilot).	NF		79	76	Refined equipment time to reflect typical use exclusive to patient.
		L037A	Electrodiagnostic Technologist.	NF	Monitor pt. following service/ check tubes, monitors, drains.	5	2	CMS clinical review.
96920	Laser tx skin < 250 sq cm.	EF031	table, power	NF		20	26	Refined equipment time to reflect typical use exclusive to patient.
		EQ161	laser, excimer	NF		20	26	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		17	26	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/ check tubes, monitors, drains.	3	1	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff.	3	2	CMS clinical review.
		SF028	laser tip (single use).	NF		1	0	CMS clinical review.
		SJ029	ice pack, instant	NF		4	1	CMS Code correction.
96921	Laser tx skin 250–500 sq cm.	EF031	table, power	NF		23	29	Refined equipment time to reflect typical use exclusive to patient.
		EQ161	laser, excimer	NF		23	29	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		23	29	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/ check tubes, monitors, drains.	3	1	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff.	3	2	CMS clinical review.
		SF028	laser tip (single use).	NF		1	0	CMS clinical review.
		SJ029	ice pack, instant	NF		4	2	CMS Code correction.

TABLE 74—CPT CODES WITH REFINED DIRECT PE RECOMMENDATIONS FOR CY 2013 INTERIM CODES—Continued

CPT code	CPT code description	CMS code	CMS code description	Nonfactor/ factor	Labor activity (if applicable)	AMA RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment
96922	Laser tx skin >500 sq cm.	EF031	table, power	NF		33	39	Refined equipment time to reflect typical use exclusive to patient.
		EQ161	laser, excimer	NF		33	39	Refined equipment time to reflect typical use exclusive to patient.
		EQ168	light, exam	NF		30	39	Refined equipment time to reflect typical use exclusive to patient.
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/ check tubes, monitors, drains.	3	1	CMS clinical review.
		L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff.	3	2	CMS clinical review.
		SF028	laser tip (single use).	NF		1	0	CMS clinical review.
97150	Group therapeutic procedures.	EQ248	ultrasonic biometry, pachymeter.	NF		10	5	Refined equipment time to reflect typical use exclusive to patient.
		EQ269	blood pressure monitor, ambulatory, w-battery charger.	NF		1	0	CMS clinical review.
		SA007	kit, cooking activity ingredients (mac-cheese).	NF		1	0	CMS clinical review.
99495	Trans care mgmt 14 day disch.	L042A	RN/LPN	F	communication (with patient, family members, guardian or caretaker, surrogate decision makers, and/or other professionals) regarding aspects of care, etc.	0	45	CMS clinical review.
99496	Trans care mgmt 7 day disch.	L042A	RN/LPN	NF	communication (with patient, family members, guardian or caretaker, surrogate decision makers, and/or other professionals) regarding aspects of care, etc.	60	70	CMS clinical review.
				F		0	70	CMS clinical review

c. Establishing CY 2013 Interim Final Malpractice Crosswalks

According to our malpractice methodology discussed in section III.C.1 of this CY 2013 PFS final rule with comment period, we have assigned malpractice RVUs for CY 2013 new and revised codes by utilizing a crosswalk to a source code with a similar malpractice risk-of-service. We have reviewed the AMA RUC-recommended malpractice source code crosswalks for CY 2013 new and revised codes, and we are accepting all of them on an interim final basis for CY 2013.

For CY 2013, we created several HCPCS G-codes. HCPCS code G0452 (Molecular pathology procedure; physician interpretation and report) was created to replace CPT code 83912 (Molecular diagnostics; interpretation and report), which is deleted effective January 1, 2013. We believe CPT code 83912 has a similar malpractice risk-of-service as HCPCS code G0452. Therefore, we are assigning an interim final malpractice crosswalk of CPT code 83912 to HCPCS code G0452 on an interim final basis for CY 2013.

For CY 2013, we created HCPCS code G0453 (Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient), each 15 minutes) to replace new CPT code 95941 (Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour) which will have a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services) for CY 2013, as discussed in section III.M.3.a. of this CY 2013 PFS final rule with comment period. The AMA RUC recommended a malpractice crosswalk of CPT code 95920 (Intraoperative neurophysiology testing, per hour (List separately in addition to code for primary procedure)) for CPT code 95941. We believe CPT code 95920 has a similar malpractice risk-of-service as HCPCS code G0453. Therefore, we are assigning an interim final malpractice crosswalk of CPT code 95920 to HCPCS code G0453 for CY 2013.

For CY 2013, we created HCPCS code G0454 (Physician documentation of face-to-face visit for Durable Medical Equipment determination performed by Nurse Practitioner, Physician Assistant or Clinical Nurse Specialist) for payment to a physician who documents that a PA, NP, or CNS practitioner has performed a face-to-face encounter for the list of specified DME covered items. As discussed in section IV.C. of this CY 2013 PFS final rule with comment period, we have assigned HCPCS code G0454 a work RVU of 0.18, which is a crosswalk to CPT code 99211 (Level 1 office or other outpatient visit, established patient). We believe CPT code 99211 has a similar malpractice risk-of-service as HCPCS code G0454. Therefore, we are assigning an interim final malpractice crosswalk of CPT code 99211 to HCPCS code G0454 for CY 2013.

For CY 2013, we created HCPCS code G0455 (Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen) to replace new CPT code 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen) which will have a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services) for CY 2013, as discussed in section III.M.3.a. of this CY 2013 PFS final rule with comment period. The AMA RUC recommended a malpractice crosswalk of CPT code 91065 (Breath hydrogen test (eg, for detection of lactase deficiency, fructose intolerance, bacterial overgrowth, or oro-cecal gastrointestinal transit) for CPT code 44705. We believe CPT code 91065 has a similar malpractice risk-of-service as HCPCS code G0455. Therefore, we are assigning an interim final malpractice crosswalk of CPT code 91065 to HCPCS code G0455 for CY 2013.

In accordance with our malpractice methodology, we have adjusted the malpractice RVUs of the CY 2013 new/revised codes for the difference in work RVUs (or, if greater, the clinical labor portion of the fully implemented PE RVUs) between the source code and the new/revised codes to reflect the specific risk-of-service for the new/revised codes. Table 75 lists the CY 2012 new/revised HCPCS codes and their respective source codes used to set the interim final CY 2013 malpractice RVUs. Revised CPT codes that are crosswalked to themselves (that is, CPT code 11300 to 11300) are not listed. The malpractice RVUs for these services are reflected in Addendum B of this CY 2013 PFS final rule with comment period.

TABLE 75—MALPRACTICE CROSSWALKS FOR CY 2013 NEW/REVISED CODES USED TO ESTABLISH MALPRACTICE RVUS

CY 2013 new, revised, or potentially misvalued HCPCS code		Malpractice risk factor crosswalk HCPCS code	
22586	Prescrl fuse w/instr l5/s1	22558	Lumbar spine fusion.
23473	Revis reconst shoulder joint	23472	Reconstruct shoulder joint.
23474	Revis reconst shoulder joint	23210	Resect scapula tumor.
24370	Revise reconst elbow joint	24363	Replace elbow joint.
24371	Revise reconst elbow joint	24363	Replace elbow joint.
31647	Bronchial valve init insert	31636	Bronchoscopy bronch stents.
31648	Bronchial valve addl insert	31638	Bronchoscopy revise stent.
31649	Bronchial valve remov init	31637	Bronchoscopy stent add-on.
31651	Bronchial valve remov addl	31637	Bronchoscopy stent add-on.
31660	Bronch thermoplsty 1 lobe	31636	Bronchoscopy bronch stents.
31661	Bronch thermoplsty 2/> lobes	31638	Bronchoscopy revise stent.
32551	Insertion of chest tube	19260	Removal of chest wall lesion.
32554	Aspirate pleura w/o imaging	32421	Thoracentesis for aspiration.
32555	Aspirate pleura w/imaging	32422	Thoracentesis w/tube insert.
32556	Insert cath pleura w/o image	32422	Thoracentesis w/tube insert.
32557	Insert cath pleura w/image	32551	Insertion of chest tube.
32701	Thorax stereo rad targetw/tx	33468	Revision of tricuspid valve.
33361	Replace aortic valve perq	33880	Endovasc taa repr incl subcl.
33362	Replace aortic valve open	33880	Endovasc taa repr incl subcl.
33363	Replace aortic valve open	33880	Endovasc taa repr incl subcl.
33364	Replace aortic valve open	33880	Endovasc taa repr incl subcl.
33365	Replace aortic valve open	33979	Insert intracorporeal device.
33367	Replace aortic valve w/byp	33979	Insert intracorporeal device.
33368	Replace aortic valve w/byp	33979	Insert intracorporeal device.
33369	Replace aortic valve w/byp	33305	Repair of heart wound.
33990	Insert vad artery access	33240	Insrt pulse gen w/singl lead.
33991	Insert vad art&vein access	33240	Insrt pulse gen w/singl lead.
33992	Remove vad different session	33240	Insrt pulse gen w/singl lead.
33993	Reposition vad diff session	33240	Insrt pulse gen w/singl lead.
36221	Place cath thoracic aorta	36200	Place catheter in aorta.
36222	Place cath carotid/inom art	36216	Place catheter in artery.
36223	Place cath carotid/inom art	36216	Place catheter in artery.
36224	Place cath carotd art	36217	Place catheter in artery.

TABLE 75—MALPRACTICE CROSSWALKS FOR CY 2013 NEW/REVISED CODES USED TO ESTABLISH MALPRACTICE RVUS—Continued

36225	Place cath subclavian art	36215	Place catheter in artery.
36226	Place cath vertebral art	36217	Place catheter in artery.
36227	Place cath xtrnl carotid	36218	Place catheter in artery.
36228	Place cath intracranial art	36218	Place catheter in artery.
37197	Remove intrvas foreign body	37183	Remove hepatic shunt (tips).
37211	Thrombolytic art therapy	37184	Prim art mech thrombectomy.
37212	Thrombolytic venous therapy	37184	Prim art mech thrombectomy.
37213	Thromblytic art/ven therapy	37184	Prim art mech thrombectomy.
37214	Cessj therapy cath removal	37184	Prim art mech thrombectomy.
38243	Transplj hematopoietic boost	38242	Lymphocyte infuse transplant.
52287	Cystoscopy chemodenervation	51715	Endoscopic injection/implant.
64615	Chemodenerv musc migraine	64612	Destroy nerve face muscle.
78012	Thyroid uptake measurement	78000	Thyroid single uptake.
78013	Thyroid imaging w/blood flow	78010	Thyroid imaging.
78014	Thyroid imaging w/blood flow	78007	Thyroid image mult uptakes.
78071	Parathyrd planar w/wo subtrj	78803	Tumor imaging (3D).
78072	Parathyrd planar w/spect&ct	78452	Ht muscle image spect mult.
86153	Cell enumeration phys interp	88361	Tumor immunohistochem/comput.
90785	Psytx complex interactive	90846	Family psytx w/o patient.
90791	Psych diagnostic evaluation	90846	Family psytx w/o patient.
90792	Psych diag eval w/med srvcs	90846	Family psytx w/o patient.
90832	Psytx pt&/family 30 minutes	90846	Family psytx w/o patient.
90833	Psytx pt&/fam w/e&m 30 min	90846	Family psytx w/o patient.
90834	Psytx pt&/family 45 minutes	90846	Family psytx w/o patient.
90836	Psytx pt&/fam w/e&m 45 min	90846	Family psytx w/o patient.
90837	Psytx pt&/family 60 minutes	90846	Family psytx w/o patient.
90838	Psytx pt&/fam w/e&m 60 min	90846	Family psytx w/o patient.
91112	Gi wireless capsule measure	91110	Gi tract capsule endoscopy.
92920	Prq cardiac angioplast 1 art	92982	Coronary artery dilation.
92921	Prq cardiac angio addl art	92984	Coronary artery dilation.
92924	Prq card angio/athrect 1 art	92995	Coronary atherectomy.
92925	Prq card angio/athrect addl	92995	Coronary atherectomy.
92928	Prq card stent w/angio 1 vsl	92980	Insert intracoronary stent.
92929	Prq card stent w/angio addl	92981	Insert intracoronary stent.
92933	Prq card stent/ath/angio	92980	Insert intracoronary stent.
92934	Prq card stent/ath/angio	92981	Insert intracoronary stent.
92937	Prq revasc byp graft 1 vsl	92980	Insert intracoronary stent.
92938	Prq revasc byp graft addl	92981	Insert intracoronary stent.
92941	Prq card revasc mi 1 vsl	92980	Insert intracoronary stent.
92943	Prq card revasc chronic 1vsl	92980	Insert intracoronary stent.
92944	Prq card revasc chronic addl	92981	Insert intracoronary stent.
93653	Ep & ablate supravent arrhyt	93620	Electrophysiology evaluation.
93654	Ep & ablate ventric tachy	93620	Electrophysiology evaluation.
93655	Ablate arrhythmia add on	93620	Electrophysiology evaluation.
93656	Tx atrial fib pulm vein isol	93620	Electrophysiology evaluation.
93657	Tx l/r atrial fib addl	93620	Electrophysiology evaluation.
95017	Perq & icut allg test venoms	95010	Percut allergy titrate test.
95018	Perq&ic allg test drugs/biol	95010	Percut allergy titrate test.
95076	Ingest challenge ini 120 min	95180	Rapid desensitization.
95079	Ingest challenge addl 60 min	95180	Rapid desensitization.
95782	Polysom <6 yrs 4/> paramtrs	95810	Polysomnography 4 or more.
95783	Polysom <6 yrs cpap/bilvl	95811	Polysomnography w/cpap.
95907	Motor&/sens 1–2 nrv cndj tst	95904	Sense nerve conduction test.
95908	Motor&/sens 3–4 nrv cndj tst	95904	Sense nerve conduction test.
95909	Motor&/sens 5–6 nrv cndj tst	95904	Sense nerve conduction test.
95910	Motor&sens 7–8 nrv cndj test	95904	Sense nerve conduction test.
95911	Motor&sen 9–10 nrv cndj test	95904	Sense nerve conduction test.
95912	Motor&sen 11–12 nrv cnd test	95904	Sense nerve conduction test.
95913	Motor&sens 13/> nrv cnd test	95904	Sense nerve conduction test.
95921	Autonomic nrv parasym inervj	95923	Autonomic nerv function test.
95922	Autonomic nrv adrenrg inervj	95923	Autonomic nerv function test.
95924	Ans parasymp & symp w/tilt	95923	Autonomic nerv function test.
95940	Ionm in operatng room 15 min	95920	Intraop nerve test add-on.
99485	Suprv interfacilty transport	99471	Ped critical care initial.
99486	Suprv interfac trnsport addl	99472	Ped critical care subsq.
99487	Cmplx chron care w/o pt vsit	99374	Home health care supervision.
99488	Cmplx chron care w/pt vsit	99215	Office/outpatient visit est.
99489	Complx chron care addl30 min	99374	Home health care supervision.
99495	Trans care mgmt 14 day disch	99214	Office/outpatient visit est.
99496	Trans care mgmt 7 day disch	99215	Office/outpatient visit est.
G0452	Molecular pathology interpr	83912	Genetic examination.
G0453	Cont intraop neuro monitor	95920	Intraop nerve test add-on.
G0454	MD document visit by NPP	99211	Office/outpatient visit est.

TABLE 75—MALPRACTICE CROSSWALKS FOR CY 2013 NEW/REVISED CODES USED TO ESTABLISH MALPRACTICE RVUS—Continued

G0455	Fecal microbiota prep instil	91065	Breath hydrogen test.

N. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate

1. Medicare Sustainable Growth Rate (SGR)

The SGR is an annual growth rate that applies to physicians' services paid by Medicare. The use of the SGR is intended to control growth in aggregate Medicare expenditures for physicians' services. Payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted based on a comparison of allowed expenditures (determined using the SGR) and actual expenditures. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased.

Section 1848(f)(2) of the Act specifies that the SGR for a year (beginning with CY 2001) is equal to the product of the following four factors:

(1) The estimated change in fees for physicians' services;

(2) The estimated change in the average number of Medicare fee-for-service beneficiaries;

(3) The estimated projected growth in real GDP per capita; and

(4) The estimated change in expenditures due to changes in statute or regulations.

In general, section 1848(f)(3) of the Act requires us to publish SGRs for 3 different time periods, no later than November 1 of each year, using the best data available as of September 1 of each year. Under section 1848(f)(3)(C)(i) of the Act, the SGR is estimated and subsequently revised twice (beginning with the FY and CY 2000 SGRs) based on later data. (The Act also provides for adjustments to be made to the SGRs for FY 1998 and FY 1999. See the February 28, 2003 **Federal Register** (68 FR 9567) for a discussion of these SGRs). Under section 1848(f)(3)(C)(ii) of the Act, there are no further revisions to the SGR once it has been estimated and subsequently revised in each of the 2 years following the preliminary estimate. In this final rule with comment, we are making our preliminary estimate of the CY 2013 SGR, a revision to the CY 2012 SGR, and our final revision to the CY 2011 SGR.

a. Physicians' Services

Section 1848(f)(4)(A) of the Act defines the scope of physicians' services covered by the SGR. The statute indicates that ''the term physicians' services includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare+Choice plan enrollee.''

We published a definition of physicians' services for use in the SGR in the November 1, 2001 **Federal Register** (66 FR 55316). We defined physicians' services to include many of the medical and other health services listed in section 1861(s) of the Act. Since that time, the statute has been amended to add new Medicare benefits. As the statute changed, we modified the definition of physicians' services for the SGR to include the additional benefits added to the statute that meet the criteria specified in section 1848(f)(4)(A).

As discussed in the CY 2010 PFS final rule with comment period (74 FR 61961), the statute provides the Secretary with clear discretion to decide whether physician-administered drugs should be included or excluded from the definition of ''physicians' services.'' Accordingly, we removed physician-administered drugs from the definition of physicians' services in section 1848(f)(4)(A) of the Act for purposes of computing the SGR and the levels of allowed expenditures and actual expenditures beginning with CY 2010, and for all subsequent years. Furthermore, in order to effectuate fully the Secretary's policy decision to remove drugs from the definition of physicians' services, we removed physician-administered drugs from the calculation of allowed and actual expenditures for all prior years.

Thus, for purposes of determining allowed expenditures, actual expenditures for all years, and SGRs beginning with CY 2010 and for all subsequent years, we specified that physicians' services include the following medical and other health services if bills for the items and services are processed and paid by Medicare carriers (and those paid through intermediaries where specified) or the equivalent services processed by the Medicare Administrative Contractors:

- Physicians' services.
- Services and supplies furnished incident to physicians' services, except for the expenditures for drugs and biologicals which are not usually self-administered by the patient.
- Outpatient physical therapy services and outpatient occupational therapy services.
- Services of PAs, certified registered nurse anesthetists, certified nurse midwives, clinical psychologists, clinical social workers, nurse practitioners, and certified nurse specialists.
- Screening tests for prostate cancer, colorectal cancer, and glaucoma.
- Screening mammography, screening pap smears, and screening pelvic exams.
- Diabetes outpatient self-management training (DSMT) services.
- MNT services.
- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests (including outpatient diagnostic laboratory tests paid through intermediaries).
- X-ray, radium, and radioactive isotope therapy.
- Surgical dressings, splints, casts, and other devices used for the reduction of fractures and dislocations.
- Bone mass measurements.
- An initial preventive physical exam.
- Cardiovascular screening blood tests.
- Diabetes screening tests.
- Telehealth services.
- Physician work and resources to establish and document the need for a power mobility device.
- Additional preventive services.
- Pulmonary rehabilitation.
- Cardiac rehabilitation.
- Intensive cardiac rehabilitation.
- Kidney disease education services.
- Personalized prevention plan services.

b. Preliminary Estimate of the SGR for 2013

Our preliminary estimate of the CY 2013 SGR is—19.7 percent. We first estimated the CY 2013 SGR in March 2012, and we made the estimate available to the MedPAC and on our Web site. Table 76 shows the March 2012 estimate and our current estimates of the factors included in the CY 2013

SGR. The majority of the difference between the March estimate and our current estimate of the CY 2013 SGR is explained by changes in estimated enrollment after our March estimate was prepared.

TABLE 76—CY 2013 SGR CALCULATION

Statutory factors	March estimate	Current estimate
Fees	0.5 percent (1.005)	0.3 percent (1.003).
Enrollment	5.1 percent (1.051)	3.6 percent (1.036).
Real Per Capita GDP	0.7 percent (1.007)	0.7 percent (1.007).
Law and Regulation	−23.6 percent (0.764)	−23.3 percent (0.767).
Total	−18.7 percent (0.813)	−19.7 percent (0.803).

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, 1.003 × 1.036 × 1.007 × 0.767.= 0.803). A more detailed explanation of each figure is provided below in this final rule with comment period.

c. Revised Sustainable Growth Rate for CY 2012

Our current estimate of the CY 2012 SGR is 5.1 percent. Table 77 shows our preliminary estimate of the CY 2012 SGR that was published in the CY 2012 PFS final rule with comment period (76 FR 73269) and our current estimate. The majority of the difference between the preliminary estimate and our current estimate of the CY 2012 SGR is explained by adjustments to reflect intervening legislative changes that have occurred since publication of the CY 2012 final rule with comment period.

TABLE 77—CY 2012 SGR CALCULATION

Statutory factors	Estimate from CY 2012 final rule	Current estimate
Fees	0.6 percent (1.006)	0.6 percent (1.006).
Enrollment	3.5 percent (1.035)	1.6 percent (1.016).
Real Per Capita GDP	0.6 percent (1.006)	0.7 percent (1.007).
Law and Regulation	−20.7 percent (0.793)	2.1 percent (1.021).
Total	−16.9 percent (0.831)	5.1 percent (1.051).

Note: A more detailed explanation of each figure is provided in below in this final rule with comment period.

d. Final Sustainable Growth Rate for CY 2011

The SGR for CY 2011 is 4.7 percent. Table 78 shows our preliminary estimate of the CY 2011 SGR from the CY 2011 PFS final rule with comment period, our revised estimate from the CY 2012 PFS final rule with comment period, and the final figures determined using the best available data as of September 1, 2012.

TABLE 78—2011 SGR CALCULATION

Statutory factors	Estimate from CY 2010 final rule	Estimate from CY 2011 final rule	Final
Fees	0.2 percent (1.002)	0.2 percent (1.002)	0.2 percent (1.002).
Enrollment	2.4 percent (1.024)	1.8 percent (1.018)	1.0 percent (1.010).
Real Per Capita GDP	0.7 percent (1.007)	0.6 percent (1.006)	0.6 percent (1.006).
Law and Regulation	−16.2 percent (0.838)	3.3 percent (1.033)	2.8 percent (1.028).
Total	−13.4 percent (0.866)	6.0 percent (1.060)	4.7 percent (1.047).

Note: A more detailed explanation of each figure is provided below in this final rule with comment period.

e. Calculation of CYs 2013, 2012, and 2011 Sustainable Growth Rates

(1) Detail on the CY 2013 SGR

All of the figures used to determine the CY 2013 SGR are estimates that will be revised based on subsequent data. Any differences between these estimates and the actual measurement of these figures will be included in future revisions of the SGR and allowed expenditures and incorporated into subsequent PFS updates.

(a) Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2013

This factor is calculated as a weighted average of the CY 2013 changes in fees for the different types of services included in the definition of physicians' services for the SGR. Medical and other health services paid using the PFS are estimated to account for approximately 87.7 percent of total allowed charges included in the SGR in CY 2013 and are updated using the percent change in the MEI. As discussed in section C, the percent change in the MEI for CY 2013 is 0.8 percent. Diagnostic laboratory tests are estimated to represent approximately 12.3 percent of Medicare allowed charges included in the SGR for CY 2013. Medicare payments for these tests are updated by the Consumer Price Index for Urban Areas (CPI–U), which is 1.7 percent for CY 2013. Section 1833(h)(2)(A)(iv(l) of the Act requires that the CPI–U update applied to clinical laboratory tests be reduced by a multi-factor productivity adjustment (MFP adjustment) and, for each of years 2011 through 2015, by 1.75 percentage

points (percentage adjustment). The MFP adjustment will not apply in a year where the CPI–U is zero or a percentage decrease. Further, the application of the MFP adjustment shall not result in an adjustment to the fee schedule of less than zero for a year. However, the application of the percentage adjustment may result in an adjustment to the fee schedule being less than zero for a year and may result in payment rates for a year being less than such payment rates for the preceding year. The applicable productivity adjustment for CY 2013 is −0.9 percent. Adjusting the CPI–U update by the productivity adjustment results in a 0.8 percent (1.7 percent (CPI–U) −0.9 percent (MFP adjustment) update for CY 2013. Additionally, the percentage reduction of 1.75 percent is applied for CYs 2011 through 2015, as discussed previously, and an additional adjustment of −2.0 percent specified in the Middle Class Tax Relief and Job Creation Act. Therefore, for CY 2013, diagnostic laboratory tests will receive an update of −3.0 percent (rounded). Table 79 shows the weighted average of the MEI and laboratory price changes for CY 2013.

TABLE 79—WEIGHTED-AVERAGE OF THE MEI AND LABORATORY PRICE CHANGES FOR CY 2013

	Weight	Update
Physician	0.877	0.8%
Laboratory	0.123	−3.0%
Weighted-average	1.000	0.3%

We estimate that the weighted average increase in fees for physicians' services in CY 2013 under the SGR (before applying any legislative adjustments) will be 0.3 percent.

(b) Factor 2—The Percentage Change in the Average Number of Part B Enrollees From CY 2012 to CY 2013

This factor is our estimate of the percent change in the average number of fee-for-service enrollees from CY 2012 to CY 2013. Services furnished to Medicare Advantage (MA) plan enrollees are outside the scope of the SGR and are excluded from this estimate. We estimate that the average number of Medicare Part B fee-for-service enrollees will increase by 3.6 percent from CY 2012 to CY 2013. Table 80 illustrates how this figure was determined.

TABLE 80—AVERAGE NUMBER OF MEDICARE PART B FEE-FOR-SERVICE ENROLLEES FROM CY 2012 TO CY 2013

[Excluding beneficiaries enrolled in MA plans]

	CY 2012	CY 2013
Overall	46.560 million	48.136 million.
Medicare Advantage (MA)	13.545 million	13.935 million.
Net	33.016 million	34.201 million.
Percent Increase		3.6 percent.

An important factor affecting fee-for-service enrollment is beneficiary enrollment in MA plans. Because it is difficult to estimate the size of the MA enrollee population before the start of a CY, at this time we do not know how actual enrollment in MA plans will compare to current estimates. For this reason, the estimate may change substantially as actual Medicare fee-for-service enrollment for CY 2013 becomes known.

(c) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in CY 2013

We estimate that the growth in real GDP per capita from CY 2012 to CY 2013 will be 0.7 percent (based on the annual growth in the 10 year moving average of real GDP per capita (2004 through 2013)). Our past experience indicates that there have also been changes in estimates of real GDP per capita growth made before the year begins and the actual change in real GDP per capita growth computed after the year is complete. Thus, it is possible that this figure will change as actual information on economic performance becomes available to us in CY 2013.

(d) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2013 Compared With CY 2012

The statutory and regulatory provisions that will affect expenditures in CY 2013 relative to CY 2012 are estimated to have an impact on expenditures of −23.3 percent. The impact is primarily due to the expiration of the physician fee schedule update specified in statute for CY 2012 only.

(2) Detail on the CY 2012 SGR

A more detailed discussion of our revised estimates of the four elements of the CY 2012 SGR follows.

(a) Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2012

This factor was calculated as a weighted-average of the CY 2012 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2012.

We estimate that services paid using the PFS account for approximately 90.3 percent of total allowed charges included in the SGR in CY 2012. These services were updated using the CY 2012 percent change in the MEI of 0.6 percent. We estimate that diagnostic laboratory tests represent approximately 12.3 percent of total allowed charges included in the SGR in CY 2012. For CY 2012, diagnostic laboratory tests received an update of 0.7 percent.

Table 81 shows the weighted-average of the MEI and laboratory price changes for CY 2011.

TABLE 81—WEIGHTED-AVERAGE OF THE MEI, AND LABORATORY PRICE CHANGES FOR CY 2012

	Weight	Update
Physician	0.903	0.6
Laboratory	0.097	0.7
Weighted-average	1.000	0.6

After considering the elements described in Table 81, we estimate that the weighted-average increase in fees for physicians' services in CY 2012 under the SGR was 0.6 percent. Our estimate of this factor in the CY 2012 PFS final rule with comment period was 0.6 percent (76 FR 73271).

(b) Factor 2—The Percentage Change in the Average Number of Part B Enrollees From CY 2011 to CY 2012

We estimate that the average number of Medicare Part B fee-for-service enrollees (excluding beneficiaries enrolled in Medicare Advantage plans) increased by 1.6 percent in CY 2012. Table 82 illustrates how we determined this figure.

TABLE 82—AVERAGE NUMBER OF MEDICARE PART B FEE–FOR–SERVICE ENROLLEES FROM CY 2011 TO CY 2012

[Excluding beneficiaries enrolled in MA plans]

	2011	2012
Overall	44.879 million	46.560 million.
Medicare Advantage (MA)	12.382 million	13.545 million.
Net	32.498 million	33.016 million.
Percent Increase		1.6 percent.

Our estimate of the 1.6 percent change in the number of fee-for-service enrollees, net of Medicare Advantage enrollment for CY 2012 compared to CY 2011, is different than our original estimate of an increase of 3.5 percent in the CY 2012 PFS final rule with comment period. (76 FR 73271). While our current projection based on data from 8 months of CY 2012 differs from our original estimate of 3.5 percent when we had no actual data, it is still possible that our final estimate of this figure will be different once we have complete information on CY 2012 fee-for-service enrollment.

(c) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in CY 2012

We estimate that the growth in real GDP per capita will be 0.7 percent for CY 2012 (based on the annual growth in the 10-year moving average of real GDP per capita (2003 through 2012)). Our past experience indicates that there have also been differences between our estimates of real per capita GDP growth made prior to the year's end and the actual change in this factor. Thus, it is possible that this figure will change further as complete actual information on CY 2012 economic performance becomes available to us in CY 2013.

(d) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2012 Compared With CY 2011

The statutory and regulatory provisions that affected expenditures in CY 2012 relative to CY 2011 are estimated to have an impact on expenditures of 2.8 percent. This is primarily an effect of the statutory requirements surrounding the temporary physician fee schedule update in CY 2012.

(3) Detail on the CY 2011 SGR

A more detailed discussion of our final revised estimates of the four elements of the CY 2011 SGR follows.

(a) Factor 1—Changes in Fees for Physicians' Services for CY 2011

This factor was calculated as a weighted average of the CY 2011 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2011.

We estimate that services paid under the PFS account for approximately 90.7 percent of total allowed charges included in the SGR in CY 2011. These services were updated using the CY 2011 percent change in the MEI of 0.4 percent. We estimate that diagnostic laboratory tests represent approximately 9.3 percent of total allowed charges included in the SGR in CY 2011. For CY 2011, diagnostic laboratory tests received an update of −1.8 percent.

Table 83 shows the weighted-average of the MEI and laboratory price changes for CY 2011.

TABLE 83—WEIGHTED-AVERAGE OF THE MEI, LABORATORY, AND DRUG PRICE CHANGES FOR CY 2011

	Weight	Update
Physician	0.907	0.4
Laboratory	0.093	−1.8
Weighted-average	1.00	0.2

After considering the elements described in Table 83, we estimate that the weighted-average increase in fees for physicians' services in CY 2011 under the SGR (before applying any legislative adjustments) was 0.2 percent. This figure is a final one based on complete data for CY 2011.

(b) Factor 2—The Percentage Change in the Average Number of Part B Enrollees From CY 2010 to CY 2011

We estimate the change in the number of fee-for-service enrollees (excluding beneficiaries enrolled in MA plans) from CY 2010 to CY 2011 was 1.0 percent. Our calculation of this factor is based on complete data from CY 2011. Table 84 illustrates the calculation of this factor.

TABLE 84—AVERAGE NUMBER OF MEDICARE PART B FROM CY 2010 TO CY 2011

[Excluding beneficiaries enrolled in MA plans]

	2010	2011
Overall	43.871	44.879 million.
Medicare Advantage (MA)	11.692	12.382 million.
Net	32.179	32.498 million.
Percent Change	.....	1.0.

(c) Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in CY 2011

We estimate that the growth in real per capita GDP was 0.6 percent in CY 2011 (based on the annual growth in the 10-year moving average of real GDP per capita (2002 through 2011)). This figure is a final one based on complete data for CY 2011.

(4) Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2011 Compared With CY 2010

Our final estimate for the net impact on expenditures from the statutory and regulatory provisions that affect expenditures in CY 2011 relative to CY 2010 is 2.8 percent. This is primarily an effect of the statutory requirements surrounding the temporary physician fee schedule update in CY 2011.

2. The Update Adjustment Factor (UAF)

Section 1848(d) of the Act provides that the PFS update is equal to the product of the MEI and the UAF. The UAF is applied to make actual and target expenditures (referred to in the statute as ''allowed expenditures'') equal. As discussed previously, allowed expenditures are equal to actual expenditures in a base period updated each year by the SGR. The SGR sets the annual rate of growth in allowed expenditures and is determined by a formula specified in section 1848(f) of the Act.

a. Calculation Under Current Law

Under section 1848(d)(4)(B) of the Act, the UAF for a year beginning with CY 2001 is equal to the sum of the following—

• *Prior Year Adjustment Component.* An amount determined by—

+ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (the year prior to the year for which the update is being determined) and the amount of the actual expenditures for those services for that year;

+ Dividing that difference by the amount of the actual expenditures for those services for that year; and

+ Multiplying that quotient by 0.75.

• *Cumulative Adjustment Component.* An amount determined by—

+ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for those services during that period;

+ Dividing that difference by actual expenditures for those services for the prior year as increased by the SGR for the year for which the UAF is to be determined; and

+ Multiplying that quotient by 0.33.

Section 1848(d)(4)(E) of the Act requires the Secretary to recalculate allowed expenditures consistent with section 1848(f)(3) of the Act. As discussed previously, section 1848(f)(3) specifies that the SGR (and, in turn, allowed expenditures) for the upcoming CY (CY 2013 in this case), the current CY (that is, CY 2012) and the preceding CY (that is, CY 2011) are to be determined on the basis of the best data available as of September 1 of the current year. Allowed expenditures for a year generally are estimated initially and subsequently revised twice. The second revision occurs after the CY has ended (that is, we are making the second revision to CY 2011 allowed expenditures in this final rule with comment).

Table 85 shows the historical SGRs corresponding to each period through CY 2013. Note that these figures have been revised to reflect a correction to the historical clinical laboratory expenditure data.

TABLE 85—ANNUAL AND CUMULATIVE ALLOWED AND ACTUAL EXPENDITURES FOR PHYSICIANS' SERVICES FROM APRIL 1, 1996 THROUGH THE END OF THE CURRENT CALENDAR YEAR

Period	Annual allowed expenditures ($ in billions)	Annual actual expenditures ($ in billions)	Cumulative allowed expenditures ($ in billions)	Cumulative actual expenditures ($ in billions)	FY/CY SGR %
4/1/96–3/31/97	47.0	47.0	47.0	47.0	.....
4/1/97–3/31/98	48.5	47.2	95.6	94.3	3.2
4/1/98–3/31/99	50.6	48.1	146.2	142.4	4.2
1/1/99–3/31/99	12.7	12.5	146.2	142.4	.....
4/1/99–12/31/99	40.5	37.2	186.7	179.6	6.9
1/1/99–12/31/99	53.2	49.7	186.7	179.6	.....
1/1/00–12/31/00	57.1	54.4	243.7	234.0	7.3
1/1/01–12/31/01	59.7	61.5	303.4	295.5	4.5
1/1/02–12/31/02	64.6	64.8	368.0	360.3	8.3
1/1/03–12/31/03	69.3	70.4	437.3	430.7	7.3
1/1/04–12/31/04	73.9	78.5	511.2	509.1	6.6
1/1/05–12/31/05	77.0	83.8	588.2	593.0	4.2
1/1/06–12/31/06	78.2	85.1	666.4	678.1	1.5
1/1/07–12/31/07	80.9	85.1	747.2	763.1	3.5
1/1/08–12/31/08	84.5	87.3	831.8	850.4	4.5
1/1/09–12/31/09	89.9	91.1	921.7	941.5	6.4

TABLE 85—ANNUAL AND CUMULATIVE ALLOWED AND ACTUAL EXPENDITURES FOR PHYSICIANS' SERVICES FROM APRIL 1, 1996 THROUGH THE END OF THE CURRENT CALENDAR YEAR—Continued

Period	Annual allowed expenditures ($ in billions)	Annual actual expenditures ($ in billions)	Cumulative allowed expenditures ($ in billions)	Cumulative actual expenditures ($ in billions)	FY/CY SGR %
1/1/10–12/31/10	97.9	96.0	1,019.6	1,037.4	8.9
1/1/11–12/31/11	102.5	99.4	1,122.2	1,136.9	4.7
1/1/12–12/31/12	107.8	102.0	1,230.0	1,238.9	5.1

[1] Allowed expenditures in the first year (April 1, 1996–March 31, 1997) are equal to actual expenditures. All subsequent figures are equal to quarterly allowed expenditure figures increased by the applicable SGR. Cumulative allowed expenditures are equal to the sum of annual allowed expenditures. We provide more detailed quarterly allowed and actual expenditure data on our Web site at the following address: *http://www.cms.hhs.gov/SustainableGRatesConFact/*. We expect to update the Web site with the most current information later this month.
[2] Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR.
[3] Allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.

Consistent with section 1848(d)(4)(E) of the Act, Table 85 includes our second revision of allowed expenditures for CY 2011, a recalculation of allowed expenditures for CY 2012, and our initial estimate of allowed expenditures for CY 2013. To determine the UAF for CY 2013, the statute requires that we use allowed and actual expenditures from April 1, 1996 through December 31, 2012 and the CY 2013 SGR. Consistent with section 1848(d)(4)(E) of the Act, we will be making further revisions to the CY 2012 and CY 2013 SGRs and CY 2012 and CY 2013 allowed expenditures. Because we have incomplete actual expenditure data for CY 2012, we are using an estimate for this period. Any difference between current estimates and final figures will be taken into account in determining the UAF for future years.

We are using figures from Table 85 in the following statutory formula:

$$UAF_{13} = \frac{Target_{12} - Actual_{12}}{Actual_{12}} \times 0.75 + \frac{Target_{4/96-12/12} - Actual_{4/96-12/12}}{Actual_{12} \times SGR_{13}} \times 0.33$$

UAF_{13} = Update Adjustment Factor for CY 2013 = 0.6 percent
$Target_{12}$ = Allowed Expenditures for CY 2012 = $107.8 billion
$Actual_{12}$ = Estimated Actual Expenditures for CY 2012 = $102.0 billion
$Target_{4/96-12/12}$ = Allowed Expenditures from 4/1/1996–12/31/2012 = $1230.0 billion
$Actual_{4/96-12/12}$ = Estimated Actual Expenditures from 4/1/1996–12/31/2012 = $1238.9 billion
SGR_{13} = −19.7 percent (0.803)

$$\frac{\$107.8 - \$102.0}{\$102.0} \times 0.75 + \frac{\$1230.0 - \$1238.9}{\$102.0 \times 0.803} \times 0.33 = 0.6\%$$

Section 1848(d)(4)(D) of the Act indicates that the UAF determined under section 1848(d)(4)(B) of the Act for a year may not be less than −0.07 or greater than 0.03. Since 0.006 (0.6 percent) is between −0.07 and 0.03, the UAF for CY 2013 will be 0.006.

Section 1848(d)(4)(A)(ii) of the Act indicates that 1.0 should be added to the UAF determined under section 1848(d)(4)(B) of the Act. Thus, adding 1.0 to 0.006 yields 1.006.

3. The Percentage Change in the Medicare Economic Index (MEI)

The Medicare Economic Index (MEI) is required by section the fourth sentence of 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that the higher level is justified by year-to-year economic changes. The current form of the MEI was detailed in the CY 2011 PFS final rule with comment period (75 FR 73262) which updated the cost structure of the index from a base year of 2000 to 2006.

The MEI measures the weighted-average annual price change for various inputs needed to furnish physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide multifactor productivity. This index, which has CY 2006 base year weights, is comprised of two broad categories: (1) Physician's own time; and (2) physician's practice expense (PE).

The physician's compensation (own time) component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents: (1) Wages and salaries; and (2) fringe benefits.

The physician's practice expense (PE) category represents nonphysician inputs used in the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff and other nonlabor inputs. The physician's PE component also includes the following categories of nonlabor inputs: Office expenses; medical materials and supplies; professional liability insurance; medical equipment; medical materials and supplies; and other professional expenses.

Table 86 presents a listing of the MEI cost categories with associated weights and percent changes for price proxies for the 2013 update. The CY 2013 final MEI update is 1.8 percent and reflects a 1.9 percent increase in physician's own time and a 1.7 percent increase in physician's PE. Within the physician's PE, the largest increase occurred in chemicals, which increased 7.1 percent,

and rubber and plastic products, which increased 6.1 percent.

For CY 2013, the increase in the MEI is 0.8 percent, which reflects an increase in the non-productivity adjusted MEI of 1.8 percent and a productivity adjustment of 1.0 percent (which is based on the 10-year moving average of economy-wide private nonfarm business multifactor productivity). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private non-farm business multi-factor productivity (MFP). Please see *http://www.bls.gov/mfp/*, which is the link to the BLS historical published data on the measure of MFP.

TABLE 86—ANNUAL PERCENT CHANGE IN THE REVISED AND REBASED MEI CY 2013, ALL CATEGORIES

Cost categories	2006 weight [2] %	CY 2013 percent changes
MEI Total, productivity adjusted	100.000	0.8
Productivity: 10-year moving average of MFP [1]	[5] N/A	1.0
MEI Total, without productivity adjustment	100.000	1.8
Physician Compensation (Own Time) [3]	48.266	1.9
Wages and Salaries	43.880	1.8
Benefits	4.386	2.9
Practice Expenses	51.734	1.7
Nonphysician Compensation	19.153	1.9
Nonphysician Wages	13.752	1.7
P&T	6.006	1.6
Management	1.446	1.8
Clerical	4.466	1.8
Services	1.834	1.3
Nonphysician Benefits	5.401	2.6
Other Practice Expenses	26.308	1.6
Office Expenses	20.035	2.0
Utilities	1.266	1.5
Chemicals	0.723	7.1
Paper	0.657	1.9
Rubber & Plastics	0.598	6.1
Telephone	1.501	−0.3
Postage	0.898	3.6
All Other Services	3.582	1.5
All Other Products	0.500	2.1
Fixed Capital	8.957	1.8
Moveable Capital	1.353	1.5
PLI [4]	4.295	0.5
Medical Equipment	1.978	−0.6
Medical supplies	1.760	0.5
Other Professional Expenses	4.513	2.1

[1] The forecasts are based upon the latest available Bureau of Labor Statistics data on the 10-year average of BLS private nonfarm business multifactor productivity published on June 26, 2012. (*http://www.bls.gov/news.release/prod3.nr0.htm*)

[2] The weights shown for the MEI components are the 2006 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres-type input price index whose category weights indicate the distribution of expenditures among the inputs to physicians' services for CY 2006. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2006 weight. The sum of these products (weights multiplied by the price index levels) overall cost categories yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.

[3] The measures of productivity, average hourly earnings, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics Web site at *http://stats.bls.gov.*

[4] Derived from a CMS survey of several major commercial insurers.

[5] Productivity is factored into the MEI categories as an adjustment; therefore, no explicit weight exists for productivity in the MEI.

4. Medicare Economic Index Technical Advisory Panel

From May 2012 through September 2012, the MEI Technical Advisory Panel conducted a technical review of the MEI, including analyses of the inputs, input weights, price-measurement proxies, and productivity adjustment. Details regarding the Panel's work and documents such as transcripts, meeting summaries, and presentations can be found at the following Web site: *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP.html.*

The Panel concluded its public work on July 11, 2012 and submitted a final report complete with its recommendations to the Secretary of Health and Human Services on August 27, 2012.

Comment: We received one comment requesting that CMS engage in dialogue with affected parties regarding the analyses and recommendations of the Technical Advisory Panel to the MEI prior to proposed rulemaking to implement any such findings.

Response: The MEI Technical Advisory Panel was chartered according to the Federal Advisory Committee Act. As a result, all of the Panel's meetings were open to the public. In each meeting, including the final meeting where the Panel's findings and recommendations were finalized, time was allotted to allow for any public comment. As we find appropriate, any recommended changes to the MEI will be proposed via the rulemaking process. Given the time made available for public comment during the MEI Technical Advisory Panel's meetings, as well as the opportunity for public comment during rulemaking, we disagree with the commenter's request that we engage in further dialogue prior to proposing possible changes.

5. Physician and Anesthesia Fee Schedule Conversion Factors for CY 2013

The CY 2013 PFS CF is $25.0008. The CY 2012 national average anesthesia CF is $15.93.

a. Physician Fee Schedule Update and Conversion Factor

(1) CY 2013 PFS Update

The formula for calculating the PFS update is set forth in section 1848(d)(4)(A) of the Act. In general, the PFS update is determined by multiplying the CF for the previous year by the percentage increase in the MEI less productivity times the UAF, which is calculated as specified under section 1848(d)(4)(B) of the Act.

(2) CY 2013 PFS Conversion Factor

Generally, the PFS CF for a year is calculated in accordance with section 1848(d)(1)(A) of the Act by multiplying the previous year's CF by the PFS update.

We note section 101 of the Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) provided a 1-year increase in the CY 2007 CF and specified that the CF for CY 2008 must be computed as if the 1-year increase had never applied. Section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) provided a 6-month increase in the CY 2008 CF, from January 1, 2008, through June 30, 2008, and specified that the CF for the remaining portion of CY 2008 and the CFs for CY 2009 and subsequent years must be computed as if the 6-month increase had never applied. Section 131 of the MIPPA extended the increase in the CY 2008 CF that applied during the first half of the year to the entire year, provided for a 1.1 percent increase to the CY 2009 CF, and specified that the CFs for CY 2010 and subsequent years must be computed as if the increases for CYs 2007, 2008, and 2009 had never applied. Section 1011(a) of the DODAA and section 5 of the TEA specified a zero percent update for CY 2010, effective January 1, 2010 through March 31, 2010. Section 4 of the Continuing Extension Act of 2010 (CEA) extended the zero percent update for CY 2010 through May 31, 2010. Subsequently, section 101(a)(2) of the PACMBPRA provided for a 2.2 percent update to the CF, effective from June 1, 2010 to November 30, 2010. Section 2 of the Physician Payment and Therapy Relief Act of 2010 (Pub. L. 111–286) extended the 2.2 percent through the end of CY 2010. Section 101 of the MMEA provided a zero percent update for CY 2011, effective January 1, 2011 through December 31, 2011, and specified that the CFs for CY 2012 and subsequent years must be computed as if the increases in previous years had never applied. Section 301 of the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) provided a zero percent update effective January 1, 2012 through February 29, 2012, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had never applied. Section 3003 of the Middle Class Tax Relief and Job Creation Act of 2012 (Job Creation Act) provided a zero percent update for effective March 1, 2012 through December 31, 2012, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had never applied. Therefore, under current law, the CF that would be in effect in CY 2012 had the prior increases specified above not applied is $24.6712.

In addition, when calculating the PFS CF for a year, section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what it would have been in the absence of these changes. If this threshold is exceeded, we must make adjustments to preserve budget neutrality. We estimate that CY 2012 RVU changes would result in an increase in Medicare physician expenditures of more than $20 million. Accordingly, we are decreasing the CF by −0.1% to offset the estimated increase in Medicare physician expenditures due to the CY 2012 RVU changes. We calculate the CY 2013 PFS CF to be $25.0008. This final rule with comment period announces a reduction to payment rates for physicians' services in CY 2013 under the SGR formula. These payment rates are currently scheduled to be reduced under the SGR system on January 1, 2013. The total reduction in the conversion factor between CY 2012 and CY 2013 under the SGR system will be −26.5 percent. By law, we are required to make these reductions in accordance with section 1848(d) and (f) of the Act, and these reductions can only be averted by an Act of Congress. While Congress has provided temporary relief from these reductions every year since 2003, a long-term solution is critical. We will continue to work with Congress to fix this untenable situation so doctors and beneficiaries no longer have to worry about the stability and adequacy of their payments from Medicare under the Physician Fee Schedule.

We illustrate the calculation of the CY 2013 PFS CF in Table 87.

TABLE 87—CALCULATION OF THE CY 2013 PFS CF

Conversion Factor in effect in CY 2012		$34.0376
CY 2012 Conversion Factor had statutory increases not applied		$24.6712
CY 2013 Medicare Economic Index	0.8 percent (1.008)	
CY 2013 Update Adjustment Factor	0.6 percent (1.006)	
CY 2013 RVU Budget Neutrality Adjustment	−0.1 percent (0.99932)	
CY 2013 Conversion Factor		$25.0008
Percent Change from Conversion Factor in effect in CY 2012 to CY 2013 Conversion Factor.		−26.5%

We note payment for services under the PFS will be calculated as follows:

Payment = [(RVU work × GPCI work) + (RVU PE × GPCI PE) + (RVU malpractice × GPCI malpractice)] × CF.

b. Anesthesia Conversion Factor

We calculate the anesthesia CF as indicated in Table 88. Anesthesia services do not have RVUs like other PFS services. Therefore, we account for any necessary RVU adjustments through an adjustment to the anesthesia CF to simulate changes to RVUs. More specifically, if there is an adjustment to the work, PE, or malpractice RVUs, these adjustments are applied to the respective shares of the anesthesia CF as these shares are proxies for the work, PE, and malpractice RVUs for anesthesia services. Information regarding the anesthesia work, PE, and malpractice shares can be found at the following: *https://www.cms.gov/center/anesth.asp*.

The anesthesia CF in effect in CY 2012 is $21.52. As explained previously, in order to calculate the CY 2013 PFS CF, the statute requires us to calculate the CFs for all previous years as if the various legislative changes to the CFs for those years had not occurred. Accordingly, under current law, the anesthesia CF in effect in CY 2012 had statutory increases not applied is $15.60. The percent change from the anesthesia CF in effect in CY 2012 to the CF for CY 2013 is –26.0 percent. We illustrate the calculation of the CY 2013 anesthesia CF in Table 88.

TABLE 88—CALCULATION OF THE CY 2013 ANESTHESIA CF

2012 National Average Anesthesia Conversion Factor in effect in CY 2011		$21.52
2012 National Anesthesia Conversion Factor had Statutory Increases Not Applied		$15.60
CY 2013 Medicare Economic Index	0.8 percent (1.008)	
CY 2013 Update Adjustment Factor	0.6 percent (1.006)	
CY 2013 Budget Neutrality Work and Malpractice Adjustment	−0.1 percent (0.99932)	
CY 2013 Anesthesia Fee Schedule change due to Practice Expense	0.8 percent (1.008)	
CY 2013 Anesthesia Conversion Factor		$15.93
Percent Change from 2012 to 2013		−26.0%

III. Other Provisions of the Final Rule With Comment Period

A. Ambulance Fee Schedule

1. Amendment to section 1834(l) (13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

Sections 3105(a) and 10311(a) of the Affordable Care Act further amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2010 and before January 1, 2011. In the CY 2011 PFS final rule (75 FR 73385 and 73386, 73625), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Section 106(a) of the MMEA again amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2011 and before January 1, 2012. In the CY 2012 End-Stage Renal Disease Prospective Payment System (ESRD PPS) final rule (76 FR 70228, 70284 through 70285, 70315), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. However, in doing so, paragraphs (c)(1)(ii)(A) and (B) were inadvertently deleted from the Code of Federal Regulations. Thus, in the proposed rule, we proposed to reinstate paragraphs (c)(1)(ii)(A) and (B) as further revised below. We did not receive any comments on this proposal. Therefore, we are finalizing our proposal to reinstate paragraphs (c)(1)(ii)(A) and (B), as further revised below to conform to subsequent legislation.

Subsequently, section 306(a) of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78) (TPTCCA) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through February 29, 2012; and section 3007(a) of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96) (MCTRJCA) further amended section 1834(l)(13)(A) to extend these payment add-ons through December 31, 2012. Thus, these payment add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2012 and before January 1, 2013. In the proposed rule, we proposed to revise § 414.610(c)(1)(ii) to conform the regulations to these statutory requirements. We did not receive any comments on this proposal. Accordingly, we are finalizing our proposal to revise § 414.610(c)(1)(ii) to conform to the statutory requirements described above. These statutory requirements are self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

2. Amendment to section 146(b)(1) of MIPPA

Section 146(b)(1) of the MIPPA amended the designation of rural areas for payment of air ambulance services. This section originally specified that any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must continue to be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009.

Sections 3105(b) and 10311(b) of the Affordable Care Act amended section 146(b)(1) of MIPPA to extend this provision for an additional year, through December 31, 2010. In the CY 2011 PFS final rule (75 FR 73385 through 86, 73625 through 26), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Section 106(b) of the MMEA amended section 146(b)(1) of MIPPA to extend this provision again through December 31, 2011. In the CY 2012 ESRD PPS final rule (76 FR 70284 through 70285, 70315), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Subsequently, section 306 (b) of the TPTCCA amended section 146(b)(1) of MIPPA to extend this provision through February 29, 2012; and section 3007(b) of the MCTRJCA further amended section 146(b)(1) of MIPPA to extend this provision through December 31, 2012. Thus, we proposed to revise § 414.610(h) to conform the regulations to these statutory requirements. We did not receive any comments on this proposal. Therefore, we are finalizing our proposal to revise § 414.610(h) to conform to the statutory requirements described above. These statutory requirements are self-implementing. A plain reading of the statute requires only

a ministerial application of a rural indicator, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for areas that were designated as rural on December 31, 2006, and were subsequently re-designated as urban, we have re-established the ''rural'' indicator on the ZIP Code file for air ambulance services through December 31, 2012.

3. Amendment to Section 1834(l)(12) of the Act

Section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) added paragraph (12) to section 1834(l) of the Act, which specified that in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area''; that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract).

Sections 3105(c) and 10311(c) of the Affordable Care Act amended section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. In the CY 2011 PFS final rule (75 FR 73385 through 73386 and 73625), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 106(c) of the MMEA again amended section 1834(l)(12)(A) of the Act to extend the rural bonus described above for an additional year, through December 31, 2011. Therefore, in the CY 2012 ESRD PPS final rule (76 FR 70284 through 70285, 70315), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Subsequently, section 306 (c) of the TPTCCA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through February 29, 2012; and section 3007(c) of the MCTRJCA further amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2012. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service on or after January 1, 2012 and before January 1, 2013 where transportation originates in a qualified rural area.

This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims adjudicative process via the use of a data field included on the CMS-supplied ZIP Code File.

In the proposed rule, we proposed to revise § 414.610(c)(5)(ii) to conform the regulations to the statutory requirements set forth at section 306(c) of the TPTCCA and section 3007(c) of the MCTRJCA. We did not receive any comments on this proposal. Accordingly, we are finalizing our proposal to revise § 414.610(c)(5)(ii) to conform the regulations to these statutory requirements. These statutory requirements are self-implementing. Together, these provisions require a one-year extension of the rural bonus (which was previously established by the Secretary) through December 31, 2012, and do not require any substantive exercise of discretion on the part of the Secretary.

B. Part B Drug Payment: Average Sales Price (ASP) Issues

Section 1847A of the Act requires use of the average sales price (ASP) payment methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology applies to most drugs furnished incident to a physician's service, many drugs furnished under the DME benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

1. Widely Available Market Price (WAMP)/Average Manufacturer Price (AMP) Price Substitution

If the ASP payment limit for a drug or biological exceeds the WAMP or AMP by a threshold percentage, section 1847A(d)(3)(C) of the Act authorizes the Secretary to substitute the lesser of the widely available market price for the drug or biological, or 103 percent of the average manufacturer price as determined under section 1927(k)(1) of the Act.

The applicable threshold percentage is specified in section 1847A(d)(3)(B)(i) of the Act as 5 percent for CY 2005. For CY 2006 and subsequent years, section 1847A(d)(3)(B)(ii) of the Act authorizes the Secretary to specify the threshold percentage for the WAMP or the AMP, or both. In the CY 2006 (70 FR 70222), CY 2007 (71 FR69680), CY 2008 (72 FR 66258), CY 2009 (73 FR 69752), and CY 2010 (74 FR 61904) PFS final rules with comment period, we specified an applicable threshold percentage of 5 percent for both the WAMP and AMP. We based this decision on the fact that data was too limited to support an adjustment to the 5 percent threshold. Beginning in CY 2011, we treated the WAMP and AMP based adjustments to the applicable threshold percentages separately.

a. WAMP Threshold and Price Substitution

After soliciting and reviewing comments, we finalized proposals to continue the 5 percent WAMP threshold for CY 2011 (75 FR 73469), and CY 2012 (76 FR 73287). For CY 2013, we again had no additional information from OIG studies or other sources that led us to consider an alternative threshold. When making comparisons to the WAMP, we proposed that the applicable threshold percentage remain at 5 percent until such time that a change in the threshold amount is warranted, and we proposed to update § 414.904(d)(3)(iv) accordingly. As mentioned above, the threshold has remained at 5 percent since 2005. Our proposal will eliminate the need for annual rulemaking until a change is warranted.

For CY 2013, we did not propose any WAMP based price substitutions. As we noted in the CY 2011 PFS final rule with comment period (75 FR 73470) and reiterated in CY 2012 PFS final rule with comment period (76 FR 73287), we understand that there are complicated operational issues associated with the WAMP based substitution policy, and we continue to proceed cautiously in this area. We remain committed to providing stakeholders, including providers and manufacturers of drugs impacted by potential price substitutions with adequate notice of our intentions, including the opportunity to provide input with regard to the processes for substituting the WAMP for the ASP.

Comment: Several commenters agreed with continuing a cautious approach

regarding WAMP-based price substitutions and agreed with maintaining a 5 percent threshold. One commenter agreed with the elimination of annual rulemaking provided that access to drugs is not impacted and that the value can be modified with advance notice to stakeholders. One commenter suggested a higher threshold for the WAMP substitution due to concern about drug shortages and suggested that CMS study the threshold value issue further.

Response: The majority of commenters agreed with maintaining a 5 percent WAMP threshold. Because, as noted in the proposed rule and above, available data are limited, and we continue to have no information that would lead us to believe a different threshold is necessary, we disagree with implementing a higher threshold at this time. We also decline to actively study the matter further until such time as future study is warranted, for example, if better information were available for such study. The threshold can be reviewed as warranted and as WAMP-based price substitution policies develop and it can be modified as needed at a later time through rulemaking. Therefore, we are finalizing § 414.904(d)(3)(iv) as proposed.

b. AMP Threshold

The AMP threshold has remained at 5 percent since 2005. As with the WAMP threshold, we had no information that led us to believe that the 5 percent threshold percentage for AMP-based price substitution is inappropriate or should be changed for CY 2013. We proposed that the applicable threshold percentage remain at 5 percent until such time that a change in the threshold amount is warranted, and we proposed to update § 414.904(d)(3)(iii) accordingly. Our proposal eliminates the need for annual rulemaking until a change is warranted.

Comment: Two commenters agreed with maintaining the 5 percent AMP price substitution threshold. One commenter suggested a higher threshold for the AMP substitution due to concern that a low threshold would trigger price substitution which would then affect the manufacture of drugs. The commenter suggested that CMS study the threshold value issue further.

Response: We disagree with increasing the threshold or studying the threshold value further. Although we acknowledge that the definition of AMP is continuing to evolve, this threshold has been in place since 2005 and we have no specific information that persuades us to believe that a change in the AMP threshold is necessary at this time. Also, as with the WAMP threshold discussed in the section above, the AMP threshold can be reviewed as warranted, as price substitution policies evolve, and the threshold can be modified as needed at a later time through rulemaking. Therefore, we are finalizing § 414.904(d)(3)(iii) as proposed.

c. AMP Price Substitution-Additional Conditions

In the CY 2012 PFS rule, we specified that the substitution of AMP for ASP will be made only when the ASP exceeds the AMP by 5 percent in 2 consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter, and that matching sets of NDCs had to be used in the comparison (76FR 73289 through 73295). The value of the AMP based price substitution must also be less than the ASP payment limit that is calculated for the quarter in which the substitution is applied. Also, the price substitution remains in effect for one quarter.

We did not apply the price substitution policy in April 2012 because access concerns led us to reconsider whether it was prudent to proceed with price substitution during a developing situation that was related to a drug shortage that had not met the definition of a public health emergency under section 1847A(e) of the Act. In light of recent concerns about drug shortages, the resulting impact on patient care, beneficiary and provider access, as well as the potential for shortages to suddenly affect drug prices for the provider, under the authority in section 1847A(d)(3)(C) of the Act, we proposed adding § 414.904(d)(3)(ii)(C), which would prevent the AMP price substitution policy from taking effect if the drug and dosage form represented by the HCPCS code are reported by the FDA on their Current Drug Shortage list (or other FDA reporting tool that identifies shortages of critical or medically necessary drugs) to be in short supply at the time that ASP payment limits are being finalized for the next quarter. Further, we also clarified that this proposal to add to the safeguards finalized in CY 2012 only applied to calculations under the AMP-based price substitution policy. Our proposal intended to continue the cautious approach described in previous rules and to strike a balance between operational requirements associated with receiving manufacturers' ASP reports, calculating the payment limits, and posting stable payment limits that will be used to pay claims. We believe that this approach also addresses concerns about access to care, known program issues identified by the OIG, and provides an opportunity for some modest program savings. However, we did not propose any other changes to the safeguards, timing, or notification that identifies the codes that will be substituted each quarter. We asked for comments on our approach as well as comments regarding additional specific safeguards for the AMP price substitution policy.

Comment: In general, commenters supported implementation of a safeguard that would prevent AMP-based substitution of drugs that are known to be in short supply. Several commenters supported our proposal that prevents an AMP-based price substitution from taking effect for drugs that are reported to be in short supply. Two comments supported the use of the FDA's drug shortage list while another commenter suggested that the American Society of Health-System Pharmacists (ASHP) shortage list be used because it might better identify impending shortages. One commenter suggested that the provision be expanded to include drugs that are potentially in short supply, but did not provide additional detail. One commenter supported the proposed shortage safeguard if CMS does not further delay the implementation of the AMP substitution policy.

Response: We understand the commenters' reasoning for suggesting that we use the ASHP list, which includes information about shortages that may not affect overall supply-for example the unavailability of a certain vial size from one manufacturer. We believe that such detailed information is very useful to clinicians and those who must procure drugs. Nevertheless, we believe that using the FDA list, which is compiled from information that is required to be reported by statute and represents shortages where overall demand is not being met, will provide us with a consistent standard that reflects national drug supply. Thus, we decline to include the ASHP list in our standard. Also, after consultation with the FDA, we are also deleting the phrase ''critical or medically necessary'' from the proposed regulation text in order to make clear that CMS will not further interpret FDA's drug shortage list. In other words, we are clarifying that a drug's presence on the list will be sufficient to meet the standard in our final rule, and we will not be taking a position as to whether the drug is ''critical or medically necessary'' for this purpose. We believe that this modification will also help maintain a consistent standard on which we base

our decisions. After reviewing the public comments, we are finalizing our proposal and corresponding regulation text at § 414.904(d)(3)(ii)(C) with the modification described in this paragraph.

Comment: Although we did not receive any detailed suggestions for new safeguards, two commenters also suggested creating safeguards that address AMP data errors and calculations be implemented.

Response: We are acknowledging these comments, but since no specific recommendations were made, we will not be addressing them at this time.

Comment: Several commenters stated that implementation of the AMP-based price substitution should be delayed until the AMP regulation is finalized and/or additional experience with calculating AMPs has been gained. Commenters expressed concerns about the differences in the calculation methodology for ASP and AMP and the uncertainty about how ''5i'' drugs will be affected.

Response: We appreciate these comments; however, delaying the AMP-based substitution process is outside the scope of our proposals and we will not further delay implementation of the AMP-based price substitution policy at this time. In the proposed rule (77 FR 44793), we stated that we are not proposing any other changes to the safeguards, timing or notification procedures for the AMP-based price substitution. We have explained our reasons for proceeding with the AMP-based substitution in the CY 2012 PFS final rule (76 FR 73294–95), where we also discussed the evolving definition of AMP and ''5i'' drugs. In the CY 2012 PFS final rule we stated that we ''understand that the updated definition of AMP encompasses sales of injected, infused, instilled, inhaled, and implanted drugs that are not generally dispensed through a retail community pharmacy, including a wider range of customers and discounted sales to non-pharmacy entities, and commenters' concerns that implementation of the most recent definition could decrease AMP for certain drugs. However, we do not have any specific information from commenters that persuades us to believe that the AMP-based price substitution policy will be applied frequently or to high cost/high volume items, despite the changes to the definition of AMP.'' We also continue to believe that the safeguards finalized in the CY 2012 PFS rule and the additional safeguard finalized in this rule provide assurance that the price substitution policy will be applied only when appropriate. In summary, we appreciate the commenters' concerns, but our assessment of the overall situation has not changed.

Additional Part B drug-related comments that are outside the scope of this rule are listed in section 3 below.

2. Billing for Part B Drugs Administered Incident to a Physician's Services.

This section discusses payment policies regarding billing for certain drugs under Medicare Part B. In 2010 and 2011, we issued two change requests (CRs 7109 and 7397) that summarized a number of longstanding drug payment policy and billing requirements. We considered these CRs to be merely clarifying, rather than changing, our policy. However, one item in the CRs, which stated that pharmacies may not bill for drugs that are used incident to physician's service, has caused some concern. Specifically, we understood that some nonphysician suppliers—operating in part on the basis of erroneous guidance from a Medicare contractor—have been submitting claims for drugs that they have shipped to physicians' offices for use in refilling implanted intrathecal pumps. In light of concern over its potential effect on suppliers, we delayed implementation of the most recently updated CR (CR 7397 Transmittal 2437, April 4, 2012) until January 1, 2013 so that we could undertake rulemaking, evaluate public comments on this issue, and determine whether CR 7397 should be implemented as planned, revised, or rescinded.

Implanted pumps may qualify as Durable Medical Equipment (DME); however, unlike external pumps used to administer drugs, implanted pumps are typically refilled in a physician's office. The implanted intrathecal pump is refilled by injecting the drug into a pump's reservoir, which lies below the patient's skin. The reservoir is connected to the pump, which delivers the drug to the intrathecal space through a tunneled catheter. The procedure of refilling an intrathecal pain pump is a service that is typically performed by the physician because of risk and complexity.

To be covered by Medicare Part A or Part B, an item or service must fall within one or more benefit categories within such Parts, and must not be otherwise excluded from coverage. Drugs and biologicals paid under Medicare Part B drugs fall into three basic categories as follows:

- *Drugs furnished ''incident to'' a physician's services.* These are typically injectable drugs that are bought by the physician, administered in the physician's office, and then billed by the physician to the Medicare Administrative Contractor (MAC). By definition, ''incident to a physician's professional service'' requires the item or service to be billed by the physician.
- *Drugs administered through a covered item of DME.* These drugs are supplies necessary for the effective use of DME and are typically furnished to the beneficiary by suppliers that are pharmacies (or general DME suppliers that utilize licensed pharmacists) for administration in a setting other than the physician's office. Most DME drugs are billed to the DME MAC.
- *Drugs specified by the statute.* These include a variety of drugs, such as oral immunosuppressives and certain vaccines.

Depending on the circumstances, drugs used to refill an implanted intrathecal pump can be paid under either the ''incident to'' or the DME benefit category or Medicare Part D. The CMS Benefit Policy Manual (100–02 Chapter 15 Section 50.3) states that drugs paid under the ''incident to'' provision are of a form that is not usually self-administered; are furnished by a physician; and are administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision. Section 60.1 A requires that ''to be covered, supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing.'' In what we believe is a typical situation, when physicians' services are used to refill an intrathecal pump, the ''incident to'' requirements can be met because, consistent with our guidance and longstanding policy, the physician or other professional employed by his or her office performs a procedure to inject the drug into the implanted pump's reservoir (that is, the drug is not self-administered), and the drug represents a cost to the physician because he or she has purchased it.

Conversely, we believe that in the typical situation, payment to a pharmacy or other nonphysician supplier under the DME benefit for a drug dispensed for use in the physician's office is both inappropriate and inconsistent with existing guidance. For example, DME prosthetics, orthotics, and supplies (POS) policy does not permit payment for prosthetics dispensed prior to the procedure that makes necessary the use of the device. Moreover, in the case of prescription drugs used in conjunction with DME, our guidance is clear that the entity that dispenses the drug needs to furnish it directly to the patient for whom a prescription is written. An arrangement whereby a pharmacy (or supplier) ships

a drug to a physician's office for administration to a patient does not constitute furnishing the drug directly to the patient.

We note that payment to pharmacies (or suppliers) for drugs used to refill an implanted pump can be made under the DME benefit category where the drug is directly dispensed to a patient and the implanted pump is refilled without a physician's service. However, it is our understanding that implanted pumps are rarely refilled without utilizing the service of a physician.

In the proposed rule, we stated our concern about stakeholders' reports that, due to incorrect guidance from a contractor, Medicare payment policy on this issue has been applied in an inconsistent manner. We stated that we consider the contractor's guidance to be erroneous. This inconsistency has permitted supplier claims for drugs dispensed by pharmacies to physicians' offices to be paid in some jurisdictions and denied in others. We understand that the inconsistent application of our payment policy has influenced the business and professional practices of pharmacies/DME suppliers that prepare drugs for implanted pumps. We stated that we do not believe that payment for drugs used to refill implanted DME should continue to be made because such action is not supported under long standing policy and, as discussed above, is not appropriate.

We proposed to clarify that we consider drugs used by a physician to refill an implanted item of DME to be within the ''incident to'' benefit category and not the DME benefit category. Therefore, for the drug to be paid under Part B, the physician must buy and bill for the drug, and a non-physician supplier that has shipped the drug to the physician's office may not do so. We asked for comments on this proposal and its potential impact on beneficiaries and providers.

Comment: One commenter questioned CMS's assumptions in proposing the policy clarification and contends that contrary to these assumptions, pharmacy billing for drugs used by a physician to refill an implanted pump under the DME benefit is appropriate. Specifically, the commenter questioned CMS's assertion that the physician refilling the implanted pump is ''administering'' the drug, contending instead that the pump administers the drug and that the physician does not exclusively administer the drug. Second, the commenter disagrees with CMS's statement that pharmacies' shipping drugs to physician offices are not furnishing drugs directly to the patient and contends that these medications are dispensed specifically to the patient at the physician's office.

Response: We disagree with these comments. With respect to whether the physician is administering these drugs, we understand that the implanted pump serves to release the drug into a specific region of the patient's body over a prolonged time period. However, the process of refilling the implanted pump, determining the correct pump settings, and making adjustments to those settings as needed is usually carried out by a licensed healthcare provider, typically a physician. In our view, the pump's role is analogous to a drug with a sustained release rate (for example, leuprolide depot injection) that is injected or implanted into the body, which is similarly furnished incident to a physician's professional service. Further, the relevant inquiry is not whether a drug is ''exclusively'' administered by a physician, but rather whether the drug is ''not usually self-administered by the patient'' and furnished incident to a physician's professional service. Thus, even if the physician did not ''exclusively'' administer the drug because of the action of the pump, it does not follow that a more appropriate benefit category for such a drug would be the DME benefit category.

Under the incident to provision, we associate payment for the drug with the physician's professional service, and the drug is a key component of the billable procedure that is paid incident to a physician's professional service. As we have described earlier, when an implanted article of DME is refilled in the physician's office, the drug required for the service must meet the three conditions of the incident to benefit described in the Claims Processing manual, Chapter 15, Section 50.1, where the drug or biological must be of a form that is not usually self-administered; must be furnished by the physician; and must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision. Based on discussion with stakeholders, it is our understanding that most refills of implanted DME that are done in the physician's office meet these conditions. In contrast, under the DME benefit category, a pharmacist dispenses the drug as a supply necessary for the effective use an item of DME (including, an implanted pump) and a physician's service is not utilized for the drug administration process.

In addition, we disagree with the commenter's assertion that by sending a drug to the physician's office for a specific patient, it is furnishing the drug directly to the patient, because such delivery would not be made without the physician's being at the delivery location to administer the drug in his or her office. It is notable that the commenter neglected to describe what happens to the drug that it asserts is delivered ''directly'' to the patient at the physician's office if the patient cannot receive a pump refill at the time of such delivery. Presumably the physician's office or the pharmacy, rather than the patient, would be responsible for the storage of the drug until it could be safely used or for disposal or return of an unused and unopened dose, which would indicate that at no time did the patient take ''delivery'' of the drug. In any event, in light of the physician's integral role in receipt and administration of the drug, the DME benefit category does not appropriately apply to this situation. Moreover, the incident to benefit category does not permit pharmacy billing for the incident to drug. Pharmacy/DME supplier dispensed drugs that are to be used incident to a physician's service do not meet the ''incident to'' conditions because the pharmacist does not refill the implanted pump.

However, we believe that it is important to preserve the potential for paying a pharmacy for a drug that is used to refill implanted pumps in certain limited instances where a physician's service is not used. Although patients and caregivers do not typically refill implanted pumps, it is our understanding that in rare situations persons other than a physician (as defined by section 1861(r) of the Act) could refill the pump, for example, when a patient cannot be transported to a physician's office, but a suitably trained individual is available at the home. We believe that this situation is very uncommon, but we also believe that in certain situations, for example in remote locations, it may facilitate the administration of refills of implanted durable medical equipment in situations where a beneficiary cannot be transported to the office, but a qualified individual is available to fill the pump and the drug is dispensed directly to the patient at home. In these situations, the drug is not being administered by the physician, and therefore the drug cannot be billed incident to a physician's service. As there is no service incident to a physician's service and the drug is being dispensed directly to the beneficiary in the home for use in an implanted item of DME, the pharmacy may bill and be paid for the drug.

Comment: Several commenters note that the proposed rule describes the error as being associated with only one

contractor, but that several others since have allowed for and paid direct pharmacy claims for drugs used by physicians to refill implanted pumps. A comment from a group of pharmacies that compounds drugs for use in implanted pumps states that four contractors across 13 States have paid pharmacies directly in these instances. Commenters located in other states supported adoption of the erroneous approach in their states. One commenter stated that the majority of pharmacies in the country are in compliance with the buy and bill approach.

Response: Although the proposed rule (77 FR 44793) stated that erroneous guidance came from ''one contractor,'' in the same paragraph we acknowledged that payments were made in some jurisdictions and denied in others. Thus, the proposed rule indicated that we understood that several contractors had paid pharmacies under the erroneous approach. Although we understand that the use of the erroneous approach has expanded, this does not persuade us to make a national policy decision that incorporates a payment policy that is based on contractor error simply because it has become utilized in some areas. Moreover, the commenters recommending adoption of the erroneous approach notably did not assert that the physician ''buy and bill'' method has been problematic in their states, and these comments, in our view, support our belief that the erroneous approach is not a widespread problem.

Comment: Several comments mentioned that regulation text at § 424.57 permits pharmacy suppliers to be paid for drugs used with DME. One comment stated that administrative law judge (ALJ) decisions favorable to pharmacies that furnished drugs under the erroneous guidance were based on this regulation text.

Response: We agree that pharmacy suppliers can be paid for drugs used as supplies for DME. This provision applies most frequently to situations like drugs used with nebulizers or external pumps where multiple doses of drugs are dispensed and delivered to a patient for use over a given time period. However, instances in which direct billing by a pharmacy or DME supplier for these drugs, which are self-administered via an item of DME, are distinguishable from the situation here, where a licensed healthcare provider's professional service is required to ensure that the drug may be used with the item of DME. Physicians who refill these pumps in the office are generally not acting as DME suppliers.

With respect to the assertion about ALJ decisions, we are persuaded only that they are evidence that our payment policy has been applied inconsistently, and do not consider them to be indicators of what the correct payment policy is or should be.

Comment: Several commenters believe that our proposed clarification is in conflict with state and federal laws regarding the dispensing and/or distribution of controlled substances and Food and Drug Administration (FDA) guidance. Specifically, commenters asserted that our proposed clarification is inconsistent with Drug Enforcement Administration (DEA) rules that apply to dispensing of controlled substances and that operating under a distribution model would require them to register with the DEA as manufacturers, which would raise concerns under applicable state law. Further, two commenters suggested that our Part B drug billing policy instructs pharmacies to sell compounded products to physicians for resale to the patient in contravention of FDA guidance regarding pharmacy compounding compliance. Commenters noted that FDA's policy guidance delineates ''acts of drug manufacturing'' that would apply to pharmacies complying with our proposed clarification because it would require them to sell compounded products to third parties who resell to individual patients, and it would cause them to fail to operate in conformance with applicable state law regulating the practice of pharmacy. Commenters, including one state board of pharmacy, also contended that with respect to compounded controlled substances used to refill implanted pumps, the procedures that would be required under our proposed clarification would not be allowable under state law.

Response: We understand that the laws and regulations pertaining to how compounded doses of drugs used to refill implanted DME are obtained by the office are complex and may include requirements from a variety of sources, including the DEA, the FDA, and the states. This rule does not seek to interpret applicable laws, regulations, or guidance from these and other relevant sources, nor does it seek to distinguish among the varying uses of terms by these agencies, including terms such as compound, manufacture, distribute, or resell, which may have context-dependent, specific definitions that are important, but also can confuse issues related to Medicare Part B payment policy. This rule pertains solely to Part B payment policy, and we take no position on any issue other than which party must bill for a drug used by a physician to refill an implanted item of DME. Thus, this rule does not address whether a pharmacy, for example, should be dispensing or distributing a drug used to refill implanted DME. Indeed, we do not have authority to interpret or apply FDA, DEA or state laws or regulations.

That being said, we wish to respond to these comments as fully as we can, in the interest of transparency. We do not agree with the suggestions that the buy and bill approach for obtaining drugs used by physician for refilling implanted pumps in the office is strictly prohibited, because if it were, our payment policy for drugs used to refill implanted DME, with which the majority of physician offices and pharmacies already comply, would have raised concerns from stakeholders across the country long before we issued the two CRs last year.

Further, we disagree that our policy is in conflict with laws pertaining to controlled substances. First, we note that our policy is not specific to controlled substances, and the comments do not persuade us to adopt a different policy for controlled substances used by a physician to refill an implanted item of DME from the Part B payment policy for all other controlled substances administered incident to a physician's professional service. It has long been our policy that drugs furnished incident to a physician's professional service must be purchased and billed by the physician, and in general physicians buy and bill for controlled substances furnished under the incident to benefit without being in violation of DEA requirements. We have consulted with DEA about the issue of controlled substances used in implanted DME, and they have confirmed our understanding of DEA rules as discussed below.

It is our understanding from discussions with the DEA that it is a criminal violation of the law when a DEA-registered pharmacy dispenses a controlled substance and knowingly or intentionally delivers that substance to any person other than the patient or a member of the patient's household. We understand that the DEA provides for registration of entities, including pharmacies, as DEA registered manufacturer/distributors that may distribute controlled substances to providers under conditions outlined by the DEA. We understand that the DEA's ''5 percent rule'' may apply to pharmacies that are not manufacturers and that wish to provide these drugs to the office; however, we also understand that the 5 percent rule may not apply to situations where a drug must be compounded from bulk chemicals. In

any event, we have confirmed with the DEA that pharmacies can register with the DEA as a distributor/manufacturer and under such a registration, can sell these drugs to a physician's office. The office would order the drugs using DEA Form 222 (*http://www.deadiversion.usdoj.gov/faq/dea222.htm*) which facilitates purchasing and tracking of controlled substances between registrants and accountability at the pharmacy and the office. We also note that the DEA provides its own specific definition of a manufacturer. Additional information is at *http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm*.

Thus, we believe pharmacies can be in compliance with the DEA regulations in providing controlled substances to physicians who can then bill Medicare under the ''incident to'' benefit category. Indeed, we are concerned that current practices described by some commenters are inconsistent with DEA regulations. Some commenters described dispensing activities that appear to deliver the drugs to the office on behalf of the patient (that is, ''dispensing for a patient'') in a manner that may not be consistent with DEA regulations, which require that controlled substances be dispensed directly to the patient, and not to an agent, person, or other entity that is acting on the patient's behalf. We also have concerns about the ad hoc record keeping methods (like delivery logs) for controlled substance prescription delivery that were described in some comments. Such an approach does not appear to comply with practices that are required by the DEA for transfers or sales of drug between registrants. This process involves the use of DEA Form 222 and related record keeping that is described in DEA regulation.

We also note that not all of the drugs used in implanted pumps are drugs are controlled substances. Some of the analgesics (for example, ziconitide and clonidine) often used in implanted pumps are not opiates, and are not always used in conjunction with opiates. Agents used to treat spasiticy (baclofen) are also not opiates. These medications are not controlled substances, and the DEA provisions discussed above do not apply.

With respect to comments about conflicts with FDA guidance, we cannot make statements about when the FDA may require that compounding pharmacies be considered manufacturers; as noted above, this is outside of CMS's scope of authority and expertise. Nevertheless, we disagree that our proposed clarification would, in itself, require that compounding pharmacies be considered manufacturers. The FDA Compliance Policy Guidance on pharmacy compounding (*http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm*) states that the guidance ''does not create or confer any rights for or on any person and does not operate to bind FDA or the public.'' The policy states that in determining whether to take enforcement action the FDA ''will consider whether the pharmacy engages in * * * [certain] acts.'' Points 7 and 9 in the list of acts referred to by one commenter include the act of reselling a drug and State law. The use of an individualized dose of a drug that has been prepared by a pharmacy for use upon a physician's order for a specific patient and is administered by a physician in an office incident to a procedure in the office is not reselling a drug.

Finally, many of the comments pertaining to State law involved dispensing activities. However, our proposal did not address, and we do not take a position now, with respect to whether a pharmacy should dispense or distribute a drug used by a physician to refill an implanted item of DME in the physician office. We understand that State laws pertaining to dispensing of prescriptions may be problematic because they are not uniform across States and the interpretation of all requirements may vary. However, the comments did not foreclose the possibility that an appropriately registered and licensed pharmacy could sell the drug to the physician's office, for example when the pharmacy does not act as a dispenser of a prescription, but acts as a distributor of a drug. In response to the state board of pharmacy's comment, we note that the comment appears to indicate that prescriptions in the state must be dispensed in accordance with DEA requirements. As stated above, we believe it is possible to comply with DEA requirements under the buy-and-bill method.

Our approach also minimizes program integrity concerns and avoids a situation where billing for a procedure and an item necessary for the procedure is done by two different entities that may submit claims with two dates of service. Such corresponding services are difficult to match during claims processing and the presumption that a drug that has been dispensed in advance of the pump refill will always be administered to the beneficiary may not always be correct. In other words, our approach minimizes the opportunity for fraud and abuse caused by splitting up payment for related components of a service between providers that bill separately.

Further, as noted above and as borne out by our experience administering and overseeing the Medicare program, the buy and bill approach does not appear to be problematic in a majority of the country. Therefore, in considering these comments, we continue to believe that it is appropriate for Medicare payment policy to be uniform, in spite of the fact that suppliers in certain states may need to adjust their regulatory standing with the state in order to comply with our payment rules. As stated above, inconsistent application of the policy has influenced the business and professional practices of pharmacies/DME suppliers that prepare drugs for implanted pumps. Specifically, pharmacies that have been allowed to bill directly to Medicare have marketed this approach to physicians at the expense of pharmacies that have not been allowed to direct bill. Inconsistent application of the policy has given a distinct economic advantage to some pharmacies relative to others that we do not believe is equitable. A uniform policy is more fair and predictable for beneficiaries and health care providers, and is easier to administer and oversee and, as stated above, is consistent with longstanding Medicare law and regulations and minimizes the potential for fraud and abuse.

Nevertheless, if a physician does not have a cost for these drugs, the physician does not meet the requirements to bill for these drugs under Medicare Part B as an ''incident to'' drug. As explained above, these drugs are also not billable under Part B as DME supplies because the drugs are not being furnished directly to the beneficiary. However, these drugs may be payable to the pharmacy under Part D if the ingredients that are being compounded independently meet the definition of a Part D drugs—generally a commercial FDA approved drug product.

We have considered the implications of the proposed clarification on patient care and Medicare providers (including physicians and pharmacies). Review of the comments also indicated that the issue is not national, but does affect the south central region of the contiguous United States more than other regions and therefore we believe that providers in most states follow the proposed approach and most states' laws do not create insurmountable barriers for physician offices that administer refills of implanted DME equipment to obtain drugs. We do not believe that major revisions to policy should be based on

erroneous guidance that originated from a single contractor, nor do we believe that we should permit an inconsistent practice to continue indefinitely, because the delay is affecting both those who are in compliance with national payment policy, as well as those who are not.

Comment: We received several comments on the potential impact of our proposal. Most commenters expressed concern about the financial impact of our proposal on physician practices, especially small practices. Three major concerns stated were the financial impact of having to buy potentially expensive drugs, the labor involved in submitting claims, and the time that elapses between the administration of the drug and when the drug claim is paid. Physicians and office staff that currently are obtaining the drugs through pharmacies that also bill for the drug were concerned that obtaining these drugs using a buy and bill approach is not financially sustainable and would lead practices to discontinue providing pump refills. Several commenters stated that practices relied on the pharmacy-dispensed and pharmacy-billed approach. Two groups of pharmacies asserted that this clarification will affect their ability to be paid under Medicare Part B for providing intrathecal pain medications, especially medications that contain Schedule II controlled substances.

Comments about the potential impact to beneficiaries included suggestions that some practices would charge beneficiaries up front, that some physicians might convert medication regimens to the oral route—which may not be as well tolerated or as efficacious, or that access could be impaired.

Response: We acknowledge that our policy clarification will affect physicians, suppliers and beneficiaries in cases where the pharmacies have been billing for drugs used by the physician to refill implanted DME. Based on the comments on our proposal, we do not believe that these pharmacies represent all or the majority of pharmacies or the providers who obtain pharmacy prepared drugs in their offices. As we have discussed elsewhere, we believe that the drug distribution pathway is available for physician offices to purchase these drugs from appropriately licensed and registered pharmacies in cases where the drugs cannot be dispensed.

We do not believe we should incorporate a change or permit continued inconsistent application of our policies based on erroneous guidance. As we have stated above and in the proposed rule, the erroneous guidance significantly conflicts with longstanding national policies for drugs provided incident to physicians' services and items furnished under the DME benefit.

Based on the comments, we understand that many pharmacies that prepare drugs used to refill implanted pumps and the providers with whom they have a relationship are unaffected by the policy clarification in the CRs and this rule. Based on publicly available information, we understand that some pharmacies that prepare doses of intrathecally administered medications for Medicare beneficiaries (including some of the commenters who opposed our clarification) are already registered with the DEA as drug distributors. We understand that these entities can receive orders for controlled substances via the DEA 222 form and can sell (that is, distribute) the individually prepared doses to the physician provider, who in turn administers the drug and bills Medicare Part B.

As discussed above, our approach also minimizes program risk that arises from billing for a procedure and an item necessary for the procedure by two different entities that may submit claims with two dates of service. We believe fraud and abuse risk is minimized by requiring the same entity to bill for the drug and its administration.

We are concerned by comments that suggested that some practices may charge Medicare patients up front. We would like to remind physicians that Medicare providers who accept assignment may not charge up front, and note that section 1842(o)(3)(A) of the Act requires these drugs to be paid on an assignment-related basis. Also, the routine use of advance beneficiary notices (ABNs) is not allowed (See the Medicare Claims Processing Manual, chapter 30, Section 40.3.6 at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf*).

Comment: Several comments stated that CMS' proposed approach will cause physicians to discontinue the use of intrathecal pain managements and to switch to oral analgesics, thereby increasing the risk of diversion.

Response: We do not believe this policy clarification will increase the risk of drug diversion. We acknowledge that diversion can occur, perhaps particularly in instances where an individual receives high doses of analgesics, but we do not believe that either the oral or injectable approach is entirely risk free. The risk of drug diversion and pump tampering also exists with implanted pumps and has been reported in literature.

Comment: One commenter stated that CMS policy, as reflected in the Benefit Policy Manual, allows a physician to be paid for administering a drug that has not been bought by the office. The commenter suggests that CMS policy would permit the physician to bill for administration of a drug used to refill an implanted pump even if the physician did not incur the cost for it, and for this reason, the drug should be payable under the DME benefit.

Response: We disagree with the commenter's conclusion. The Benefit Policy Manual the commenter cites (Chapter 15, section 60.1A) uses the example of drug administration in the case where the patient has purchased the drug, stating that the drug administration service would be covered, even though drug would not be. We do not believe it follows from this example that drugs used by a physician to refill an implanted item of DME should be included in the DME benefit category. In fact, we believe the manual provision cited by the commenter actually supports our position—namely, that the drug in question is not covered under Part B if the physician administering it incident to a professional service has not incurred the cost for it.

Comment: Two commenters expressed support for our clarification. One commenter described the policy as longstanding and believed that most pharmacies are in compliance with this standard. Another commenter stressed the importance of consistent payment policy and expressed concern that pharmacies that billed under the incident to provision not be subject to audits or recoupment if they were acting on good faith based on contractor guidance.

Response: We agree with the comments that supported our policy clarification. We thank those who commented on additional issues for their thoughts. As we have stated previously, we believe Medicare's policy on this issue has been longstanding. However, we acknowledge that there are pharmacies that were relying on incorrect contractor guidance to bill Medicare directly for these drugs. For these reasons, we do not plan to take enforcement action for incorrect billing of drugs used to refill an implanted item of DME furnished in a physician's office by pharmacies prior to January 1, 2013 if that incorrect billing stemmed directly from guidance from a Medicare contractor.

Comment: Some commenters expressed concerns that the clarification

is a change in policy. Another commenter believes that the fact that we delayed the CR amounts to a tacit approval of pharmacy billing for drugs used by physicians to refill implanted pumps.

Response: We disagree that this is a change in our policy. As we stated in the proposed rule, we consider the contractor guidance on pharmacy billing of drugs used to refill implanted items of DME to be erroneous. We believe it was erroneous for other contractors to adopt similar processes. Nevertheless, in light of stakeholder concerns, we delayed the implementation of two CRs and undertook this rulemaking process to ensure that even if our clarification were considered a change in policy, potentially affected parties would have notice and a meaningful opportunity to comment. Thus, our decision to delay the CRs' implementation was not because we approved of, or even condoned, pharmacy billing for these drugs. Rather, we delayed the CRs' implementation to permit further consideration of this issue and ultimately, this rulemaking process. As we undertake rulemaking with respect to payment for Part B drugs generally on an annual basis, we proposed this clarification at the earliest available opportunity.

Moreover, in addition to the other indications discussed elsewhere, our claims processing structure indicates that these drugs generally are billed by physicians incident to their professional service. CMS Change Request 2227 dated July 22, 2002 required that ''bills for implanted DME * * * accessories and supplies for the implanted DME must be billed to local carriers.'' This instruction removed claims processing for drugs used to refill implanted DME from the DME MAC environment (where pharmacy-based Part B claims are typically submitted) and assigned the responsibility to the local carrier, now referred to as a Medicare Administrative Contractor (MAC) (where physicians' claims are typically submitted). This instruction, now 10 years old, indicates that we have long intended that payment for drugs used to refill implanted pumps in the physician's office be received primarily by the physician's office rather than non-physician providers/DME suppliers.

Finally, we wish to clarify one other point. In the proposed rule, we stated that in the case of drugs used to refill an implantable item of DME, ''the physician must buy and bill for the drug, and a nonphysician supplier that has shipped the drug to the physician's office may not do so (except as may be permitted pursuant to a valid reassignment).'' Our reference to a ''valid reassignment'' was intended to refer only to the fact that in certain limited cases, as specified in section 1842(b)(6) of the Act and its implementing regulations, a physician may reassign a claim for Medicare payment. To the extent that our reference to a ''valid reassignment'' in the proposed rule implied that a physician could permissibly reassign a claim for a drug used to refill an implanted item of DME to a pharmacy supplier, it was in error.

Conclusion: After considering the comments and the potential impact on beneficiaries, health care providers and Medicare payment policy for DME and drugs used incident to a physician's service, we are finalizing the provision as proposed. We are finalizing the clarification that we consider drugs used by a physician to refill any implanted item of DME to be within the ''incident to'' benefit category and not the DME benefit category, and we are adding regulation text at § 410.26 to codify our policy. Therefore, to bill under the ''incident to'' benefit, the physician must buy and bill for the drug, and a non-physician supplier that has shipped the drug to the physician's office may not do so. In certain circumstances, for example if the physician does not incur an expense for the drug, Medicare Part D may be able provide payment to the pharmacy for these drugs. We believe that our position is straightforward, is consistent with how national Part B drug payment policy is applied in the physician office setting, and is already adhered to across most of the country. Consistent with this final rule, CR 7397 will go into effect on January 1, 2013.

We maintain that CR 7397 (and its predecessor CR 7109) does not change longstanding Part B drug payment policy for drugs paid under section 1847A of the Act, in particular, that a drug provided incident to a physician's service must represent an expense to the physician. Neither laws nor regulations that authorize such payment have been changed since the erroneous guidance was brought to CMS' attention. Corresponding instructions in the Benefit Policy Manual (Publication 100–02, Chapter 15, sections 50.3 and 60.1) also have not changed. The instructions in the CRs that clarified that payment for drugs furnished incident to the filling or refilling of an implanted pump or reservoir are determined under section 1847A of the Act and pharmacies (including DME suppliers that utilize pharmacists to dispense medications) may not bill Medicare Part B for drugs provided to a physician for administration to a Medicare beneficiary also have not changed. We believe that these facts confirm that our policy clarification is consistent with longstanding statute, regulation, and manual instructions that pertain to Medicare national policy and that our policy remains the appropriate one.

3. Out of Scope Comments

In addition to comments requesting us to delay AMP-based price substitution that were discussed at the end of Section 1.c., we received comments pertaining to the creation of unique HCPCS codes for new branded drugs and biologicals, the payment amount for part B drugs, supply and dispensing fees, concerns about the timeliness of claims processing and claims denials, payment incentives that would decrease the impact of drug shortages, the duration of the quarterly AMP-based price substitution, notice of price substitution for manufacturers, and safeguards for WAMP-based price substitution.

In the proposed rule, we stated that we are not proposing any other changes to the safeguards, timing or notification procedures for the AMP-based price substitution. Comments on these and other issues listed in the paragraph above are outside the scope of this rule, and therefore, are not addressed in this final rule with comment period.

C. Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery

1. Background

Sections 1832, 1834, and 1861 of the Act establish that the provision of durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) is a covered benefit under Part B of the Medicare program.

Section 1834(a)(11)(B)(i) of the Act, as redesignated by the Affordable Care Act, authorizes us to require, for Specified Covered Items, that payment may only be made under section 1834(a) of the Act if a physician has communicated to the supplier a written order for the item, before delivery of the item. Section 1834(h)(3) of the Act states that section 1834(a)(11) applies to prosthetic devices, orthotics, and prosthetics in the same manner as it applies to items of durable medical equipment (DME). In a December 7, 1992 final rule (57 FR 57675), we implemented this provision in § 410.38(g), for DME items and § 410.36(b) for prosthetic devices, orthotics, and prosthetics. Together these sections state that as a requirement for payment, CMS, a

carrier, or, more recently, a Medicare Administrative Contractor (MAC) may determine that an item of durable medical equipment, and prosthetic and orthotic supplies (DMEPOS) requires a written physician order before delivery. In addition to the regulations listed at § 410.38(g) and § 410.36(b), we have stated in Chapter 5, Section 5.2.3.1 of the Program Integrity Manual, that the following items require a written order prior to delivery: (1) Pressure reducing pads, mattress overlays, mattresses, and beds; (2) seatlift mechanisms; (3) transcutaneous electrical nerve stimulation (TENS) units; (4) power operated vehicles (POVs) and power wheelchairs.

Section 6407(b) of the Affordable Care Act amended section 1834(a)(11)(B) of the Act. The Affordable Care Act added language to the Act that requires for certain items of DME, a physician documenting that a physician, a physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary pursuant to the written order. Under section 1834(h)(3) of the Act, the items that require a written order verifying a face to face encounter may also include prosthetic devices, orthotics, and prosthetics. The encounter must occur during the 6 months prior to the written order for each item or during such other reasonable timeframe as specified by the Secretary.

2. Provisions of the Proposed Regulations and Summary of the Public Comments

We have made a series of modifications to the rule based on response to comments. As a result of comments, we are implementing several changes and clarifications to limit burden and still protect the Medicare Trust Funds. We have clarified that this requirement will begin only for new orders written after the effective date. We believe it is important to apply this requirement prospectively and not retroactively. To allow sufficient time for implementation, the effective date of this provision is July 1, 2013. Therefore, covered items ordered on or after July 1, 2013 will require a face-to-face encounter. Additionally, we have modified the timeline to require that a face-to-face encounter occur within 6 months before the written order. We have also added an additional criterion to remove items from the list of covered items. This is discussed in further detail below.

Comment: Several commenters questioned if these requirements adequately address the central drivers of fraud in the home health care and DME supply industries. If the goal is to eliminate the situation where a physician signs a DME order for a patient they know little about, having a physician sign off on a PA note does little to meet the goal.

Response: We believe that increasing physician involvement will help limit waste, fraud, and abuse while encouraging beneficiaries to maintain access to the necessary services. We believe physician involvement will not only assist in reducing waste, fraud and abuse but it will also help to ensure that beneficiaries receive high quality DME to meet their specific needs. Further, because a face-to-face encounter documented by a physician is a statutory requirement, CMS is required to implement this provision.

Comment: One commenter noted that the proposed rule does not address the role of the Certificate of Medical Necessity (CMN) under the DME face-to-face policy.

Response: The commenter is correct that the face-to-face requirement addressed in this regulation does not change existing policy related to CMNs. The face-to-face requirement does not change the CMN process for those items that require a face-to-face. The face-to-face encounter can be completed at the same time as the CMN.

Comment: A commenter noted that, the rule requiring face-to-face encounters and written orders prior to DME delivery uses the terms ''physician'' and ''practitioner'' inconsistently. Specifically, physician is the only term used to describe those authorized to order DME, which seems to imply that physicians are the only practitioners who may order DME. The proposal then goes on to state that PAs, NPs and physicians may perform the face-to-face visit for DME.

Response: We would like to clarify that under section 1834(a)(11)(B)(ii) of the Act, physicians, physician assistants, clinical nurse specialists and nurse practitioners are authorized to conduct the face-to-face encounter. We collectively refer to physicians, NPs, PAs and CNSs as ''practitioners.'' However, according to the statute, the physician must document that the face-to-face encounter occurred when performed by the PA, NP, or CNS. Items of DME can be ordered as outlined in the scope of practice for the respective practitioners subject to applicable Medicare rules. However, the face-to-face must be performed by the physician, PA, NP or CNS and documented by a physician.

Comment: Several commenters requested that CMS clarify whether the hospitalist ordering the DME for the inpatient and who has the face-to-face encounter with the patient prior to discharge must meet the face-to-face encounter requirement.

Response: Medicare beneficiaries discharged from a hospital do not need to receive a separate face-to-face encounter, as long as the physician or treating practitioner who performed the face-to-face encounter in the hospital issues the DME order within 6 months after the date of discharge.

Comment: Several commenters requested clarification that this requirement is for *new* DME orders and not for existing orders. Commenters were concerned that if the proposed face-to-face encounter requirements were to apply retroactively to orders already written (that is, each new shipment after the effective date of the final rule would need to comply with the requirements), suppliers may be required to obtain new physician orders for all of the Medicare beneficiaries whom they serve.

Response: We clarify that this requirement is for new DME orders only. That is, items that have been ordered on or after the effective date of this final rule.

Comment: Several commenters requested that the effective date of the rule be delayed until July 1, 2013, or such later date as found reasonable to provide adequate education to patients and suppliers about the new requirements. Commenters recommended that CMS provide extensive education on the documentation requirements, and alert beneficiaries to the new co-payment possibility associated with the face-to-face encounter while emphasizing the improved quality of care aspect of this rule.

Response: We agree, and are, therefore, delaying the implementation date until July 1, 2013. We believe that provides sufficient time to prepare for implementation.

Comment: A few commenters stated that to ensure the integrity of the competitive bidding program's single payment amounts, CMS must either (1) ensure that the final rule adopts provisions that are wholly consistent with the current documentation requirements dictated by the LCDs; (2) exempt items subject to competitive bidding from the proposed documentation requirements during the bid program; or (3) permit suppliers to resubmit bids for these items that take these additional costs into account.

Response: This requirement is a condition of payment that applies uniformly to these items regardless of

whether they are paid for under the fee schedule or the competitive bidding program. There are no exceptions for items that are furnished in a competitive bidding area. Moreover, as noted in the impact analysis, we believe that this requirement will not result in significant costs for suppliers.

a. DME Face-to-Face Encounters

(1) General Requirements

We had proposed to revise § 410.38(g) to require, as a condition of payment for certain covered items of DME, that a physician must have documented and communicated to the DME supplier that the physician or a PA, an NP, or a CNS has had a face-to-face encounter with the beneficiary no more than 90 days before the order is written or within 30 days after the order is written. As described in the CY 2013 PFS proposed rule (77 FR 44794), we outlined the rationale for the 90 days before or 30 days after the order was written.

During the face-to-face encounter, the physician, a PA, NP, or CNS must have evaluated the beneficiary, conducted a needs assessment for the beneficiary or treated the beneficiary for the medical condition that supports the need for each covered item of DME. As a matter of practice, this information would be part of the beneficiary's medical record and include the identity of the practitioner who provided the face-to-face assessment. We believe that requiring a face-to-face encounter to document the medical condition that supports the need for the covered item of DME reduces the risk of fraud, waste, and abuse since these visits help ensure that a beneficiary's condition warrants the covered item of DME.

Section 1834(a)(11)(B)(ii) of the Act, as amended by section 6407(b) of the Affordable Care Act, states that a physician must document that the physician, a PA, NP, or CNS has had a face-to-face encounter (other than with respect to encounters in which ''incident to'' services are involved) with the beneficiary. ''Incident to'' services are defined in section *1861(s)(2)*(A) of the Act. Likewise, for the purpose of this regulation, a face-to-face encounter must be documented by a physician and any encounter that is covered as an ''incident to'' service does not satisfy the requirements of this regulation.

The following is a summary of the comments we received regarding the documentation of a face-to-face encounter and the timeframe in which it must occur.

Comment: Many commenters suggested that CMS revise the rule to require that face-to-face encounters occur only *before* the date of the written order, and not after the written order is issued.

Response: After consideration of these comments we have removed the option for the face-to-face encounter to occur 30 days after the written order. We believe it is critical that the face-to-face be conducted *before* the item is delivered to the beneficiary's home. Allowing face-to-face encounters to occur 30 days after the order could result in medically unnecessary items being delivered to beneficiaries. Further, suppliers could deliver the item but then be unable to bill Medicare if the face-to-face encounter does not occur.

Comment: Many commenters believed the timeframe should be revised to allow the face-to-face encounter to occur in the 6-month period preceding the order, as authorized by the statute.

Response: In response to comments, CMS is modifying the encounter timeframe so that the face-to-face encounter must now occur 6 months prior to the written order, as opposed to the 3 months we previously had proposed. We believe this modified timeframe best balances the need to protect the Medicare Trust Funds by limiting waste, fraud and abuse while limiting burden.

Comment: Many commenters stated that the 30 days after the written order specifically puts the suppliers at financial risk. Many commenters expressed concern that it is not reasonable to expect suppliers to furnish the item without documentation that the in-person encounter took place. Once a beneficiary has received the Specified Covered Item of DME, he or she has little incentive to see a doctor. The supplier, meanwhile, will not be paid for the item unless it has obtained a signed Advance Beneficiary Notice of Noncoverage (ABN) from the beneficiary. Therefore, many commenters suggested that the face-to-face encounter should not be allowed to occur after the written order and delivery of the Specified Covered Item. They believed neither the beneficiary, nor the physician will have much impetus to follow through with the encounter once the equipment is delivered, and the supplier will then be unable to bill Medicare. A few commenters suggested that if the timeframe is not revised, CMS should compensate suppliers for the first 30 days if the physician does not present documentation.

Response: We concur that it is critical that the face-to-face encounter be conducted before the item is furnished to the beneficiary's home. We are revising the timeframe for the face-to-face encounter to occur and removing the 30 days after the written order. The face-to-face encounter must occur in the 6 months before the order is written. We will not offer any compensation or liability waivers because the supplier should be able to obtain the documentation before supplying the item.

Comment: A few commenters suggested that if the timeframe is not revised, CMS must make clear that suppliers would be entitled to payment under the waiver of liability provisions in section 1879(a)(1) of the Act in the event that the beneficiary does not follow through with the face-to-face visit, as the DME supplier would have no way to know that the visit would not take place. According to the commenters, section 1879(a)(1) clearly states that if a contractor denies payment because of a determination that the services was medically unnecessary, which would include a denial for a lack of a face-to-face encounter, the supplier should nonetheless be paid if the supplier did not know and had no reason to know that the payment would be denied.

Response: As noted previously, we are revising the encounter timeframe to be in the 6 months before the DME order is written. We believe it is critical that the face-to-face encounter be conducted before the item is delivered to the beneficiary's home. Since we have removed the 30 days after the order requirement, the waiver of liability provisions do not need to be addressed.

Comment: Several practitioner organizations supported the proposed 90 days before or 30 days after the order is written timeframe for the face-to-face encounter. These commenters believed it was a reasonable timeframe for the face-to-face to occur.

Response: The vast majority of commenters expressed concerns about the proposed timeframe. The supplier industry specifically expressed serious concerns regarding the provision in the proposed rule that allowed the face-to-face order to occur 30 days after the written order. Therefore, with this final rule with comment period, we are eliminating the option for the face-to-face encounter to occur 30 days after the written order and revising the timeframe for a face-to-face encounter to occur 6 months preceding the written order.

We will monitor the implementation of this rule to ensure there are no unintended consequences that negatively impact the practitioner, supplier, and beneficiary communities. In addition, we do not believe the new timeframe will have a significant impact

on beneficiaries' access to medically necessary, quality DME, since we believe that many beneficiaries already see their practitioner during a 6-month period of time. We believe the new timeframe will make it easier for beneficiaries to access DME then the previously proposed timeframe.

Comment: A few commenters cautioned that this proposal will cause a certain amount of confusion since certain DME items, such as power mobility devices (PMDs) as outlined in § 410.38(c), have a 45 day face-to-face encounter requirement as opposed to the proposed 90 day requirement for other DME items. Commenters believe greater consistency among face-to-face requirements for DME will reduce confusion and improve compliance by healthcare professionals. Several commenters expressed a desire to have this regulation supersede the PMD face-to-face regulation.

Response: This regulation implements section 1834(a)(11)(B) of the Act. It does not supersede the PMD regulation as specified in § 410.38(c), which we issued under different authority. We believe that a longer timeframe is necessary for these DME items than the 45-day timeframe for PMDs because of the wide variety of DME items covered by this rule. This regulation does not apply to PMDs and does not supersede other regulations specific to PMDs. We look forward to engaging in extensive education to help to clarify the requirements.

Comment: Several commenters suggested that CMS should consider a risk-based approach where specified conditions would be excluded from the face-to-face encounter requirement within the proposed timeframe. Prior to finalizing the proposed rule, most commenters suggested that CMS should work more closely with physicians and supplier stakeholders to determine the best approach in establishing a timeframe for the face-to-face encounter.

Response: In response to comments, we have removed the requirement allowing the face-to-face encounter to occur 30 days after the written order and instead are requiring the face-to-face to be conducted in the 6 months preceding the written order. However, we are not using a risk based approach to determine the methodology and timeframe for the DME face-to-face requirement. We believe that a risk based approach would be difficult to implement and would create undue confusion. We further believe that it is unnecessary particularly in light of the longer timeframe.

Comment: Several commenters expressed concerns that the longstanding Medicare policy allows beneficiaries to receive items they urgently need by allowing verbal communication between practitioners and suppliers; then a written order is required before billing. Commenters caution that the coverage policy should not prevent Medicare beneficiaries from receiving statutorily-covered, medically necessary items.

Response: We do not believe this provision will prevent Medicare beneficiaries from receiving medically necessary DME. Regarding the longstanding policy, outlined in the Program Integrity Manual, Chapter 5, for items that do not require a written order before delivery, suppliers are allowed to dispense DME to the beneficiary based upon a verbal order, however a supplier must have a written order before submitting a claim for payment. For items that do require a written order before delivery, a supplier must have a *written* order (with the face-to-face documentation) prior to delivery when submitting a claim for payment. This provision will ensure that beneficiaries are only receiving medically necessary DME. We encourage open communication between the practitioners and suppliers to ensure that beneficiaries receive medically necessary items in a timely fashion. In addition, we will monitor the implementation of this rule to ensure there are no unintended consequences that negatively impact the beneficiary, practitioner and supplier communities.

Comment: Several commenters believe that the agency is implementing a flawed statute, and urge the Secretary to carefully consider the impact on patients, particularly in rural and urban underserved areas. These commenters were especially concerned that NPs and Clinical Nurse Midwives (CNMs) are not able to fulfill the face-to-face requirement for DME. Commenters cautioned that ordering DME is clearly an activity that is within the scope of practice of nurse practitioners. They believed that a statutory barrier preventing nurse practitioners from independently documenting face-to-face encounters limits the agency and, most importantly, the patient's ability to receive timely and important care.

Response: We recognize the concerns commenters have expressed regarding the impact that this statute might have on beneficiaries, particularly in rural and urban underserved areas if NPs are not allowed to fulfill the face-to-face requirement. NPs, PAs, and CNSs can still conduct the face-to-face encounter and order DME within their scope of practice. However, in this final rule, we are implementing the statutory requirement in section 1834(a)(11)(B)(ii) of the Act, that a physician must *document* that the face-to-face encounter occurred when performed by a PA, NP, or CNS. CNMs are not listed in the statute as a practitioner that may conduct the face-to-face encounter. Moreover, we believe that CNMs are distinct from CNSs.

Comment: A few commenters expressed concerns that NPs have no control over how quickly physicians will actually document the face-to-face encounters that they conduct. The commenters were concerned that there may be instances in which it will be difficult to ensure documentation is submitted by the physician to the supplier within 30 days after an order is written, potentially delaying patient access to the equipment they need while documentation is being completed.

Response: We have removed the ability for the face-to-face encounter to occur up to 30 days after the order. We are implementing a statutory requirement that the physician must document the face-to-face encounter even when performed by a PA, NP or CNS within the 6 months preceding the written order. We urge physicians, PAs, NPs and CNSs to work together to ensure that all beneficiaries receive needed DME. Additionally, we believe that 6 months prior to the written order provides sufficient time for coordination between the NP, PA, or CNS and the physician to document the face-to-face encounter. In addition, we will monitor the implementation of this rule to ensure there are no unintended consequences that negatively impact the practitioner, supplier, and beneficiary communities.

Comment: Several commenters stated that CMS should assume that practitioners' medical judgment determined that the face-to-face encounter is valid.

Response: We appreciate the commenters' recommendation that physicians/treating practitioners should be given the presumption that their medical judgment determined that the face-to-face encounter is valid or medically necessary. However, we must ensure that all CMS requirements are met, and cannot accept this recommendation. Therefore, just because a face-to-face encounter is performed does not mean that all CMS requirements are met, including medical necessity.

Comment: Several commenters expressed concern that there is no evidence that requirements for physician oversight or supervision increases quality or reduces fraud. The commenter further stated that during

the past 15 years, there is little evidence that NPs and CNSs engaged in fraudulent or abusive ordering of DME and there is little efficiency or true accountability in relying on documentation by a physician who has not evaluated the patient rather than the NP or CNS who has performed that examination.

Response: This rule does not address the ordering practices of NPs and CNSs. Rather, the statute requires that physicians document the face-to-face encounters of NPs, CNSs and PAs with beneficiaries for certain covered items of DME. Section 1834(a)(11)(B)(ii) of the Act requires that a physician must document that the face-to-face encounter occurred when performed by a PA, NP, or CNS. The degree to which NPs and CNSs are engaged in fraudulent or abusive ordering of DME is not specifically addressed by this Affordable Care Act provision; however, as we stated earlier and also in the proposed rule, we believe that requiring a face-to-face encounter that supports the need for the covered item of DME will reduce the risk of fraud, waste, and abuse since these visits help ensure that a beneficiary's condition warrants the covered item of DME.

Comment: Several commenters stated that for some beneficiaries needing items such as transcutaneous electrical nerve stimulation (TENS), it is common for physical therapists, occupational therapists, chiropractors, and other participating Medicare health care professionals to conduct the face-to-face encounter while physicians continue to be responsible for producing the written order and documenting that the face-to-face encounter has occurred. A few commenters stated that it should be sufficient for a speech pathologist to conduct the face-to-face encounter for items such as a speech generating device. A few commenters stated that sleep physicians should also be allowed to provide DME.

Response: We appreciate these commenters' suggestions regarding including additional types of practitioners that could potentially provide DME face-to-face encounters. It is important to keep in mind that chiropractors are not allowed to bill Medicare for DME items. Other practitioners must be working within their scope of practice. The statute specifies that while the physician must document his or her own face-to-face encounter, only a physician, NP, PA, or CNS may conduct the face to face encounter, however it must be documented by a physician. Moreover, a sleep physician who meets the Medicare definition of physician can be considered a physician for purposes of this face-to-face encounter.

Comment: Several commenters stated that if this rule is to prevent fraud on the physician/non-physician side, then having a strong rationale for the DME equipment in their encounter note should provide sufficient documentation to determine the medical need for the DME. The commenters believe this documentation establishes the trail of the request and justification for each piece of DME. No additional paperwork should be transmitted and no interpretation of the encounter note (by non-clinician DME suppliers) would need to be done. The process could create a clear auditing trail for investigators.

Response: We appreciate these comments; however, we must implement the regulation based on the provisions of section 1834(a)(11)(B)(ii) of the Act, which requires a physician to document the occurrence of a face-to-face encounter for covered items of DME. Throughout the development of the proposed rule and based on comments, we attempted to balance the implementation of the statute while limiting burden on providers, suppliers and beneficiaries, and while ensuring that beneficiaries continued to have access to medically necessary DME.

In response to comments, we removed language that allowed the face-to-face encounter to occur 30 days after the written order and modified the timeframe to now be within the 6 months preceding the written order. We believe that this will allow suppliers to deliver medically necessary DME while trying to eliminate the possibility that the face-to-face encounter will never be conducted.

In the proposed rule, we noted that a face-to-face encounter may be accomplished via a telehealth encounter if all Medicare telehealth requirements as defined under section 1834(m) of the Act and the implementing regulations in § 410.78 and § 414.65 are met as described in more detail in the CY 2013 PFS proposed rule (77 FR 44794). Further, a single face-to-face encounter, including those facilitated through the appropriate use of telehealth, can support the need for multiple covered items of DME as long as it is clearly documented in the pertinent medical record that the beneficiary was evaluated or treated for a condition that supports the need for each covered item, during the specified timeframe.

As described in more detail in the CY 2013 PFS proposed rule (77 FR 44795), we proposed requirements for a written order as a condition of payment. For purposes of this final rule with comment period, which is focused on implementing section 1834(a)(11)(B) of the Act and reducing fraud, waste, and abuse, an order without minimum elements would be considered incomplete and would not support a claim for payment.

The following is a summary of the comments we received regarding the written order proposal.

Comment: Many commenters expressed a belief that instructions and requirements related to the order need to be clear and less burdensome. Commenters expressed the need for clarity and/or requested removal of the need for physicians to describe ''necessary and proper usage instructions'', diagnosis codes, and the National Provider Identifier (NPI) in the written order.

Response: We appreciate the commenters' recommendation. We agree that instructions that limit burden are important. We have removed the proposed requirement for orders to include: ''necessary and proper usage instructions'' and the diagnosis. Due to the large number of covered DME items and the fact that there could be many diagnoses and usage instructions for each, we agree that these proposed requirements may be overly burdensome. While this information will not be required on the DME order under this regulation, we will still expect to see related diagnoses included in the beneficiary's medical record. We would also expect ''necessary and proper usage instructions'' to be provided to the beneficiary or care giver for proper usage of the item. The remaining five elements listed: (1) The beneficiary name; (2) the item of DME ordered; (3) prescribing practitioner NPI; (4) the signature of the prescribing practitioner; and (5) the date of the order are the minimum needed for CMS to consider the order valid. This does not supersede other requirements.

Comment: Several commenters stated that for some DME items, the proposed face-to-face encounter requirements represent a significant change for Medicare beneficiaries, providers and DME suppliers. Commenters noted that even though some of the proposals are relatively minor, such as requiring the prescribing practitioner's NPI to be included on the written orders, they require providers and suppliers to change their standard practices. Such ''minor'' changes are significant since non-compliance may adversely affect the payment for DME.

Response: We appreciate these comments. Our goal is to limit provider and supplier burden while still preventing waste, fraud and abuse. To

that end, in response to comments, we have removed the requirement that instructions for necessary and proper usage, and the diagnosis be included on the order. However, we are retaining the other requirements as a way to limit waste, fraud and abuse.

As a result of the comments, we are requiring at a minimum, the written order contains: (1) The beneficiary name; (2) the item of DME ordered; (3) the signature of the prescribing practitioner; (4) prescribing practitioner NPI; (5) the date of the order. Orders should still comply with standards of practice and therefore may be more detailed.

As noted previously, section 1834(h)(3) of the Act incorporates by cross reference prosthetic devices, orthotics, and prosthetics to the items encompassed by section 1834(a)(11)(B) of the Act. At this time, we are not implementing the proposed changes to § 410.36(b) to require documentation of a face-to-face encounter for prosthetic devices, orthotics, and prosthetics that, according to § 410.36(b), require a written order before delivery in this final rule. We intend to use future rulemaking to determine which prosthetic devices, orthotics, and prosthetics, require, as a condition of payment, a written order before delivery supported by documentation of a face-to-face encounter with the beneficiary consistent with section 1834(a)(11)(B)(ii) of the Act.

The following is a summary of comments we received regarding prosthetic devices, orthotics, and prosthetics.

Comment: In many cases, the acute condition (for example, amputation, stroke, polio, etc.) that caused the initial medical need for the prosthesis or orthotics no longer requires specific medical treatment by a physician. In this scenario, Medicare beneficiaries often look to their orthotist or prosthetist to continue to provide the prosthetics or orthotics (P & O) necessary to restore and maintain functional abilities. Commenters were concerned that if applied to P & O patients, the face-to-face requirement for P & O care would result in extensive administrative burdens for P & O clinicians and the physicians who prescribe these services, as well as pose a significant impediment for their patients.

Response: We appreciate this comment and will consider it as we contemplate future rule making for P & O.

Comment: For prosthetic devices, orthotics, and prosthetics, commenters urged CMS to conduct an evaluation of the impact of the requirements for selected DME items before deciding whether there should be any expansion to other product categories. Second, commenters believed that CMS should limit any such requirement to items for which there is sufficient evidence of fraud and abuse, and not based solely on the reimbursement amount of the item. Commenters continued to have concerns about what data CMS used to establish and verify the level of fraud among Medicare physicians, specifically as related to that data comparing physician suppliers vs. commercial suppliers, and by specialty area within physician suppliers.

Several commenters noted that when CMS considers whether to apply the new face-to-face encounter requirements to enteral nutrition, CMS should be mindful of the existing requirements and not impose redundant requirements or request duplicative information.

Response: We appreciate these comments, and will consider them, including physician vs. commercial suppliers, as we consider future rule making for P & O.

We also stated in the proposed rule that none of our proposals superseded any regulatory requirements that more specifically address a face-to-face encounter requirement for a particular item of DME.

(2) Physician Documentation

The statute requires that a physician document that the physician or a PA, NP or CNS has had a face-to-face encounter with the beneficiary. As described in the CY 2013 PFS proposed rule (77 FR 44795), we proposed two options for how this could be done.

The following is a summary of the comments we received regarding the physician documentation proposal.

Comment: Several commenters believed a standardized form that documents the elements CMS and its contractors require for coverage of a DME item should be recognized by CMS as part of the beneficiary's medical record and should establish the beneficiary's medical need for the item.

Response: The amount of necessary clinical information needed to demonstrate that all coverage and coding requirements are met will vary depending on the item/service. For example, we have National and Local Coverage Determinations which address many of these items/services. The commenters appear to be describing a template. However, we do not prohibit the use of templates to facilitate record-keeping. We also do not endorse or approve any particular templates. A physician or practitioner may choose any template to assist in documenting medical information.

We do caution, however, that some templates provide limited options and/or space for the collection of information such as by using ''check boxes,'' predefined answers, and limited space to enter information. We discourage the use of such templates. Our experience with claim review shows that 'limited space' templates often fail to capture sufficient detailed clinical information to demonstrate that all coverage and coding requirements are met. Furthermore, physicians or practitioners should be aware that templates designed to gather selected information primarily for reimbursement purposes are often insufficient to demonstrate that all coverage and coding requirements are met. These 'limited space' documents often do not provide sufficient comprehensive information to adequately show that the medical necessity criteria for the item/service have been met.

Comment: A few commenters expressed a belief that the documentation requirements should be the same for physicians as they are for nurse practitioners and other non-physician providers.

Response: We agree that the documentation requirements for the face-to-face encounter should be the same. However, it is duplicative to have the physician document that the face-to-face occurred when they themselves conducted the face-to-face encounter. Therefore, we are not requiring additional documentation requirements for the physician in addition to what they are required to document during the actual face-to-face encounter.

As a result of the comments, the submission of the pertinent portion of the medical record documented by the physician is sufficient to document that the face-to-face encounter has occurred, when the physician conducts the face-to-face encounter. Documentation of the face-to-face encounter must include an evaluation of the beneficiary, needs assessment for the beneficiary, or treatment of the beneficiary for the medical condition that supports the need for each covered item of DME. A written order is still required for these covered items of DME.

(3) Physician Documentation of Face-to-Face Encounters Performed by a Physician Assistant, Nurse Practitioner, or Clinical Nurse Specialist

As described in the CY 2013 PFS proposed rule (77 FR 44795), we had considered four options for the physician documentation of a face-to-

face encounter performed by a PA, NP, or CNS.

The following is a summary of the comments we received regarding how physician documentation requirements should be handled when the face-to-face encounter with the beneficiary is conducted by a PA, NP, or CNS.

Comment: Many commenters believed that CMS should allow each of the outlined options so that practices may choose which option will best meet their needs and those of the patient.

Response: We believe there needs to be a standard accepted practice for documenting the face-to-face encounter when performed by a PA, NP or CNS. We believe that this will promote consistency and ensure that there is clear guidance on the requirements.

Comment: Some commenters believe that if an ordering physician certifies the date of a face-to-face encounter on the signed written order that should be sufficient documentation for the supplier to establish medical necessity for the DME items. This method of documentation is most efficient for physicians, and it is easily verified by DME suppliers when establishing that medical necessity requirements are met.

Response: While we appreciate this comment, a verification of a date added to a written order does not prove that an adequate face-to-face occurred. Detailed face-to-face documentation is required to ensure the item of DME is medically necessary and appropriate for the individual beneficiary.

Comment: Commenters believe there is no justification for requiring less information on the beneficiary's medical need for DME if a physician personally conducts the evaluation than if a nurse practitioner assesses the patient. Typically, the physician communicates the order directly to the supplier who, in turn, initiates intake and assessment based on a written confirmation of the physician's verbal order, which is later ratified by the physician's signature and date.

Response: We are not requiring less information on the need for DME if a physician conducts the evaluation than would be deemed appropriate if a nurse practitioner assesses the patient. We are not requiring additional documentation requirements for the physician above what they are required to perform in documenting the actual face-to-face encounter.

Comment: Many commenters expressed a desire to limit their burden. Commenters expressed that overly unnecessary copying, drafting, and distribution of records from the MD/DO to the physician supplier is burdensome at the very least, interferes with the physician-patient relationship, and is generally not in the best interests of the Medicare beneficiary.

Response: We have worked to develop a rule that weighs our responsibility to implement the statutory provision, while minimizing provider and supplier burden. As a result of comments, we are allowing flexibility on how the supplier is notified of the face-to-face encounter. We have tried to limit the burden by requiring that the physician sign/cosign the pertinent portion of the medical record to document when a face-to-face encounter was performed by a NP, PA or CNS. This step is not needed when the physician personally conducts the face-to-face encounter.

As a result of the comments, we are requiring the physician documenting the face-to-face encounter performed by a NP, PA or CNS, must sign or cosign the pertinent portion of the medical record indicating the occurrence of a face-to-face encounter for the beneficiary for the date of the face-to-face encounter, thereby documenting that the beneficiary was evaluated or treated for a condition relevant to an item of DME on that date of service. Other signature requirements described in the manual, such as those for determining a legible signature remain in force. This option provides evidence that the physician reviewed the relevant documentation to support that a face-to-face encounter occurred for that date of service. A signed order (in contrast to a signed medical record) would not satisfy the requirement described in this option that the physician ''sign/cosign the pertinent portion of the medical record.''

(4) Supplier Notification

Since the supplier submits the claims for the covered items of DME, the supplier must have access to the documentation of the face-to-face encounter. All documentation to support the appropriateness of the item of DME ordered, including documentation of the face-to-face encounter, must be available to the supplier. As with certain other items and services submitted for Medicare payment, we require the entity submitting the claim to maintain access to the written order and supporting documentation relating to written orders for covered items of DME and provide them to us upon our request or at the request of our contractors.

As described in CY 2013 PFS proposed rule (77 FR 44795), we had considered four options for the supplier notification of the face-to-face encounter.

The following is a summary of the comments we received regarding the supplier notification proposal.

Comment: Several commenters expressed concerns that physicians have reported deceptive practices by DME suppliers who have sent letters to physicians on letterhead appearing to be co-branded with CMS but without CMS authorization. The letters have indicated that because the DME supplier is undergoing a CMS audit, the physician must produce extensive and costly medical record documentation and submit it to the DME supplier.

Response: Suppliers are required to have the documentation available upon request by CMS. CMS has worked to limit the burden associated with this regulation. However, the CMS seal and logo are for the official use of CMS and its authorized contractors only and must not be used by suppliers or others within the private sector. Under section 1140 of the Act, individuals or organizations may be subject to a civil money penalty for the misuse of words, symbols, or emblems or names in reference to Social Security or Medicare. If physicians have information about suppliers or others who are misusing CMS words, symbols, or emblems, they should contact the HHS Office of Inspector General. Organizations or individuals concerned about suppliers who may be misrepresenting themselves or CMS should contact the contractor that processes their claims. CMS requires that suppliers have access to the documentation to support their claims. Suppliers may request supporting documentation, including documentation of a face-to-face encounter, from the physician, but suppliers must not misuse CMS words, symbols, or emblems when making those requests. Suppliers may, of course, share unaltered CMS educational material.

Comment: Commenters suggested that CMS clarify in its regulation that after a physician or beneficiary has submitted a medical record and documentation of the face-to-face visit to the DME supplier, the DME supplier must retain a copy of that already-submitted record, and the physician is not required to supply subsequent medical records or documentation to the DME supplier.

Response: The face-to-face encounter is a condition of payment for the supplier. Suppliers must make this information available to CMS upon request.

Comment: Commenters urged CMS to give physicians and other practitioners maximum flexibility by allowing them to choose among the options CMS has proposed. To avoid creating new

burdens for physicians, commenters recommend that the new process for communicating documentation to suppliers resemble, as closely as possible, current processes used by physicians. Commenters believe that this may be similar to the second option discussed in the proposed rule, and, if this is the case, they recommended using that option.

Response: In response to comments, we are not requiring a particular method of transmission for supplier notification that the face-to-face encounter has occurred in order to limit burden and not create a hindrance to access to care. Practitioners and suppliers can communicate the information and requirements through existing business processes for transmitting this information. CMS will monitor the effects of this provision on beneficiaries' access to medically necessary DME. We also note that this documentation must be made available to suppliers to allow them to ensure all requirements are met. Suppliers must make this documentation available to CMS upon request.

Comment: Many commenters believe that the adopted rules should give adequate protection to downstream DME suppliers who act in good faith in response to information communicated by physician practices. Commenters believe that whatever documentation and communication policies CMS adopts for face-to-face encounters should give suppliers absolute peace of mind that their subsequent dispersing of DME items will not later be second-guessed by CMS or its contractors.

Response: We believe that by removing the ability for the face-to-face encounter to occur 30 days after the written order suppliers will be afforded more protection as all documentation will be available at the time of order. Completion of the face-to-face requirement is a condition of payment and could be subject to audit. Therefore, this documentation must be available to CMS on request. CMS will monitor the effects of this provision on beneficiaries' access to medically necessary DME.

Comment: A few commenters strongly opposed the fourth option of requiring the physician to provide a copy of the face-to-face documentation to the beneficiary and disagreed with the reasoning that this option would, ''ensure that the supplier receives the documentation of face-to-face encounter directly and limits the supplier's need to rely on the PA, NP, or CNS to receive this documentation completed by the physician.''

Response: We appreciate this concern, and therefore, will not require this particular method for transmission of this communication.

Comment: Several commenters expressed a concern that the ordering practitioner has little interest or incentive to ensure the necessary paperwork is provided to the supplier since the practitioner/physician still gets reimbursed for their services regardless of whether they have inadequate documentation and fail to provide such documentation to the suppliers. A few commenters stated that the DME supplier should not be responsible for scheduling the face-to-face visits to ensure the requirement is met. Commenters also believed physicians who are continually noncompliant with the rule should be subject to corrective action.

Response: We encourage suppliers and practitioners to work together to ensure that beneficiaries receive necessary and appropriate care. Completion of the face-to-face requirement is a condition of payment. Therefore, this documentation must be available to CMS upon request. We believe that by removing the 30 days after the order is written timeframe for the face-to-face encounter, the supplier will be able to know before delivery if all requirements have been meet. CMS does provide education on documentation requirements to physicians and other practitioners including through MLN articles.

As a result of the comments received, we are not requiring a particular method of supplier notification. Instead, since this is a condition of payment, we only require that the supplier must have all documentation to support the claim upon request. We believe this will limit the burden on practitioners and suppliers while helping to ensure beneficiary access to DME.

b. Covered Items

Section 1834(a)(11)(B)(i) of the Act (as redesignated by the Affordable Care Act authorizes us to specify covered items that require a written order prior to delivery of the item. Under section 1834(a)(11)(B)(ii) of the Act, these orders must be written pursuant to a physician documenting that a face-to-face encounter has occurred. Accordingly, to reduce the risk of fraud, waste, and abuse, we proposed a list of Specified Covered Items that would require a written order prior to delivery. Our final list of Specified Covered Items is in Table 89. In future years, updates to this list will appear annually in the **Federal Register** and the full updated list will be available on the CMS Web site.

As highlighted in the January 2007 Government Accountability Office (GAO) report entitled, ''Improvements Needed to Address Improper Payments for Medical Equipment and Supplies,'' it is estimated that there were $700 million in improper payments across the spectrum of DMEPOS from April 1, 2005, through March 31, 2006. GAO did not specifically recommend the use of DME face-to-face encounters as a remedial action in its report. However, the GAO did recommend making improvements to address improper payments in the DMEPOS arena. This final rule with comment period is one way in which we are working to prevent DME improper payments.

Though we initially considered making all items encompassed by section 1834(a)(11)(B) of the Act (including prosthetic and orthotic items described in section 1834(h)(3) of the Act) subject to a face-to-face encounter requirement, we have first proposed a more limited criteria- driven list to balance a comprehensive face-to-face requirement to prevent fraud, waste, and abuse while mitigating any undue negative effect on practitioners and suppliers by including all items. We welcomed comments on limiting the associated burden of this proposed rule by refining the number of items subject to a face-to-face encounter, while still protecting the Medicare Trust Funds.

The following is a summary of the comments we received regarding the covered items proposal.

Comment: Commenters appreciated CMS's efforts to reduce fraud, waste, and abuse. Commenters expressed that ''as CMS implicitly acknowledges'' in the preamble to the proposed rule that the statute does not compel the Secretary to require a written order prior to delivery for all DME. Rather, the Secretary ''is authorized'' to require a written order prior to delivery for DME items that are ''specified covered items''. However, for any DME items that are Specified Covered Items, the Secretary is obligated to require documentation by a physician that the order is based on a face-to-face encounter between the beneficiary and an authorized practitioner. Commenters stated that CMS should apply the new encounter and documentation requirements initially to a smaller number of HCPCS codes and first evaluate the impact of the requirements on beneficiary access to DME and costs to providers before expanding the list in the future. Commenters suggested the new face-to-face encounter requirements should not apply to instances where a physician is ordering an item of DME

that is substantially similar to the item already being used by the beneficiary.

Response: We believe that this is an important provision aimed at reducing fraud, waste, and abuse. We used a criterion driven approach to select these items, and did not receive sufficiently detailed alternative criteria to those proposed. We believe limiting new face-to-face encounter requirements only to instances where a physician is ordering an item of DME that is substantially similar to the item already being used by the beneficiary is insufficiently broad to make significant inroads into reducing fraud, waste and abuse. It would also be difficult to determine and what qualifies as ''substantially similar.''

Comment: Commenters stated that requiring that a physician sign-off on commonly prescribed items, such as blood glucose monitors and standard wheelchairs that are currently ordered by NP, PA, and Advance Practice Nurses including CNSs may create a barrier for consumers, many of whom routinely receive this needed equipment from nonphysician practitioners, and runs contrary to current Medicare reimbursement practice. Several commenters raised concerns that the agency's broad list of proposed covered items includes several items that NPs and CNSs order routinely for frequent conditions and diagnoses, such as glucose monitors. Commenters stated that requiring physician documentation before these items may be supplied is likely to delay patient care and potentially lead to serious complications and more severe conditions.

Response: We are implementing the statutory requirements of this provision to require a physician has to document the occurrence of a face-to-face encounter for certain covered items of DME. Face-to-face encounters conducted by NPs, PAs, and CNS are allowed, but as the statute states these encounters must be documented by a physician. CMS does not believe that this regulation will create a barrier to beneficiaries including those who are prescribed orders from PAs, NPs and Advance Practice Registered Nurses including CNSs.

We use a criterion driven approach to select these items and are implementing this provision in accordance with the statute. We do not believe that this requirement will delay a beneficiary from getting necessary care particularly with the longer timeframe. In addition, we will monitor the implementation of this rule to ensure there are no unintended consequences that negatively impact the practitioner, supplier, and beneficiary communities.

Comment: Commenters recommended that CMS exercise its discretion and create a smaller list. Commenters suggested excluding from the list of Specified Covered Items any DME covered under an NCD or LCD that requires a physician to see the beneficiary before ordering the item. These include oxygen and oxygen equipment (E0441, E0442, E0443, and E0444) and all ventilators including CPAPs and RADs.

Additionally, commenters recommended any items necessary to ensure a safe discharge from an inpatient stay and preserve continuity of care, including wheelchairs, infusion pumps, hospital beds and accessories, negative pressure wound therapy (NPWT), and ambulatory items, be excluded from the list of Specified Covered Items.

Commenters stated that the need for glucometers and nebulizers (E0570, E0575, E0580) for this population is obvious; if translated to office or clinic visits needed to monitor then in the absence of the availability of this equipment, or even the extra time it will take physicians and nurse practitioners to obtain the extra documentation to order these items. This represents a significant amount of unnecessary time and cost with poorer patient outcomes.

Many commenters expressed the view that a face-to-face encounter for speech generating device (SGD) should be excluded since it will adversely affect an aphasia patient's ability to obtain the equipment required for function communication. They believe the face-to-face encounter requirement is an undue hardship for people needing a speech generating device. A SGD already requires a Certificate of Medical Necessity before ordering.

Commenters noted the current proposed list of Specified Covered Items includes equipment that have a fee schedule amount well below $1000, including accessories to the primary equipment. To require a separate face-to-face encounter to document need for an accessory for primary equipment already vetted in a previous face-to-face encounter and currently in the possession of the beneficiary seems unduly burdensome. To that point, commenters stated, that wheelchair accessories should not be included on the Specified Covered Item list. Section 410.38(c)(3)(ii) states that accessories for PMDs may be ordered by the physician/treating practitioner without conducting a face-to-face encounter with the beneficiary.

Response: In areas where a face-to-face is required by the NCD or LCD the documentation requirements of this regulation are in addition to those documents for the NCD or LCD. The face-to-face should comply with the requirements of the applicable NCD/LCD and its occurrence must be documented by a physician. CMS reminds providers and suppliers that multiple items can be supported by a single face-to-face encounter.

For a beneficiary who is discharged from the hospital, the face-to-face encounter may occur in that setting. This mitigates the concern of items needed to safely discharge the beneficiary.

We are removing items from the covered list of items where regulations explicitly state that a face-to-face encounter is not necessary such as power wheelchair accessories. We used a criteria-driven approach in order to create this list, and speech generating devices specifically are items meet one of our criteria. There are items below $1,000 on the list because these items still have an aggregate effect on the Medicare Trust Funds. While commenters recommended we remove individual items, we are not convinced that any of our criteria are inappropriate.

Comment: Some commenters supported the inclusion of ventilators, respiratory assist device CPAP/BiPAP, and chest wall oscillators on the list of items that require a face-to-face encounter.

Response: We agree and have included these items on the Specified Covered Item list.

Comment: Commenters questioned if aggregate rental cost was included in the $1,000 threshold.

Response: The threshold criterion does not include aggregate rental costs of DME.

Comment: Many commenters believe the overwhelming majority of orders for DME are already made in an appropriate medical context. That is, DME is typically ordered as part of a beneficiary's routine medical care consistent with coverage determinations issued by CMS and its contractors. Consequently, they believe it is unnecessary for CMS to require additional in-person evaluations or documentation for many categories of DME. Moreover, when DME is ordered on discharge from an inpatient stay, they believe it is likewise unnecessary for CMS to impose an additional face-to-face physician visit or documentation requirement because the beneficiary's need for equipment would have been evaluated during the stay. Other similar

comments are that the face-to-face encounter requirements will generate considerable additional administrative burden for physicians, patients and suppliers, and overall healthcare costs due to increases patient morbidities as a result of expired prescriptions or inability to obtain documentation that will delay getting DME. Finally, commenters believed there is no hard evidence that this provision will have a positive impact.

Response: We are implementing the statutory requirement using a criteria-driven approach in order to create this list. We have taken into account many of the comments received in revising the rule to address the potential burden concerns, extending the proposed timeline to 6 months, removing the 30 days post written order option, and allowing face-to-face encounters to occur at the hospital prior to discharge. While commenters recommended removal of individual items, there was no mention of removing any of the specific criteria, nor was a detailed alternative methodology provided. While commenters recommended individual items to remove, we must maintain a criteria-driven approach our criteria were outlined in 77 FR 44797.

Comment: Commenters were very concerned that the proposed rule does not make clear that the burden to obtain documentation of face-to-face encounters will not be placed on pharmacies.

Response: We worked to implement this statute in a way that limits burden to providers and suppliers while ensuring beneficiary access to care. All entities billing Medicare for a covered item of DME are subject to this provision. CMS does not believe that it is appropriate to carve out an exception for pharmacies. If a pharmacy bills Medicare for one of these covered items then this documentation must be available upon request.

Comment: Commenters encouraged the Agency to (1) assess regularly how additional documentation requirements could limit patient access to DME items and increase the documentation burden on providers, (2) describe what types of educational programs it will develop to help providers understand the DME documentation requirements necessary for Medicare coverage, and (3) evaluate what incentives could be offered to encourage providers to focus on reducing documentation error rates.

Response: We do not believe that this requirement will limit patient access to necessary DME particularly in light of the longer timeframe. We balanced the need to protect the Medicare Trust Funds while limiting burden. We are not being prescriptive on how the face-to-face encounter must be communicated to the supplier and believe this will help limit provider burden. CMS will issue an MLN article regarding this requirement. Incentives for document error rate are outside the scope of this regulation.

As a result of the comments, we are maintaining our criteria-driven list, however, we are removing items from the covered list of items where regulations explicitly state that a face-to-face encounter is not necessary.

As described in the CY 2013 PFS proposed rule (77 FR 44796), we described our proposed criteria, as well as the reasons we selected these criteria. We first noted that our proposed list of Specified Covered Items contains DME items only. We intended to use future rulemaking to apply section 1834(a)(11)(B)(ii) of the Act to add prosthetics and orthotics. We believe that our proposed current focus on DME items is an appropriate way of balancing our goals of reducing fraud, waste, and abuse and limiting burden on beneficiaries and the supplier community. We also proposed to focus initially on DME items for several reasons.

We welcomed comments on limiting the associated burden of this proposed regulation by refining the number of items subject to a face-to-face encounter, while still meeting the requirements of the statute.

The proposed list of Specified Covered Items contains items that meet at least one of the following four criteria: (1) Items that currently require a written order prior to delivery per instructions in our Program Integrity Manual; (2) items that cost more than $1,000; (3) items that we, based on our experience and recommendations from the Durable Medical Equipment Medicare Administrative Contractors, believe are particularly susceptible to fraud, waste, and abuse; (4) items determined by CMS as vulnerable to fraud, waste and abuse based on reports of the HHS Office of Inspector General, Government Accountability Office or other oversight entities. We are adding a criterion to remove any items where regulations explicitly state that a face-to-face encounter is not necessary. As described in the CY 2013 PFS proposed rule (77 FR 44796), we outlined each of these criteria.

Our final list of Specified Covered Items is in Table 89 of this final rule with comment period. We further proposed to update this list of Specified Covered Items annually to add any new items that are described by a HCPCS code for the following types of DME:

- TENS unit
- Rollabout chair
- Manual Wheelchair accessories
- Oxygen and respiratory equipment
- Hospital beds and accessories
- Traction-cervical

Note that the list does not include power mobility devices (PMDs), which are subject to already existing face-to-face requirements, as previously discussed. In addition, we proposed to add to the list any item of DME that in the future appears on the DMEPOS Fee Schedule with a price ceiling at or greater than $1,000. Items not included in one of the proposed automatic pathways would be added to the list of Specified Covered Items through notice and comment rulemaking.

Through updates in the **Federal Register**, we propose removing HCPCS codes from the list that are no longer covered by Medicare or that are discontinued HCPCS codes.

The DME list of Specified Covered Items are as follows, the original list was at 77 FR 44798:

TABLE 89—DME LIST OF SPECIFIED COVERED ITEMS

HCPCS code	Description
E0185	Gel or gel-like pressure mattress pad.
E0188	Synthetic sheepskin pad.
E0189	Lamb's wool sheepskin pad.
E0194	Air fluidized bed.
E0197	Air pressure pad for mattress standard length and width.
E0198	Water pressure pad for mattress standard length and width.
E0199	Dry pressure pad for mattress standard length and width.
E0250	Hospital bed fixed height with any type of side rails, mattress.
E0251	Hospital bed fixed height with any type side rails without mattress.

TABLE 89—DME LIST OF SPECIFIED COVERED ITEMS—Continued

HCPCS code	Description
E0255	Hospital bed variable height with any type side rails with mattress.
E0256	Hospital bed variable height with any type side rails without mattress.
E0260	Hospital bed semi-electric (Head and foot adjustment) with any type side rails with mattress.
E0261	Hospital bed semi-electric (head and foot adjustment) with any type side rails without mattress.
E0265	Hospital bed total electric (head, foot and height adjustments) with any type side rails with mattress.
E0266	Hospital bed total electric (head, foot and height adjustments) with any type side rails without mattress.
E0290	Hospital bed fixed height without rails with mattress.
E0291	Hospital bed fixed height without rail without mattress.
E0292	Hospital bed variable height without rail without mattress.
E0293	Hospital bed variable height without rail with mattress.
E0294	Hospital bed semi-electric (head and foot adjustment) without rail with mattress.
E0295	Hospital bed semi-electric (head and foot adjustment) without rail without mattress.
E0296	Hospital bed total electric (head, foot and height adjustments) without rail with mattress.
E0297	Hospital bed total electric (head, foot and height adjustments) without rail without mattress.
E0300	Pediatric crib, hospital grade, fully enclosed.
E0301	Hospital bed Heavy Duty extra wide, with weight capacity 350–600 lbs with any type of rail, without mattress.
E0302	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress.
E0303	Hospital bed Heavy Duty extra wide, with weight capacity 350–600 lbs with any type of rail, with mattress.
E0304	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress.
E0424	Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing.
E0431	Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing.
E0433	Portable liquid oxygen system.
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing.
E0439	Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing.
E0441	Oxygen contents, gaseous (1 month supply).
E0442	Oxygen contents, liquid (1 month supply).
E0443	Portable Oxygen contents, gas (1 month supply).
E0444	Portable oxygen contents, liquid (1 month supply).
E0450	Volume control ventilator without pressure support used with invasive interface.
E0457	Chest shell.
E0459	Chest wrap.
E0460	Negative pressure ventilator portable or stationary.
E0461	Volume control ventilator without pressure support node for a noninvasive interface.
E0462	Rocking bed with or without side rail.
E0463	Pressure support ventilator with volume control mode used for invasive surfaces.
E0464	Pressure support vent with volume control mode used for noninvasive surfaces.
E0470	Respiratory Assist Device, bi-level pressure capability, without backup rate used non-invasive interface.
E0471	Respiratory Assist Device, bi-level pressure capability, with backup rate for a non-invasive interface.
E0472	Respiratory Assist Device, bi-level pressure capability, with backup rate for invasive interface.
E0480	Percussor electric/pneumatic home model.
E0482	Cough stimulating device, alternating positive and negative airway pressure.
E0483	High Frequency chest wall oscillation air pulse generator system.
E0484	Oscillatory positive expiratory device, non-electric.
E0570	Nebulizer with compressor.
E0575	Nebulizer, ultrasonic, large volume.
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type for use with regulator or flowmeter.
E0585	Nebulizer with compressor & heater.
E0601	Continuous airway pressure device.
E0607	Home blood glucose monitor.
E0627	Seat lift mechanism incorporated lift-chair.
E0628	Separate Seat lift mechanism for patient owned furniture electric.
E0629	Separate seat lift mechanism for patient owned furniture non-electric.
E0636	Multi positional patient support system, with integrated lift, patient accessible controls.
E0650	Pneumatic compressor non-segmental home model.
E0651	Pneumatic compressor segmental home model without calibrated gradient pressure.
E0652	Pneumatic compressor segmental home model with calibrated gradient pressure.
E0655	Non-segmental pneumatic appliance for use with pneumatic compressor on half arm.
E0656	Non-segmental pneumatic appliance for use with pneumatic compressor on trunk.
E0657	Non-segmental pneumatic appliance for use with pneumatic compressor chest.
E0660	Non-segmental pneumatic appliance for use with pneumatic compressor on full leg.
E0665	Non-segmental pneumatic appliance for use with pneumatic compressor on full arm.
E0666	Non-segmental pneumatic appliance for use with pneumatic compressor on half leg.
E0667	Segmental pneumatic appliance for use with pneumatic compressor on full-leg.
E0668	Segmental pneumatic appliance for use with pneumatic compressor on full arm.
E0669	Segmental pneumatic appliance for use with pneumatic compressor on half leg.
E0671	Segmental gradient pressure pneumatic appliance full leg.
E0672	Segmental gradient pressure pneumatic appliance full arm.
E0673	Segmental gradient pressure pneumatic appliance half leg.
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency.

TABLE 89—DME LIST OF SPECIFIED COVERED ITEMS—Continued

HCPCS code	Description
E0692	Ultraviolet light therapy system panel treatment 4 foot panel.
E0693	Ultraviolet light therapy system panel treatment 6 foot panel.
E0694	Ultraviolet multidirectional light therapy system in 6 foot cabinet.
E0720	Transcutaneous electrical nerve stimulation, two lead, local stimulation.
E0730	Transcutaneous electrical nerve stimulation, four or more leads, for multiple nerve stimulation.
E0731	Form fitting conductive garment for delivery of TENS or NMES.
E0740	Incontinence treatment system, Pelvic floor stimulator, monitor, sensor, and/or trainer.
E0744	Neuromuscular stimulator for scoliosis.
E0745	Neuromuscular stimulator electric shock unit.
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spine application.
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal application.
E0749	Osteogenesis stimulator, electrical, surgically implanted.
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive.
E0762	Transcutaneous electrical joint stimulation system including all accessories.
E0764	Functional neuromuscular stimulator, transcutaneous stimulations of muscles of ambulation with computer controls.
E0765	FDA approved nerve stimulator for treatment of nausea & vomiting.
E0782	Infusion pumps, implantable, Non-programmable.
E0783	Infusion pump, implantable, Programmable.
E0784	External ambulatory infusion pump.
E0786	Implantable programmable infusion pump, replacement.
E0840	Tract frame attach to headboard, cervical traction.
E0849	Traction equipment cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible.
E0850	Traction stand, free standing, cervical traction.
E0855	Cervical traction equipment not requiring additional stand or frame.
E0856	Cervical traction device, cervical collar with inflatable air bladder.
E0958	Manual wheelchair accessory, one-arm drive attachment.
E0959	Manual wheelchair accessory-adapter for Amputee.
E0960	Manual wheelchair accessory, shoulder harness/strap.
E0961	Manual wheelchair accessory wheel lock brake extension handle.
E0966	Manual wheelchair accessory, headrest extension.
E0967	Manual wheelchair accessory, hand rim with projections.
E0968	Commode seat, wheelchair.
E0969	Narrowing device wheelchair.
E0971	Manual wheelchair accessory anti-tipping device.
E0973	Manual wheelchair accessory, adjustable height, detachable armrest.
E0974	Manual wheelchair accessory anti-rollback device.
E0978	Manual wheelchair accessory positioning belt/safety belt/pelvic strap.
E0980	Manual wheelchair accessory safety vest.
E0981	Manual wheelchair accessory Seat upholstery, replacement only.
E0982	Manual wheelchair accessory, back upholstery, replacement only.
E0983	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, joystick control.
E0984	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, Tiller control.
E0985	Wheelchair accessory, seat lift mechanism.
E0986	Manual wheelchair accessory, push activated power assist.
E0990	Manual wheelchair accessory, elevating leg rest.
E0992	Manual wheelchair accessory, elevating leg rest solid seat insert.
E0994	Arm rest.
E1014	Reclining back, addition to pediatric size wheelchair.
E1015	Shock absorber for manual wheelchair.
E1020	Residual limb support system for wheelchair.
E1028	Wheelchair accessory, manual swing away, retractable or removable mounting hardware for joystick, other control interface or positioning accessory.
E1029	Wheelchair accessory, ventilator tray.
E1030	Wheelchair accessory, ventilator tray, gimbaled.
E1031	Rollabout chair, any and all types with castors 5″ or greater.
E1035	Multi-positional patient transfer system with integrated seat operated by care giver.
E1036	Patient transfer system.
E1037	Transport chair, pediatric size.
E1038	Transport chair, adult size up to 300lb.
E1039	Transport chair, adult size heavy duty >300lb.
E1161	Manual Adult size wheelchair includes tilt in space.
E1227	Special height arm for wheelchair.
E1228	Special back height for wheelchair.
E1232	Wheelchair, pediatric size, tilt-in-space, folding, adjustable with seating system.
E1233	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system.
E1234	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system.
E1235	Wheelchair, pediatric size, rigid, adjustable, with seating system.
E1236	Wheelchair, pediatric size, folding, adjustable, with seating system.
E1237	Wheelchair, pediatric size, rigid, adjustable, without seating system.
E1238	Wheelchair, pediatric size, folding, adjustable, without seating system.
E1296	Special sized wheelchair seat height.
E1297	Special sized wheelchair seat depth by upholstery.

TABLE 89—DME LIST OF SPECIFIED COVERED ITEMS—Continued

HCPCS code	Description
E1298	Special sized wheelchair seat depth and/or width by construction.
E1310	Whirlpool non-portable.
E2502	Speech Generating Devices prerecord messages between 8 and 20 Minutes.
E2506	Speech Generating Devices prerecord messages over 40 minutes.
E2508	Speech Generating Devices message through spelling, manual type.
E2510	Speech Generating Devices synthesized with multiple message methods.
E2227	Rigid pediatric wheelchair adjustable.
K0001	Standard wheelchair.
K0002	Standard hemi (low seat) wheelchair.
K0003	Lightweight wheelchair.
K0004	High strength ltwt wheelchair.
K0005	Ultra Lightweight wheelchair.
K0006	Heavy duty wheelchair.
K0007	Extra heavy duty wheelchair.
K0009	Other manual wheelchair/base.
K0606	AED garment with electronic analysis.
K0730	Controlled dose inhalation drug delivery system.

c. Physician Payment

We understand that there is a burden associated with the requirement placed on the physician to document that a face-to-face encounter has occurred between a PA, a NP or a CNS, and the beneficiary. As discussed in section III.M.3 of this final rule with comment period, we are establishing work and malpractice RVUs for HCPCS codes for G0454 by crosswalking to the work and malpractice RVUs for CPT code 99211 ((Level 1 office or other outpatient visit, established patient). With regard to practice expense RVUs, we are not including any direct practice expense inputs for clinical labor, disposable medical supplies, or equipment in the direct PE input database for this code; practice expense RVUs will reflect resources for overhead costs only. The work, malpractice, and practice expense RVUs for HCPCS code G0454 are reflected in Addendum B of this CY 2013 PFS final rule with comment period *www.cms.gov/physicianfeesched/*. A complete list of the interim final times assigned to HCPCS code G0454 is available on the CMS Web site at *www.cms.gov/physicianfeesched/*.

This code is to compensate a physician who documented that a PA, a NP, or a CNS practitioner has performed a face-to-face encounter for the list of Specified Covered Items. This G-code becomes effective when this provision of the regulation becomes effective. We believe that the existing Evaluation and Management (E&M) codes are sufficient for practitioners furnishing face-to-face encounters. This new G-code will be specifically designed and mapped only for a physician who completes the documentation of the face-to-face encounter furnished by a PA, NP, or CNS. Only a physician who does not bill an associated E&M code for the beneficiary in question would be eligible for this G-code. If multiple written orders for covered items of DME originate from one visit, the physician can receive the G-code payment only once for documenting that the face-to-face encounter has occurred. The G-code would be mapped so that only eligible DME items would be covered. Upon request, we will need to see documentation of the face-to-face encounter in order to verify the appropriateness of the G-code payment.

The following is a summary of the comments we received regarding the physician payment proposal.

Comments: One commenter recommended against adoption of the new G-code, seeing little or no difference in the proposed documentation requirement for face-to-face encounters conducted by a physician practice's nonphysicians than other documentation requirements already imposed upon physicians. A few commenters stated that if CMS believes that physicians should be reimbursed for documenting face-to-face patient encounters conducted by nonphysicians in their employ, then the agency should more systematically determine all instances in which CMS-imposed administrative burdens on physicians warrant Medicare reimbursement and seek Congressional (statutory) authority for such reimbursement policies.

Response: In this final rule, we were only addressing additional work involved with documenting face-to-face encounters furnished by a PA, NP, or CNS for certain DME items. Other areas of CMS-imposed administrative burden on physicians are beyond the scope of our regulation. The work, malpractice, and practice expense RVUs for this code (HCPCS code G0454) are reflected in Addendum B of this CY 2013 PFS final rule with comment period at *www.cms.gov/physicianfeesched/*.

Comment: Several commenters supported the creation of a G-code, with a proposed payment of $15 to reimburse physicians for the work involved in documenting face-to-face encounters with Physician Assistants or Nurse Practitioners. Commenters believed that it is important to properly reimburse physicians for time and effort. Some commenters request more information on how the dollar figure was arrived at and whether it is truly budget neutral.

Response: The work, malpractice, and practice expense RVUs for this code (HCPCS code G0454) are reflected in Addendum B of this CY 2013 PFS final rule with comment period at *www.cms.gov/physicianfeesched/*. This code is subject to budget neutrality under the physician fee schedule and has been accommodated for in the final rule. This code is cross walked to 99211.

Comment: Many commenters raised concerns about the statement that according to CMS, ''only a physician who does not bill an E & M code for the beneficiary in question would be eligible for this G-code.'' Commenters believed appropriate policy should allow for the billing of an E & M service that is clearly unrelated to the patient's need for, and documentation of, DME authorization.

Response: We will clarify in the final rule that this code is only for use when a physician documents the face-to-face encounter performed by a PA, NP, or CNS for certain DME items.

Comment: Several commenters believed that there should be an additional payment for the suppliers in addition to the additional payment for

the practitioners conducting the face-to-face encounter.

Response: The only area available for additional payment is the physician documenting that a face-to-face encounter occurred by a PA, NP, or CNS. We believe that the other documentation of the face-to-face encounter is within the normal scope of practice. The supplier receives the payment for the item and this face-to-face encounter is a condition of payment.

Comment: This proposal fails to acknowledge the additional burden imposed on nurse practitioners and other providers who are required to coordinate with physicians to ensure the additional documentation of patient encounters in which the physician was not involved. If this unnecessary and burdensome documentation requirement cannot be eliminated, then nurse practitioners and other nonphysician providers who are required to attempt to ensure that it is complied with should also be able to bill for the proposed additional payment.

Response: We must follow the statute which states that a physician must document that the face-to-face encounter occurred. In this instance, we are recognizing the additional physician work that may be involved through the addition of a new G-code to compensate providers for this documentation requirement. We believe any necessary coordination with a physician following a face-to-face encounter with a beneficiary is covered appropriately under the corresponding E/M code that would be billed by the PA, NP, or CNS for documenting the occurrence.

D. Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review (§ 421.500 Through § 421.505)

Medical review is the process performed by Medicare contractors to ensure that billed items or services are covered and are reasonable and necessary as specified under section 1862(a)(1)(A) of the Act. We enter into contractual agreements with contractors to perform medical review functions. On December 8, 2003, the Congress enacted the MMA. Section 934 of the MMA amended section 1874A of the Act by adding a new subsection (h)—regarding random prepayment reviews and non-random prepayment complex medical reviews and requiring us to establish termination dates for non-random prepayment complex medical reviews. Although section 934 of the MMA set forth requirements for random prepayment review, our contractors do not perform random prepayment review. However, our contractors do perform non-random prepayment complex medical review.

On September 26, 2008, we published a final rule in the **Federal Register** (73 FR 55753) entitled, ''Medicare Program; Termination of Non-Random Prepayment Complex Medical Review'' that specified the criteria contractors would use for the termination of providers and suppliers from non-random prepayment complex medical review as required under the MMA. The final rule required contractors to terminate the non-random prepayment complex medical review of a provider or supplier no later than 1 year following the initiation of the complex medical review or when calculation of the error rate indicates the provider or supplier has reduced its initial error rate by 70 percent or more. (For more detailed information, see the September 26, 2008 final rule (73 FR 55753)).

On March 23, 2010, the Congress enacted the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) (together known as the Affordable Care Act). Section 1302 of the HCERA, repealed section 1874A(h) of the Act.

Section 1302 of the HCERA repealed section 1874A(h) of the Act, and therefore, removed the statutory basis for our regulation. Thus, we proposed to remove the regulatory provisions in 42 CFR part 421, subpart F, that require contractors to terminate a provider or supplier from non-random prepayment complex medical review no later than 1 year following the initiation of the medical review or when the provider or supplier has reduced its initial error rate by 70 percent or more. As a result of this proposal, contractors would not be required to terminate non-random prepayment medical review by a prescribed time but would instead terminate each medical review when the provider or supplier has met all Medicare billing requirements as evidenced by an acceptable error rate as determined by the contractor.

The following is a summary of the public comments received and our responses:

Comment: Commenters stated that the lack of statutory authority is not a valid reason for withdrawing the regulation establishing requirements for termination of non-random prepayment complex review. CMS continues to possess the general regulatory authority to maintain the regulation.

Response: We believe that the repeal of section 1874A(h) of the Act reflects Congressional intent to require CMS to repeal the regulation CMS issued under that authority. Regardless of whether or not CMS could promulgate a different regulation establishing termination dates for non-random prepayment review based on it general rulemaking authority, we nonetheless believe that the existing regulation must be removed. We also believe that sections 1815(a), 1833(e), 1862(a)(1)(A), and 1893 of the Act provide the statutory authority to conduct non-random prepayment complex medical review and we do not need to have another regulation in place for oversight of this work. We strive to balance our need to protect the integrity of the Medicare Trust Fund and our need to reduce improper payments against our interest in limiting provider and supplier burden.

Comment: Some commenters expressed concerns about the Agency's proposal to remove all protections for practitioners undergoing non-random prepayment review and the discretion of each contractor to determine an acceptable error rate for eliminating non-random prepayment review. Other commenters expressed concern that Medicare contractors will have too much power and authority. They suggested that contractors do not or cannot articulate the thresholds that must be met to be taken off prepayment review. They recommended that CMS have a uniform, rational, and predictable process that permits providers/suppliers to be removed from non-random prepayment complex medical review.

Response: We provide guidance to our contractors on the medical review process. The guidance is provided in Chapter 3 of the Program Integrity Manual (Pub. 100–08). This guidance requires contractors to minimize potential future losses to the Medicare Trust Fund through targeted claims review and through progressive corrective actions that are tailored to the types of errors contractors identify related to provider and supplier specific behavior. This requirement reflects CMS' goal to limit the burden on providers and suppliers while aiming to achieve efficiencies in the Medicare Program.

Comment: Commenters stated that the prepayment review process is burdensome and that reviews are often inconsistent and result in costly, unorganized compliance efforts for suppliers.

Response: We believe that sections 1815(a), 1833(e) and 1862(A)(1)(a) of the Act provide authority for the collection of documentation as may be necessary

to determine the amounts due to a provider or supplier and to determine medical necessity of the services rendered. We strive to balance our need to protect the integrity of the Medicare Trust Fund and our need to reduce improper payments against our interest in limiting provider burden.

Comment: Commenters suggested that CMS consider broader contractor reforms to assess contractors' activities and evaluate the appropriateness of their use of prepayment review. Commenters also suggested that CMS publish guidelines on contractor requirements, public reports of contractor initiatives, have a public complaint and resolution process (or an independent entity to review and appeal by the provider or supplier for lifting the non-random prepayment complex medical review), and increase methods of communications with suppliers and beneficiaries.

Response: CMS has many activities underway that can be found at *www.cms.hhs.gov* Web site to monitor contractor oversight and compliance with national guidelines. We welcome all suggestions on how to improve the Medicare prepayment complex medical review process.

Comment: Commenters are concerned that the entire prepayment medical review process will now be subject to agency guidelines set forth in manuals rather than formal regulation.

Response: Section 1893 of the Act provides that contractors will perform medical review of claims to promote the integrity of the Medicare program. We do not believe another regulation is necessary and that the guidance to contractors on the medical review process is set forth in statute and manuals is adequate. The guidance is provided primarily in Chapter 1 and Chapter 3 of the Program Integrity manual (Pub. 100–08).

Comment: Commenters encouraged CMS to employ greater physician education and outreach to solve the issue of improper billing before placing physicians under prepayment review.

Response: We provide physician education and outreach through various avenues including educational articles and Open Door Forums. Contractors are also instructed to provide education to physicians that are placed on prepayment review and more details can be found on the contractor's individual Web sites.

After reviewing the public comments, we are finalizing these provisions as proposed. We believe we need to do so in order to balance protection of the integrity of the Medicare Trust Fund and reduction of improper payments against limiting provider burden.

E. Ambulance Coverage—Physician Certification Statement

We proposed to revise § 410.40(d)(2) by incorporating nearly the same provision found at § 410.40(d)(3)(v) to clarify that a physician certification statement (PCS) does not, in and of itself, demonstrate that a non-emergency, scheduled, repetitive ambulance service is medically necessary for Medicare coverage. The Medicare ambulance benefit at section 1861(s)(7) of the Act allows for coverage of an ''ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but * * * only to the extent provided in regulations.'' In other words, the definition of the benefit itself embodies the clinical medical necessity requirement that other forms of transportation must be contraindicated by a beneficiary's condition. Section 410.40(d) interprets the medical necessity requirement. Notably, even aside from the requirements of section 1861(s)(7), section 1862(a)(1)(A) of the Act dictates that any service that is not medically necessary under the Act and regulations is not a covered benefit.

Despite these statutory provisions and the language of the present regulation at § 410.40(d)(2) that we believe already requires both medical necessity and a PCS, some courts have recently concluded that § 410.40(d)(2) establishes that a sufficiently detailed and timely order from a beneficiary's physician, to the exclusion of any other medical necessity requirements, conclusively demonstrates medical necessity with respect to nonemergency, scheduled, repetitive ambulance services.

Absent explicit statutorily-based exceptions, we have consistently maintained that the Secretary is the final arbiter of whether a service is reasonable and necessary and qualifies for Medicare coverage. For example, in HCFA Ruling 93–1, we said ''[i]t is HCFA's ruling that no presumptive weight should be assigned to the treating physician's medical opinion in determining the medical necessity of inpatient hospital or SNF services under section 1862(a)(1) of the Act. A physician's opinion will be evaluated in the context of the evidence in the complete administrative record. Even though a physician's certification is required for payment, coverage decisions are not made based solely on this certification; they are made based on objective medical information about the patient's condition and the services received. This information is available from the claims form and, when necessary, the medical record which includes the physician's certification.''

Medical necessity is not just an integral requirement of Medicare's ambulance benefit in particular, but, as noted above, section 1862(a)(1)(A) of the Act dictates that services must be reasonable and necessary to qualify for any Medicare coverage. Numerous U.S. Circuit Courts of Appeal have held that PCSs or certificates of medical necessity do not, in and of themselves, conclusively demonstrate medical necessity. The same applies in the context of non-emergency, scheduled, repetitive ambulance services—the PCS is not, in and of itself, the sole determinant of medical necessity, and, as we discuss below, we believe the existing regulation at § 410.40(d)(2) already demonstrates that. To erase any doubt, however, we proposed a revision to § 410.40(d)(2) to explicitly clarify this principle.

Since being finalized in the February 27, 2002 **Federal Register** (67 FR 9100, 9132), § 410.40(d)(2) has stated that ''Medicare covers medically necessary non-emergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met.'' Although a physician certifies with respect to medical necessity, the Secretary is the final arbiter of whether a service is medically necessary for Medicare coverage. As demonstrated by the inclusion of the phrase ''medically necessary,'' and by various other clarifying points, we made clear that a PCS, while necessary, does not on its own conclusively demonstrate the medical necessity of non-emergency, scheduled, repetitive ambulance services.

The preamble to the February 27, 2002 final rule (Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services (67 FR 9100)) and the 1999 final rule with comment (FRC) (Medicare Program; Coverage of Ambulance Services and Vehicle and Staff Requirements (64 FR 3637)) support this interpretation.

For example, in describing comments regarding medical necessity and physician certification in the 1999 FRC, we said: ''[t]wo ambulance suppliers commented that physicians are unaware of the coverage requirements for

ambulance services and that their decisions to request ambulance services may be based on 'family preference or the inability to safely transport the beneficiary by other means rather than on the medical necessity requirement imposed by Medicare.' '' We responded that section 1861(s)(7) of the Act allows coverage only under certain limited circumstances, and suggested that ''[t]o facilitate awareness of the Medicare rules as they relate to the ambulance service benefit, ambulance suppliers may need to educate the physician (or the physician's staff members) when making arrangements for the ambulance transportation of a beneficiary.'' We continued that ''[s]uppliers may wish to furnish an explanation of applicable medical necessity requirements, as well as requirements for physician certification, and to explain that the certification statement should indicate that the ambulance services being requested by the attending physician are medically necessary.'' (76 FR 3637, 3641) Since we recognize the significant program vulnerability—that the physicians writing PCSs might not be fully cognizant of the Medicare ambulance benefit's medical necessity requirements (and encourage suppliers to help remedy that by educating physicians), it would not be reasonable to vest exclusively in the PCS the authority to demonstrate an ambulance transport's medical necessity. We made a similar point in response to a separate comment: ''It is always the responsibility of the ambulance supplier to furnish complete and accurate documentation to demonstrate that the ambulance service being furnished meets the medical necessity criteria.'' (76 FR 3637, 3639).

In the section of the February 27, 2002 final rule preamble describing the PCS requirements, we said: ''[i]n all cases, the appropriate documentation must be kept on file and, upon request, presented to the carrier or intermediary. It is important to note that the presence of the signed physician certification statement does not necessarily demonstrate that the transport was medically necessary. The ambulance supplier must meet all coverage criteria for payment to be made.'' (67 FR 9100, 9111) Although we incorporated that passage into the final rule only at § 410.40(d)(3)(v), we intended, and we believe our intent was clear from the preamble narrative, that the principle apply equally to all nonemergency ambulance transports.

The OIG report entitled ''Medicare Payments for Ambulance Transports'' (OEI–05–02–00590) (January 2006) also supports our position. Based on its analysis of a sample of calendar year 2002 claims, the OIG reported that ''27 percent of ambulance transports to or from dialysis facilities did not meet Medicare's coverage criteria.'' The OIG added ''the ongoing and repetitive nature of dialysis treatment makes transports to and from such treatment vulnerable to abuse. Although the condition of some patients warrants repetitive, scheduled ambulance transports for dialysis treatment, many dialysis transports do not meet coverage criteria.'' The OIG recommended that we instruct our contractors to implement prepayment edits with respect to dialysis transports and have them request wide-ranging documents when conducting postpayment medical review. The fact that we agreed with the OIG's recommendations demonstrated our belief that the PCS was not the sole determinant of medical necessity. Likewise, the fact that the OIG mentioned our ambulance coverage regulations, including the PCS requirement, but did not recommend altering or clarifying the regulations with respect to medical necessity demonstrated that we were of like mind; that, while a physician certifies with respect to medical necessity, the Secretary is the final arbiter of whether a service is medically necessary.

Accordingly, we proposed to revise § 410.40(d)(2) to add nearly the same provision presently found at § 410.40(d)(3)(v), except for the reference to a ''signed return receipt'' that does not pertain to non-emergency, scheduled, repetitive ambulance services. We proposed to accomplish this by redesignating the current language as § 410.40(d)(2)(i), and adding the clarifying language to a new § 410.40(d)(2)(ii). The proposed § 410.40(d)(2)(ii) clarifies that a signed physician certification statement does not, in and of itself, demonstrate that an ambulance transport was reasonable and necessary. Rather, for all ambulance services, providers, and suppliers must retain on file all appropriate documentation and present such documentation upon request to a Medicare contractor. A CMS contractor may use such documentation to assess, among other things, whether the service satisfied Medicare's medical necessity, eligibility, coverage, benefit category, or any other criteria necessary for Medicare payment to be made. For example, the patient's condition must be such that other means of transportation would be contraindicated, and the services provided must be reasonable and necessary for the diagnosis or treatment of illness or injury.

We also proposed to fix the typographical error ''fro,'' which should be ''from'', in the existing § 410.40(c)(3)(ii).

The following is a summary of the comments received on the physician certification statement proposal and our responses:

Comment: Several commenters stated that it appears that CMS believes that the provider, not the physician signing the PCS, is responsible for the content of the PCS and that CMS does not intend to hold the physician signing the PCS responsible for the content of the PCS. Commenters also questioned whether the proposed rule would mean that the ambulance provider/supplier cannot rely on a properly physician-signed PCS as a tool in the process of proving medical necessity. The commenters disagreed with CMS' statement that 'no presumptive weight' should be assigned to the treating physician's medical opinion in determining medical necessity, recommending instead that CMS adopt a presumption that a repetitive transport is medically necessary when the ambulance provider/supplier has a valid physician-signed PCS. The commenters stated that CMS is not only requiring ambulance providers/suppliers to police themselves, but physicians as well. As a result, it is the ambulance provider/supplier who must bear the sole risk of not being reimbursed for a claim that CMS deems does not meet medical necessity.

Response: Ambulance providers are not responsible for the content of a properly prepared PCS, but, to the extent ambulance providers wish to be reimbursed by Medicare, they are responsible for ensuring they provide ambulance transports to eligible beneficiaries that meet Medicare's ambulance coverage and medical necessity criteria. We believe the PCS is one safeguard to help ensure that the medical necessity criteria of Medicare's ambulance transport benefit is met, but it is not the only safeguard. Indeed, especially since a PCS may be written as much as 2 months before the service is provided, we must be mindful of other safeguards including the totality of the medical record and the physical presentation of the beneficiary when the service is rendered. Furthermore, the ambulance provider/supplier is not obligated to provide a service in the absence of a properly signed PCS. There is no expectation by CMS that ambulance providers/suppliers police physician practice.

Comment: Several commenters stated that while the proposed rule focuses on revisions to the PCS regulations in the case of repetitive transports, they strongly urged CMS to modify the requirements for non-repetitive, non-emergency transports and to address the burden of the PCS in that context by eliminating it. Current PCS requirements, they asserted, impose unreasonable burdens on providers/suppliers that far outweigh any benefit of the PCS to the Medicare Program.

Response: We disagree because, as we note repeatedly in these responses, we believe the PCS is a valuable safeguard and an important tool that helps ensure that we pay only for claims that meet all Medicare coverage and payment criteria, and will not be making any changes in this final rule to the requirements for non-repetitive, non-emergency transports.

Comment: Several commenters stated that CMS gives ambulance providers/suppliers no assurance that Medicare will cover the service, even if they have an attending physician's order for the ambulance service. They are concerned that ambulance providers/suppliers have to decide whether they are going to disregard an order from a beneficiary's attending physician simply because the patient's insurer might not give any weight to that order.

Response: By statute and regulation, Medicare may only pay for medically necessary ambulance transports and as with any service, we have the discretion to review a claim to ensure it satisfies all Medicare coverage and payment criteria. To satisfy coverage criteria, medical necessity must be supported by adequate medical record documentation.

Comment: Several commenters stated that the DOJ strategy for pursuing ambulance providers/suppliers should not have any bearing on CMS policy for coverage of claims, that the requirement for ambulance providers/suppliers to obtain a PCS should be based on the need for medical judgment on the level of care required by the patient, and that ambulance providers/suppliers should be able to rely on the PCS for such. These commenters noted that if the PCS requirement is for some other non-medical purpose such as DOJ policy, or is simply a CMS requirement for an exercise in futility, the PCS requirement should be struck in its entirety.

Response: As noted in the responses above and by virtue of its statute and regulations, Medicare only pays for medically necessary ambulance transports. The PCS is an important tool that we use as a safeguard to help ensure medical necessity, but as we mention above, it is not the only tool, nor, in and of itself, is it a conclusive determinant of medical necessity.

Comment: Several commenters stated that CMS should also exempt from PCS requirements the two following types of transports: Ground intercepts with air ambulance; and hospital-to-hospital transports. These commenters noted that these modifications to the PCS requirement would apply for non-emergency, non-repetitive transports, thus limiting its application.

Response: Not only do we disagree since we believe the PCS is a valuable safeguard, but we note that we did not propose to relax or exempt PCS requirements in any situation.

Comment: Several commenters stated that the proposed rule ignores the fact that when ambulance providers/suppliers are contacted to transport a patient for a non-emergency transport, they are often given little information about the patient's condition. Ambulance providers/suppliers must rely on information from the attending physician who has intimate knowledge about the patient's ambulatory state.

Response: While we appreciate that obtaining information may sometimes be challenging, this does not alter our responsibility to only pay Medicare claims that satisfy all Medicare coverage and payment criteria. As we noted in the preamble to the proposed rule and in an earlier response, it may be incumbent upon ambulance providers/suppliers to help educate physicians or their staff members regarding the rules pertaining to Medicare's ambulance service benefit and to request additional information at the time ambulance transport is requested to gauge whether the transport meets Medicare's coverage and payment criteria.

Comment: Several commenters believed that a PCS from an attending physician obtained before the ambulance service should carry the same weight as physician orders that prescribe other Medicare-covered services. When a physician signs the PCS, these commenters noted, he or she is providing the same support that auditors rely upon to determine medical necessity.

Response: Although we do not disagree that a physician PCS carries the same weight as physician orders that prescribe other Medicare-covered services, we note that we similarly audit physician orders for medical necessity based on supporting medical record documentation as those orders, like the PCS in the ambulance context, in and of themselves are not determinative.

Comment: Several commenters stated that since CMS already requires ambulance providers/suppliers to maintain documentation that demonstrates medical necessity for all ambulance transports, they believe that CMS should likewise rely on documentation from ambulance providers/suppliers for the types of non-emergency transports for which a PCS is currently required, and therefore, requested that CMS eliminate the PCS requirement for all non-emergency ambulance transports and all scheduled, repetitive ambulance transports completely.

Response: We do rely on the medical documentation for ambulance transports, but, as described both in the preamble and in other responses, believe the PCS is an additional important safeguard that helps ensure medical necessity.

Comment: Several commenters expressed that obtaining a PCS remains challenging for ambulance providers/suppliers because, among other reasons, physicians may refuse to sign a PCS or because facilities and physicians sometimes confuse the PCS requirements for repetitive and non-repetitive transport patients, requiring the ambulance provider/supplier to spend substantial time justifying why they are seeking the PCS and what is required.

Response: While we understand the challenges providers/suppliers may face in obtaining a PCS, as noted above our primary responsibility is ensuring we pay only properly payable Medicare claims and we believe that the PCS is a necessary tool in helping to determine medical necessity.

Comment: Several commenters believed that CMS does not intend to hold physicians accountable for their signed certifications about medical necessity. Despite the fact that a signed PCS must be obtained from a physician, these commenters noted that ambulance providers/suppliers bear the sole burden of determining whether Medicare's medical necessity criteria have been met.

Response: The fact that ambulance providers/suppliers, just like other providers/suppliers, may face some risk of non-payment when submitting claims for Medicare payment cannot alter our primary responsibility to only pay claims that meet all Medicare coverage and payment criteria. Although, as we have explained, we cannot rely exclusively upon the PCS as a determinant of medical necessity, the PCS is an important tool to help establish medical necessity for the ambulance transport of a Medicare beneficiary.

Comment: Several commenters recommended that CMS allow additional facility personnel, such as LPNs, social workers, or case managers to be authorized signatories for the PCS requirement.

Response: We are limiting the changes in this final rule to those outlined in the proposed rule. We did not propose to revise our policy regarding who may sign a PCS. As a result, we take no position at this time on whether LPNs or other additional facility personnel should be authorized signatories.

After reviewing the public comments, we are finalizing the revisions to § 410.40(c)(3)(ii) and § 410.40(d)(2) as proposed.

F. Physician Compare Web Site

1. Background and Statutory Authority

Section 10331(a)(1) of the Affordable Care Act requires that, by no later than January 1, 2011, we develop a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals who participate in the Physician Quality Reporting System (PQRS) under section 1848 of the Act.

CMS launched the first phase of Physician Compare (*http://www.medicare.gov/find-a-doctor/provider-search.aspx*) on December 30, 2010. The initial phase included the posting of the names of eligible professionals that satisfactorily submitted quality data for the 2009 PQRS, consistent with section 1848(m)(5)(G) of the Act. Since the initial launch of the Web site, we have continued to build and improve Physician Compare. Currently users can search by selecting a location and specialty for physicians or other healthcare professionals. Search results provide basic information about approved Medicare providers, such as primary and secondary specialties, practice locations, group practice affiliations, hospital affiliations, Medicare Assignment, education, languages spoken, and gender. As required by section 1848(m)(5)(G) of the Act, we have added the names of those eligible professionals who are successful electronic prescribers under the Medicare Electronic Prescribing (eRx) Incentive Program. As such, physician and other healthcare professional profile pages indicate if professionals satisfactorily participated in the PQRS and/or are successful electronic prescribers under the eRx Incentive Program based on the most recent data available for these two quality initiatives.

2. Public Reporting of Physician Performance

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and for reporting periods that begin no earlier than January 1, 2012, we implement a plan for making publicly available through Physician Compare, information on physician performance that provides comparable quality and patient experience measures. This plan is outlined below.

Comment: We received several comments requesting that CMS clarify its plans with respect to making PQRS data publicly available through Physician Compare no later than January 1, 2013.

Response: We appreciate the commenters' interest in public reporting on Physician Compare. Please note that CMS has met the Affordable Care Act requirements to implement a plan prior to January 1, 2013 for making physician performance information available on Physician Compare, and intends to continue to outline elements of that plan through rulemaking.

To the extent that scientifically sound measures are developed and are available, we are required to include, to the extent practicable, the following types of measures for public reporting:

- Measures collected under the PQRS.
- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
- An assessment of efficiency.
- An assessment of patient experience and patient, caregiver, and family engagement.
- An assessment of the safety, effectiveness, and timeliness of care.
- Other information as determined appropriate by the Secretary.

As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan, we must include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and eligible professionals whose information is being publicly reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is provided to physicians concerning the data published on Physician Compare.
- Implementation of computer and data infrastructure and systems used to support valid, reliable, and accurate reporting activities.

Section 10331(d) of the Affordable Care Act requires us to consider input from multi-stakeholder groups in selecting quality measures for Physician Compare, which we seek to accomplish through rulemaking and focus groups. In developing the plan for making information on physician performance publicly available through Physician Compare, section 10331(e) of the Affordable Care Act requires the Secretary, as the Secretary deems appropriate, to consider the plan to transition to value-based purchasing for physicians and other practitioners that was developed under section 131(d) of the Medicare Improvements for Patients and Providers Act of 2008.

We are required, under section 10331(f) of the Affordable Care Act, to submit a report to the Congress by January 1, 2015, on Physician Compare development, and include information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice. Section 10331(g) of the Affordable Care Act provides that any time before that date, we may continue to expand the information made available on Physician Compare.

We believe section 10331 of the Affordable Care Act supports our overarching goals of providing consumers with quality of care information to make informed decisions about their healthcare, while encouraging clinicians to improve on the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, we intend to utilize Physician Compare to publicly report physician performance results.

In implementing our plan to publicly report physician performance, we will

use data reported under the existing PQRS as an initial step for making physician ''measure performance'' information public on Physician Compare. By ''measure performance'' in relation to the PQRS, we mean the percent of times that a particular clinical quality action was reported as being performed, or a particular outcome was attained, for the applicable persons to whom a measure applies as described in the denominator for the measure. For measures requiring risk adjustment, ''measure performance'' refers to the risk adjusted percentage of times a particular outcome was attained.

We previously finalized a decision to make public on Physician Compare the performance rates on the quality measures that group practices submit under the 2012 PQRS group practice reporting option (GPRO) (76 FR 73417). Therefore, we are targeting to post performance information collected through the GPRO web interface for group practices participating in the 2012 PQRS GPRO on Physician Compare in 2013 or early 2014. Specifically, we will make public performance information for measures included in the 2012 PQRS GPRO that meet the minimum sample size, and that prove to be statistically valid and reliable. As we previously established, if the minimum threshold is not met for a particular measure, or the measure is otherwise deemed not to be suitable for public reporting, the group's performance rate for that measure will be suppressed and not publicly reported. We previously established a minimum threshold of 25 patients for reporting performance information on Physician Compare (76 FR 73418). Although we considered keeping the threshold for reporting performance data on Physician Compare at 25 patients, we proposed to change the minimum patient sample size, from 25 patients to 20 patients, beginning with data collected for services furnished in 2013 (77 FR 44803).

The following is summary of the comments we received regarding the new minimum patient sample size proposal:

Comment: We received comments related to the reduction in patient threshold for public reporting. Most commenters opposed the reduction, stating that the lower threshold may be less accurate and statistically valid. One commenter pointed to literature supporting the previous threshold of 25, and suggested that CMS maintain this threshold, though the commenter did not expressly state which literature they were referencing, and one suggested a patient size of 30. We received comments stating that this reduced sample size was insufficient to apply across all measures, and that the sample size should be determined based on the measure to which it is applied. One commenter requested further detail on what it would mean for a measure to be suitable for public reporting. Several comments were supportive of the proposal stating that this may increase participation.

Response: We appreciate the commenters' feedback regarding reducing the patient sample size for public reporting from 25 patients to 20 patients. We are committed to reporting quality of care data that is statistically valid, reliable, and accurate, and will only post data that meet this standard of reliability regardless of threshold, and regardless of measure type. Should we find a measure meeting the minimum threshold to be invalid or unreliable for any reason, the measure will not be reported.

We appreciate the comment that this reduction may increase participation; however we note that this proposal only relates to Physician Compare. While the decreased threshold may increase participation for other quality reporting programs, we do not believe it will have an impact on Physician Compare.

We believe this threshold of 20 patients to be sufficient to protect patient privacy for reporting on the site, and should thus be applied to every measure reported on Physician Compare. Currently, this is the reliability threshold being finalized for both the Value-Based Modifier (VBM) and the proposed PQRS criteria for reporting measure groups. As we work to align quality initiatives and minimize reporting burden on physicians and other healthcare professionals, we will finalize our proposal to reduce the reporting threshold from 25 to 20 patients.

In the Shared Savings Program final rule (76 FR 67948), we finalized Accountable Care Organization (ACO) public reporting provisions in the interest of promoting greater transparency regarding the ACOs participating in the program. We finalized requirements for ACOs to publicly report certain data, as well as data that we would publicly report. Because ACO providers/suppliers that are eligible professionals are considered to be group practices for purposes of qualifying for a PQRS incentive under the Shared Savings Program, we indicated that performance on quality measures reported by ACOs at the ACO TIN level, on behalf of their ACO providers/suppliers who are eligible professionals, using the GPRO web interface would be reported on Physician Compare in the same way as for the groups that report under the PQRS.

In April 2012, we added functionality to Physician Compare allowing users to search for group practices in preparation for the addition of 2012 PQRS GPRO data. A full Web site redesign is slated for early 2013 to further prepare the site for the introduction of quality data and ACO information. With each enhancement, we work to improve the usability and functionality of the site, providing consumers with more tools to help them make informed healthcare decisions.

In CY 2012, we intend to enhance the accuracy of ''administrative'' information displayed on the eligible professional's profile page, and to add additional data. By administrative data, we are referring to information about eligible professionals that is pulled from the Provider Enrollment, Chain, and Ownership System (PECOS) and other readily available external data sources. Specifically, we intend to add whether a physician or other health care professional is accepting new Medicare patients, board certification information, and to improve the foreign language and hospital affiliation data. We also intend to include the names of those eligible professionals who participated in the Medicare EHR Incentive Program, as authorized by section 1848(o)(3)(D) of the Act, and the names of those eligible professionals who satisfactorily participated under the PQRS GPRO for 2011. We will continue to update the names of those eligible professionals and group practices who satisfactorily participated under the PQRS, and those who are successful electronic prescribers under the eRx Incentive Program based on the most recent program year data available.

Comment: We received one comment in support of the inclusion of eRx and PQRS Incentive Program Data or Administrative data on the site, and one comment requesting that participation information for PQRS be limited to those who satisfactorily report this information.

Response: We appreciate the commenter's feedback and support for including eRx and PQRS Incentive Program participation data on Physician Compare. We intend to continue to post the names of those eligible professionals and group practices who satisfactorily participated under the PQRS, and those who are successful electronic prescribers under the eRx Incentive Program on the Web site as we are required to report this information publicly, and Physician Compare offers

an excellent venue for making this information available to consumers.

Comment: We received comments regarding the posting of Medicare EHR Incentive Program participation and Meaningful Use participation information on Physician Compare. One commenter requested that CMS post the names of all those who participate in the Medicare EHR Incentive Program, not just those who did so successfully. One commenter requested that we add a note to distinguish what stage of Meaningful Use the eligible professional is taking part.

Response: We intend to post the names of those eligible professionals who successfully participated in the Medicare EHR Incentive Program on Physician Compare, when feasible. We will further evaluate the suggestion regarding stages of Meaningful Use, but at this time CMS does not intend to distinguish between stages of participation.

In support of the HHS-wide Million Hearts Initiative, we proposed to post the names of the eligible professionals who report the PQRS Cardiovascular Prevention measures group (77 FR 44803). This is consistent with the requirements under section 10331 of the Affordable Care Act to provide information about physicians and other eligible professionals who participate in the PQRS.

The following is a summary of the comments received regarding the proposal to post the names of eligible professionals who report the PQRS Cardiovascular Prevention measures group in support of the Million Hearts Initiative:

Comment: Commenters generally supported our proposal. Some commenters pointed out that the PQRS Cardiovascular Prevention measures group may not apply to all professionals or all specialties, and were therefore in support of the proposal only if those professionals who did not report on the measures group were not negatively represented for their lack of participation. One commenter requested that the mechanism of data submission also be reported on the site.

Response: At this time, we are targeting posting the names of eligible professionals who satisfactorily report PQRS Cardiovascular Prevention measures group in support of the Million Hearts Initiative in 2014 for the 2013 reporting period. As with all participation data of this nature on Physician Compare, if a professional is participating in this program by satisfactorily reporting on the PQRS Cardiovascular Prevention measures group, an indicator will be noted on their profile page; if a professional is not satisfactorily reporting on this measures group, no indicator will be included. We believe this approach serves to acknowledge those who participate without negative reflection on those who do not. While we appreciate the comment that data submission mechanism also be reported on the site, it is not technically feasible to report that information at this time.

3. Future Development of Physician Compare

Consistent with Affordable Care Act requirements, it is our intent to phase in an expansion of Physician Compare over the next several years by incorporating quality measures from a variety of sources, as technically feasible. For our next phase, we proposed to make public on Physician Compare, performance rates on the quality measures that group practices submit through the GPRO web interface under the 2013 PQRS GPRO and the Medicare Shared Savings Program (77 FR 44803). We indicated that we anticipated the 2013 PQRS GPRO web interface measures data would be posted no sooner than 2014. These data would include measure performance rates for measures included in the 2013 PQRS GPRO web interface that met the proposed minimum sample size of 20 patients, and that proved to be statistically valid and reliable.

When technically feasible, and targeted for posting on the site in 2014, we proposed to publicly report composite measures that reflect group performance across several related measures (77 FR 44803). As an initial step we intend to develop disease module level composite scores for PQRS GPRO measures. Under the Medicare Shared Savings Program, ACOs are required to report on composite measures for Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) (76 FR 67891). Accordingly, in an effort to align the PQRS GPRO measures with the GPRO measures under the Shared Savings Program, we proposed to add composite measures for DM and CAD into the PQRS starting in reporting year 2013. We also indicated we would consider future development of composites for the remaining disease level modules within the GPRO web interface. As more data are added to Physician Compare over time, we stated we would consider adding additional disease level composites across measure types as technically feasible and statistically valid.

The following is a summary of the comments received regarding our proposal to post performance rates on the quality measures that group practices submit through the GPRO web interface under the 2013 PQRS GPRO and the Medicare Shared Savings Program, and to report composite measures at the disease module level for 2013 GPRO data:

Comment: One commenter supported our proposal to post PQRS GPRO and ACO performance rates as it was limited to measures reported through the GPRO web interface, and suggested CMS not expand reporting to data collected via other reporting mechanisms at this time. Another commenter expressed support of our proposal to post composite measures at the disease module level, but requested that CMS postpone the posting of these composites until physicians and groups have time to review their performance as it pertains to individual elements of the composite.

Response: We are dedicated to providing quality of care data on Physician Compare as soon as feasible so that healthcare consumers have access to information to help them make informed healthcare decisions. We are finalizing our proposal to post performance rates on the quality measures that group practices submit through the GPRO web interface under the 2013 PQRS GPRO and the Medicare Shared Savings Program. In an effort to align PQRS GPRO measures with the GPRO measures under the Shared Savings Program, we are finalizing our proposal to generate composite measures for DM and CAD based on measures reported through the GPRO web interface for groups participating in program year 2013 PQRS GPRO and ACOs participating in the Shared Savings Program. This requirement regarding posting of ACO data is finalized at § 425.308. We target posting these data in 2014 for the 2013 reporting period, as technically feasible, as we believe these data are valuable to consumers in evaluating group practices and ACOs. We will provide a 30-day preview period prior to publication of quality data on Physician Compare so that ACOs and group practices can view their data as it will appear on Physician Compare before it is publicly reported.

Consistent with the requirement under section 10331(a)(2) of the Affordable Care Act to implement a plan to make comparable information on patient experience of care measures publicly available, we proposed to post patient experience survey-based measures from the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) (77 FR 44804). As discussed in section G.6.c. of this final rule with comment period, we proposed to collect the

following patient experience of care measures for group practices participating in the PQRS GPRO (77 FR 44964):

- CAHPS: Getting Timely Care, Appointments, and Information
- CAHPS: How Well Your Doctors Communicate
- CAHPS: Patients' Rating of Doctor
- CAHPS: Access to Specialists
- CAHPS: Health Promotion and Education

These measures capture patients' experiences with clinicians and their staff, and patients' perception of care. We proposed, no earlier than 2014, to publicly report 2013 patient experience data for all group practices participating in the 2013 PQRS GPRO, not limited to those groups participating via the GPRO web interface, on Physician Compare. At least for 2013, we noted that we intended to administer and collect patient experience survey data on a sample of the group practices' beneficiaries. As we intend to administer and collect the data for these surveys, we indicated that we did not anticipate any notable burden on the groups.

For ACOs participating in the Shared Savings Program, consistent with the PQRS proposal to publicly report patient experience measures on Physician Compare starting in 2013, we proposed to publicly report patient experience data in addition to the measure data reported through the GPRO web interface (77 FR 44804). Specifically, the patient experience measures that would be reported for ACOs include the CAHPS measures in the Patient/Caregiver Experience domain finalized in the Shared Savings Program final rule (76 FR 67889):

- CAHPS: Getting Timely Care, Appointments, and Information
- CAHPS: How Well Your Doctors Communicate
- CAHPS: Patients' Rating of Doctor
- CAHPS: Access to Specialists
- CAHPS: Health Promotion and Education
- CAHPS: Shared Decision Making

For patient experience data reported under either the PQRS GPRO or the Medicare Shared Savings Program, we also considered an alternative option of providing confidential feedback to group practices and ACOs using 2013 patient experience data before publicly reporting patient experience data on Physician Compare (77 FR 44804). In lieu of publicly reporting the patient experience data relating to 2013 PQRS GPRO and ACOs participating in the Shared Savings Program, we considered using the 2013 results as a baseline to be shared confidentially with the group practices and ACOs, during which time the group practices and ACOs would have the opportunity to review their data, and implement changes to improve patient experience scores. Under this alternative option, program year 2014 patient experience data would be the first to be publicly reported on Physician Compare, and we would publicly report 2014 patient experience data for ACOs and group practices participating in the 2014 PQRS GPRO on Physician Compare no earlier than 2015. We invited public comment on our proposal to begin publicly reporting patient experience data for program year 2013, and also the alternative option of delaying public reporting of patient experience of care data on Physician Compare until program year 2014 in order to give group practices and ACOs the opportunity to make changes to the processes used in their practices based on the review of their data from program year 2013 (77 FR 44804).

The following is a summary of the comments we received regarding our proposal to publicly report patient experience data:

Comment: Many commenters supported the alternate proposal to post 2014 data in 2015, and to use 2013 data as confidential feedback for providers to review their results. Most commenters believed this would give groups a chance to improve their results before they are publically reported, and some commenters suggested that groups have the opportunity to resurvey patients prior to the posting of results.

Response: We appreciate the commenters' feedback regarding the posting of patient experience data for 2014 in 2015 and using the results of patient experience data collected for program year 2013 as a confidential reporting period so that physicians can review their data and improve on their performance before the start of public reporting. We are dedicated to providing patient experience data on Physician Compare as soon as feasible so that healthcare consumers can have access to this important information to help them make informed decisions. After considering the public comments, our final decision is to provide all ACOs and group practices an opportunity to see their patient experience data in reports provided by the data collection vendor before it is published. A 30-day preview period prior to publication will allow ACOs and group practices to see their data as it will appear on Physician Compare before it is reported. This 30-day period is in line with the preview period provided for other public reporting programs such as Hospital Compare.

Understanding the strong desire from consumers for these data, and given our commitment to public reporting, we are finalizing our proposal to target the reporting of patient experience data, collected no earlier than 2013, on Physician Compare in 2014, if technically feasible, for groups of one hundred or more eligible professionals reporting via the GPRO web interface, including ACOs participating in the Shared Savings Program. The requirement regarding posting of ACO data is finalized at § 425.308. We believe that by limiting this posting requirement to group practices and ACOs participating via the GPRO web interface, and by allowing group practices and ACOs to preview their data during a 30-day preview period, we are able to address the concerns of the provider community while making this data available to healthcare consumers and meeting the mandates set forth by the Affordable Care Act. Due to patient privacy and confidentiality, we will not implement the suggestion that groups have the opportunity to resurvey patients prior to the posting of results.

Comment: Some commenters expressed concern over the cost of implementing a patient experience survey, and others questioned whether the surveys were adequately tailored to certain types of groups and settings, such as emergency departments, stating that the survey used should be validated for a variety of settings. Some of these commenters suggested that different surveys, such as S–CAHPS for surgical settings should be used based on setting. One commenter also suggested that the entire CAHPS survey should be used as opposed to only using certain domains.

Response: We are dedicated to accurate, valid, and reliable public reporting on Physician Compare and are aware that each group practice is unique in size and scope. We have closely evaluated the available data collection mechanisms, and are confident that CG–CAHPS is a well-tested collection mechanism with strong support from the healthcare community, and that it provides the best opportunity to collect useful and accurate data for the largest number of group practices. We will use only those survey domains that are applicable to group practices or ACOs respectively, and believe that these domains have been well tested, and will therefore provide the best data for the largest number of groups.

We are dedicated to supporting group practices in the reporting of these important data. Thus, we are finalizing a policy under which CMS will

administer the patient experience of care survey for calendar year 2013 and 2014 for all group practices of 100 or more eligible professionals that sign up for the PQRS GPRO web interface. Similarly, as discussed in the Shared Savings Program Final Rule, CMS will fund and administer the CAHPS survey for ACOs participating in the Shared Savings Program in 2013 (76 FR 67875).

As we continue to improve administrative and provider level data, we proposed posting the names of those physicians who earned a PQRS Maintenance of Certification Program Incentive as data becomes available, and targeted for 2014 (77 FR 44804).

The following is a summary of the comments we received related to posting the names of physicians who earned a PQRS Maintenance of Certification Program Incentive:

Comment: Many commenters were supportive so long as there were no negative reflections on those who did not receive the incentive; however, one commenter did not believe this information was relevant to Physician Compare.

Response: We are finalizing our proposal to include the names of eligible professionals who earned an incentive in the PQRS Maintenance of Certification Program Incentive as data are available, and targeted for 2014. To address concerns regarding negative impact, as with all data of this nature currently on Physician Compare, if an eligible professional is participating in the program, an indicator will be noted on their profile page; if a professional is not participating, no indicator or negative indication will be included. We believe this approach serves to acknowledge those who earned a PQRS Maintenance of Certification Program Incentive without reflecting negatively on those who did not. We also believe that this information will be helpful to healthcare consumers as they work to make informed healthcare decisions and is thus relevant to Physician Compare.

Comment: We received one comment requesting that ABMS Maintenance of Certification status be posted on the site, and one suggesting that information about ABMS Maintenance of Certification also be posted.

Response: We appreciate the commenter's feedback regarding including ABMS Maintenance of Certification data on Physician Compare. At this time, we are targeting to post the names of eligible professionals who earned a PQRS Maintenance of Certification Program incentive as data are available, and targeted for 2014. We do not currently have plans to also include the ABMS MOC information, but will consider this for future rulemaking.

We considered allowing measures that have been developed and collected by approved and vetted specialty societies to be reported on Physician Compare, as deemed appropriate, and as they are found to be scientifically sound and statistically valid (77 FR 44804). We proposed including additional claims-based process, outcome and resource use measures on Physician Compare, and noted that we intend to align measure selection for Physician Compare with measures selected for the Value Based Modifier (VBM) (section III.K).

We received several comments related to reporting measures developed and collected by specialty societies. The following is a summary of the comments we received:

Comment: Many commenters believe this was a good way to identify measures that are most appropriate for certain specialties, and to reduce the reporting burden on those specialties as the measures are already being collected, and their data are already available. Several commenters offered to assist CMS in gathering these data. A few commenters requested clarification on what measures would be posted, how CMS would vet these measures.

Response: We appreciate the commenters' feedback regarding reporting of measures developed by specialty societies on Physician Compare. We understand the importance of publicly reporting measures that are most appropriate for all specialties, and believe working with specialty societies to identify quality measure data that are already collected and available reduces the reporting burden on these specialties while providing accurate, reliable, and valid data on the site. This approach also provides an opportunity to expand public reporting to specialties and types of physicians not currently represented. We intend to work with specialty societies to identify the most appropriate data sources and mechanism for inclusion on Physician Compare.

We will work to ensure that any specialty society data included on Physician Compare is approved, vetted, scientifically sound, and statistically reliable. As with PQRS measures and other measures posted on Physician Compare, any measures under consideration will be subjected to the Measures Application Partnership (MAP) pre-rulemaking process prior to being considered for posting on the site. Please note that such measures will be addressed in future rulemaking.

We received comments related to our proposed alignment of Physician Compare with the VBM. The following is a summary of the comments we received:

Comment: One commenter did not support our proposal to align with PQRS or the VBM as they believed this data may be overwhelming to healthcare consumers. The commenter went on to say that Physician Compare should distinguish itself as a site committed to communicating validated and meaningful information, and not try to align with these programs.

Response: We appreciate the commenters' feedback regarding the proposal to align public reporting on Physician Compare with elements of PQRS and the VBM. We are committed to working toward reporting measures that are accurate and complete. Please note that not all measures collected will be posted on the site, and only those measures that are deemed appropriate for public reporting and useful to consumers will be posted. We believe alignment with PQRS and the VBM on Physician Compare provides significant opportunities as we move toward a payment model related to quality and cost efficiencies. Aligning quality initiatives also provides an opportunity for publically reporting more quality data while also minimizing the reporting burden on eligible professionals. We will continue to align our public reporting goals with these programs.

Comment: One commenter questioned how CMS is able to report performance data on Physician Compare within one year, but points out the technical infeasibility of calculating performance-based payments within that same time frame.

Response: We appreciate the commenter's feedback regarding a timeline for public reporting on Physician Compare in relation to the timeline for calculating performance-based payments. We are working on a phased approach to public reporting across a number of data sources and are looking to do so in a way that does not increase reporting burden, allows accurate reporting, and supports the agency's mission and goals. For these reasons, we are working to align the measures reported on Physician Compare with other CMS quality initiatives, such as PQRS and VBM as technically feasible. Please note that not all measures included in these other initiatives will be publicly reported on the site, and that the programs have distinct timelines. Performance-based payments require additional calculation beyond that which we proposed to

publicly report. While Physician Compare has a plan to report performance data as soon as technically feasible, we will not report that data before it has been accurately calculated, and has proved to be statistically valid and reliable.

We proposed to include group level ambulatory care sensitive condition admission measures of potentially preventable hospitalizations developed by the HHS Agency for Healthcare Research and Quality (AHRQ) that meet the proposed minimum sample size of 20 patients, and that prove to be statistically valid and reliable (measure details are available at *http://www.qualitymeasures.ahrq.gov/content.aspx?id=27275*) (77 FR 44804). We proposed reporting these measures on Physician Compare no earlier than 2015 for those group practices composed of 2–99 eligible professionals participating in the proposed 2014 PQRS GPRO, and for ACOs.

We received comments related to our proposal to post group level ambulatory care sensitive condition admission measures of potentially preventable hospitalizations developed by AHRQ. The following is a summary of the comments we received:

Comment: Most commenters opposed the posting of these measures, and one commenter stated that they strongly opposed the addition of these measures. One commenter requested clarification as to what testing and validation had been done around these measures.

Response: We are committed to only including quality of care measures on Physician Compare that are properly vetted and tested, as well as statistically valid and reliable. We have decided to allow other programs within CMS to work with these measures, gather the data, and provide feedback to the groups prior to posting on Physician Compare. We will not finalize our proposal to post group level ambulatory care sensitive condition admission measures of potentially preventable hospitalizations at this time. Instead, we will consider the input we received as we further evaluate the inclusion of such measures on Physician Compare, and address this issue in future rulemaking.

We also proposed to publicly report performance rates on quality measures included in the 2015 PQRS and VBM for individual eligible professionals (77 FR 44804). We indicated, however, that further details on what measures would be included in the 2015 reporting period will be addressed in future rulemaking. We also proposed that public reporting of 2015 PQRS and administrative claims-based quality measures for individuals would occur no earlier than 2016.

We received several comments related to the posting of individual-level measures on Physician Compare. The following is a summary of the comments we received:

Comment: Some commenters supported our proposal, and one requested that this information be made available as soon as technically feasible stating the information was valuable to consumer decision making. One commenter requested that CMS consider including data that is reported through a variety of reporting mechanisms such as claims and registries to ensure all reporting individuals would be represented regardless of reporting mechanism.

Response: We agree that individual-level measure data is important in helping consumers make informed healthcare decisions, and agree that this information should be posted on the site as soon as technically feasible. We will move up this plan and target posting individual-level measure data in 2015 using 2014 data if technically feasible. Please note that further discussion of this topic, and the measures to be included will be addressed in future rulemaking.

Comment: One commenter opposed the posting of individual-level measure data stating this data may be overwhelming to consumers. The commenter went on to caution that measures posted on Physician Compare should be selected based on how well they resonate with consumers. Another commenter expressed concerns regarding the different reporting mechanisms available in PQRS, and how measures reported through the different mechanisms would be represented.

Response: We appreciate the commenter's concerns around the posting of these measures. We are committed to including only the most accurate, statistically reliable and valid quality of care measure data on Physician Compare when the data are publicly reported. Any data found to be invalid or inaccurate for any reason will not be publicly reported. We will ensure that these data are collected and presented appropriately, regardless of the mechanism through which they are collected, and that they accurately reflect performance. Measures to be posted on the site will be selected based on a variety of criteria including consumer interest, and will be subject to consumer testing. Please note that further discussion of this topic, and the measures to be included will be addressed in future rulemaking.

For all measures publicly reported on Physician Compare, we proposed to post a standard of care, such as those endorsed by the National Quality Forum (77 FR 44804). Such information would serve as a standard for consumers to measure individual provider, and group level data.

We received comments related to our proposal to post a standard of care on Physician Compare. The following is a summary of the comments we received:

Comment: One commenter supported our proposal to post a standard such as those endorsed by the NQF. Some commenters sought clarification around the standard to be used, and expressed concerns that an NQF standard may be limiting to certain specialties, stating that NQF standards are heavily focused on primary care. Commenters also suggested consumer testing if such as standard is to be posted to insure the information is understandable to consumers.

Response: We appreciate the commenters' feedback regarding posting a standard of care on Physician Compare. We are currently considering including an NQF standard for those measures reported on Physician Compare where a standard of care is endorsed, available, and applicable. We are declining to finalize our proposal at this time and are only seeking additional comment. We will address this issue in future rulemaking.

We received several comments not directly related to our proposals which are summarized below.

Comment: The majority of commenters was concerned about the accuracy of data currently on Physician Compare, and urged CMS to consider this feedback in its plans for future development. Commenters stated that data on Physician Compare did not meet certain standards of accuracy, and one called for a cessation of the site until concerns could be addressed. Some commenters expressed frustration about the difficulty they experienced in getting their information updated or corrected, and some requested a way to update their information on the site. Some commenters requested that data be updated in a timely fashion to ensure it is up-to-date and accurate. One commenter expressed concerns related to data collection mechanisms and comparability on Physician Compare.

Response: We are committed to including accurate and up-to-date information on Physician Compare and continue to work to make improvements to the information presented. The current primary data source for Physician Compare is PECOS. In order for a physician, other healthcare

professional, or group practice's information to appear on Physician Compare, their enrollment record in PECOS must be current and in ''approved'' status, a valid physical location or address must be identified, and the professional must have an NPI. It is critical that data in PECOS be accurate and up-to-date to ensure the data on Physician Compare are also accurate and up-to-date. CMS is evaluating other options for physician, healthcare professionals and group practices to update their information, and is looking at other available data sources to validate PECOS data to further improve accuracy as we continue to improve the data presented on Physician Compare.

We are equally committed to including only the most accurate, statistically reliable and valid quality of care measure data on Physician Compare when those data are publicly reported. We are committed to ensuring that these data are comparable and presented appropriately regardless of the mechanism through which they are collected, and that they accurately reflect performance. We will ensure these data are updated in a timely fashion as technically feasible, and will provide a 30-day preview period for physicians and group practices to view their data prior to it being posted on the site.

Comment: We received comments requesting a disclaimer be placed on the site for the purpose of explaining why measures may not apply to certain groups, and that the absence of data on a particular measure does not imply poor performance or poor quality.

Response: We agree with the commenters that disclaimers and other forms of explanatory language are necessary to help inform healthcare consumers and other users of the site. Regarding the request for a disclaimer, or clarification explaining the absence of participation or measure data, we are evaluating disclaimer language for use on Physician Compare when data are published on the site, and will take this feedback into consideration.

Comment: We received several comments cautioning that too much data on the site could cause confusion for consumers and other users of the site.

Response: We appreciate the commenters' feedback, and understand their concerns. As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan to include performance data on Physician Compare, we must include, to the extent practicable, processes to ensure that the posted data are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary, as well as processes to ensure appropriate attribution of care when multiple providers are involved in the care of the patient. We understand that this information is complex, and are committed to providing data on Physician Compare that are useful to beneficiaries in assisting them to make informed healthcare decisions, while being accurate, valid, reliable, and complete. We will closely evaluate all quality measures under consideration for public reporting on the Web site to ensure they are presented in a way that is helpful to beneficiaries and, through consumer testing and stakeholder outreach, will work to ensure that the number of measures and data sources presented is done in such a way that the information is valuable to consumers.

Comment: We received several comments requesting that a section of Physician Compare be dedicated to hospital-based physicians, or that Physician Compare link to Hospital Compare for certain hospital-based physicians so users may view data on hospital-based physician through a variety of perspectives.

Response: We appreciate the commenters' feedback regarding customizing a section of Physician Compare for hospital-based physicians. Physician Compare is tasked with providing consumers with useful information about Medicare physicians and other healthcare professionals who provide services in a variety of specialties and care settings. At this time, it is not feasible to customize the Web site for specific physician groups, but we will consider this feedback as we continue to evaluate if such customization is beneficial to consumers and potentially feasible in future development. We will continue to evaluate a link between Physician Compare and Hospital Compare as appropriate.

Comment: We received comments requesting that CMS include other healthcare professionals on Physician Compare and not limit the site to physicians.

Response: We appreciate the commenter's feedback. Currently the site does feature information on physicians and other healthcare professionals as required by the Affordable Care Act.

Comment: We received one comment stating that CMS should consider a distillation of quality data into a reporting system such as star ratings for physicians and group practices.

Response: We appreciate the commenter's suggestion, and agree that a reporting system such as star ratings can be helpful to users in consuming these data. We will continue to evaluate star ratings and other methods of displaying measure data based on the measures selected for posting on the site.

Comment: We received one comment requesting that additional education, residency and administrative information for physicians and other healthcare professionals be posted on the site.

Response: We appreciate the feedback regarding the inclusion of education, and other administrative information on Physician Compare. At this time, Physician Compare includes some educational and residency information. We are working to include Board Certification information on the site as feasible, and will continue to evaluate additional information and data sources that can provide beneficial information for consumers as they are available in the future. All posting of this additional information will be addressed in future rulemaking.

We are committed to making Physician Compare a constructive tool for Medicare beneficiaries, successfully meeting the Affordable Care Act mandate, and in doing so, providing consumers with information needed to make informed healthcare decisions. We have developed a plan, and started to implement that plan with a phased approach to adding physician quality data to Physician Compare. We believe this staged approach to public reporting of physician quality information allows consumers access to information that is currently available while we continue to develop the infrastructure necessary to support additional types of data and information on physicians' quality measure performance. Implementation of subsequent phases of the plan will need to be developed and addressed in future notice and comment rulemaking, as needed.

G. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

There are several healthcare quality improvement programs that affect physician payments under the Medicare PFS. The National Quality Strategy establishes three aims for quality improvement across the nation: Better health, better healthcare, and lower costs. This strategy, the first of its kind, outlines a national vision for quality improvement and creates an opportunity for programs to align quality measurement and incentives

across the continuum of care. We believe that this alignment is especially critical for programs involving physicians. The proposals that follow facilitate the alignment of programs, reporting systems, and quality measures to make this vision a reality. We believe that alignment of CMS quality improvement programs will decrease the burden of participation on physicians and allow them to spend more time and resources caring for beneficiaries. Furthermore, as the leaders of care teams and the healthcare systems, physicians and other clinicians serve beneficiaries both as frontline and system-wide change agents to improve quality. However, we believe that to improve quality, quality measurement and reporting is an important component. It is our intent that the following requirements will improve alignment of physician-focused quality improvement programs, decrease the burden of successful participation on physicians, increase engagement of physicians in quality improvement, and ultimately lead to higher quality care for beneficiaries.

This section contains the requirements for the Physician Quality Reporting System (PQRS). The PQRS, as set forth in section 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments and payment adjustments to eligible professionals based on whether or not they satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. We note that, in developing these requirements, it was our goal to align program requirements between these quality reporting programs, such as the eRx Incentive Program, EHR Incentive Program, Medicare Shared Savings Program, and value-based payment modifier, wherever possible. We believe that alignment of these quality reporting programs will lead to greater overall participation in these programs, as well as minimize the reporting burden on eligible professionals.

Please note that, during the comment period following the proposed rule, we received comments that were not related to our specific proposals for PQRS in the CY 2013 Medicare PFS proposed rule. While we appreciate the commenters' feedback and intend to use these comments to better develop PQRS, these comments will not be specifically addressed in this CY 2013 Medicare PFS final rule, as they are beyond the scope of this rule. However, we will take these comments into consideration when developing policies and program requirements for future years.

The regulation governing the PQRS is located at § 414.90. The program requirements for years 2007–2012 of the PQRS that were previously established, as well as information on the PQRS, including related laws and established requirements, are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*. Please also note that in this final rule with comment period, we are making technical changes to § 414.90 to aid in the readability of the regulation.

1. Methods of Participation

There are two ways an eligible professional can participate in the PQRS: (1) As an individual or (2) as part of a group practice participating in the PQRS group practice reporting option (GPRO).

a. Participation as an Individual Eligible Professional—Traditional Reporting Mechanisms

As defined at § 414.90(b), the term ''eligible professional'' means any of the following: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist or a qualified speech-language pathologist; or (4) a qualified audiologist. For more information on which professionals are eligible to participate in the PQRS, we refer readers to the ''List of Eligible Professionals'' download located in the ''How to Get Started'' section of the PQRS CMS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/How_To_Get_Started.html*. There is no requirement to self-nominate to participate in the PQRS as an individual eligible professional for the incentive or to use claims, registry, or EHR reporting mechanisms.

b. Participation as a Group Practice in the GPRO

(1) Definition of Group Practice

We proposed to modify § 414.90(b) to define group practice as ''a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider (NPI), who have reassigned their Medicare billing rights to the TIN'' (77 FR 44806). We proposed to change the number of eligible professionals comprising a PQRS group practice from 25 or more to 2 or more to allow all groups of smaller sizes to participate in the GPRO. We believe that expanding the scope of group practices eligible to participate under the program will lead to greater program participation. To participate in the GPRO, a group practice would be required to meet this proposed definition at all times during the reporting period for the program year in which the group practice is selected to participate in the GPRO.

We solicited public comments on the proposed definition of group practice. The following is a summary of the comments we received regarding this proposal.

Comment: Several commenters supported our proposal to change the definition of group practice to include groups of 2–24 eligible professionals because the commenters believed that the proposal would allow more group practices to participate in the GPRO.

Response: We appreciate the commenters' feedback and are finalizing our proposal to modify § 414.90(b) to define a group practice as ''a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their billing rights to the TIN.'' We hope that expanding the GPRO to allow small group practices of 2–24 eligible professionals to participate in the GPRO will encourage greater participation in PQRS.

Comment: Although some commenters supported our proposal to change the definition of group practice to include groups of 2–24 eligible professionals, the commenters urged CMS not to make additional changes to this definition in the near future. The commenters note that CMS has changed the group practice definition every year since it was included as a PQRS reporting option in 2010, leading to confusion for many eligible professionals and group practices participating in PQRS.

Response: Each year, we have sought to improve the GPRO based on stakeholder feedback and data we receive from past participation. The GPRO has also changed due to a desire to align this GPRO with other quality reporting programs, such as the Medicare Shared Savings Program. Nonetheless, we understand the complexity and confusion caused by changing this definition each year and will keep that in mind in the future when proposals are presented.

Comment: One commenter opposed our proposal to change the definition of group practice to include groups of 2–24 eligible professionals until the implications of such a change are more clearly understood. Furthermore, the commenter believes the proposal confuses the alignment of the PQRS program with the VBM that proposes to

incorporate groups of 25 or more eligible professionals.

Response: We understand the commenters' concern and acknowledge that our proposal to define a group practice as groups of 2 or more eligible professionals does not align perfectly with our proposal to apply the Value-based Payment Modifier to physician groups of 25 or more eligible professionals (*see* section K). However, we note that, although our goal is overall alignment with the Value-based Payment Modifier, there may be instances, such as this one, where the two programs may not completely align. For example, although we are expanding the definition of group practice to define a group practice as a group of 2 or more eligible professionals, the Value-based Payment Modifier, as described in section K, will only apply to physician group practices of 100 or more in 2013. Therefore, smaller groups of 2–99 eligible professionals will remain unaffected by the final policies we are finalizing under the Value-based Payment Modifier in 2013.

When determining program requirements, we considered factors other than alignment with the Value-based Payment Modifier. For example, aside from alignment, we adopted policies that we believe will increase overall participation in PQRS, as well as increase the likelihood that eligible professionals will meet the criteria for satisfactory reporting for the 2013 and 2014 PQRS incentives and 2015 and 2016 PQRS payment adjustments. We believe that expanding the definition of group practices to groups of 2 or more eligible professionals will help to achieve these goals, because we are providing group practices with additional ways to participate in PQRS.

Comment: Some commenters disagreed with our proposal to define a group practice as ''a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their billing rights to the TIN'' rather than limiting the definition of group practice to physicians. The commenters believe this classification is misleading, as a solo physician with a nurse practitioner or other eligible professional working in the practice would be classified as a group practice under this definition.

Response: We thank the commenter for expressing their concern regarding the definition of a group practice. We note that section 1848(m)(3)(c) of the Act, which governs group practice reporting under the PQRS, explicitly identifies ''eligible professionals in a group practice'' (and further affords us the authority to define group practice). So we do not believe the definition of group practice under the PQRS is limited to physicians. We also note that the PQRS applies to ''eligible professionals,'' which is defined under section 1848(k)(3)(B) of the Act to include physicians and other types of practitioners that are specifically identified. Also, from a policy perspective, we believe it is important to measure the care given by healthcare professionals other than physicians. Therefore, we are finalizing the PQRS definition of a group practice to include all eligible professionals, not just physician group practices.

(2) Election Requirement for Group Practices Selected To Participate in the GPRO

Please note that, for group practices participating in PQRS through other Medicare programs (such as but limited to those group practices participating as Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program), certain provisions in this section may not apply. For information on how to participate in PQRS through other Medicare programs, please refer to the requirements for those respective programs.

GPRO Self-Nomination Statement. We established the process for group practices to be selected to participate in the GPRO in the CY 2012 PFS final rule with comment period (76 FR 73316). However, this section contains additional processes for a group practice's self-nomination statement that we proposed for group practices selected to participate in the GPRO for 2013 and beyond. For the requirement that group practices wishing to participate in the GPRO submit a self-nomination statement (76 FR 73316), for 2012, we accepted these self-nomination statements via a letter accompanied by an electronic file submitted in a format specified by CMS because it was not operationally feasible to receive self-nomination statements via the web at that time. In the CY 2012 Medicare PFS final rule with comment period, we noted that we anticipated that CMS would have the ability to collect self-nomination statements via the web for the 2013 PQRS. Therefore, we proposed that, for 2013 and beyond, a group practice must submit its self-nomination statement via the web.

We noted that this web-based functionality is still being developed by CMS. Therefore, in the event this web-based functionality would not be available in time to accept self-nomination statements for the 2013 PQRS, we proposed that, in lieu of submitting self-nomination statements via the web, a group practice would be required to submit its self-nomination statement via a letter accompanied by an electronic file submitted in a format specified by CMS (such as a Microsoft excel file) (77 FR 44807). We proposed that this self-nomination statement would be mailed to the following address: Centers for Medicare & Medicaid Services, Center of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850. If mailing the self-nomination statement, we would require that this self-nomination statement be received by no later than 5 p.m. Eastern Standard Time on January 31 of the year in which the group practice wishes to participate in the GPRO.

We invited public comment on the proposed method for submitting a GPRO self-nomination statement. The following is a summary of the comments we received on this proposal.

Comment: One commenter was concerned about the use and efficiency of a web portal for accepting GPRO self-nomination statements due to a potentially increased number of self-nomination statements that will be accepted through the web and potential delays in the web portal.

Response: We understand the commenter's concerns regarding the potential for delays in the web portal. However, we believe that accepting self-nomination statements via the web will be the most efficient way for group practices to complete and CMS to accept and process GPRO self-nomination statements. Therefore, we are finalizing our proposal to accept GPRO self-nomination statements via the web for 2013 and beyond. We also anticipate an increase in the number of GPRO self-nomination statements received due to our expansion of the GPRO as well as use of the PQRS GPRO for the application of the Value-based Payment Modifier. Therefore we are working to further develop the web portal to account for increased traffic. Please note that group practices submitting self-nomination statements via the web will be required to comply with CMS' security and system requirements to submit a self-nomination statement via the web. However, should a group practice wishing to self-nominate encounter issues doing so, the group practice may contact the QualityNet Help Desk for assistance with submitting a self-nomination statement.

As for our proposed contingency plan for accepting self-nomination statements via mail in the event the web-based functionality was not be available in time to accept self-nomination statements for the 2013 PQRS, or in the event we experience issues with accepting self-nomination statements via the web, we are also finalizing that proposal. While we expect that we will have the web system operational, we believe it is appropriate to have an alternative submission process available as a back-up. Therefore, if the web-based functionality is unavailable in time to accept self-nomination statements for the 2013 PQRS, or in the event we experience issues with accepting self-nomination statements via the web, in lieu of submitting self-nomination statements via the web, a group practice is required to submit its self-nomination statement via a letter accompanied by an electronic file submitted in a format specified by CMS (such as a Microsoft excel file), and a mailed to the following address: Centers for Medicare & Medicaid Services, Center of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850.

Although we proposed to require that this self-nomination statement be received by no later than 5 p.m. Eastern Standard Time on January 31 of the year in which the group practice wishes to participate in the GPRO, we believe it is appropriate to provide group practices with additional time to submit this information and self-nominate under the PQRS. Additional time for submissions may also address concerns raised by commenters about the potential for increased number of self-nomination statements and efficiency of the web portal with regard to avoiding delays. As we discuss in greater detail below in response to comments we received, we also believe it would be helpful to afford group practices additional time with regard to selecting its reporting mechanism, which group practices must include in the self-nomination statement. Therefore, we are finalizing a deadline of October 15 of the year in which the group practice wishes to participate in the GPRO. We believe this is an appropriate amount of time for group practices under the PQRS. Moreover, we note that this deadline aligns with the final policies we are adopting for the value-based payment modifier. For those group practices for whom the value-based payment modifier will apply, this extended deadline will provide groups with additional time to make decisions with regard to participation under the PQRS.

GPRO Selection of Reporting Mechanisms. In the CY 2012 Medicare PFS final rule with comment period, we established what information is required to be included in a group practice's self-nomination statement (76 FR 73316). In 2012, the group practice only had one reporting mechanism available on which to report data on PQRS quality measures: The GPRO web interface. However, beginning 2013, we proposed to allow group practices to report data on quality measures using the claims, registry, and EHR-based reporting mechanisms for the PQRS incentive and payment adjustment (77 FR 44870). Additionally, we proposed to allow group practices to use the proposed administrative claims reporting option. We proposed that a group practice wishing to participate in the GPRO for a program year would be required to indicate the reporting mechanism the group practice intends to use for the applicable reporting period in its self-nomination statement. Furthermore, once a group practice is selected to participate in the GPRO and indicates which reporting mechanism the group practice would use, we proposed that the group practice would not be allowed to change its selection. Therefore, under this proposal, the reporting mechanism the group practice indicates it would use in its self-nomination statement for the applicable reporting period would be the only reporting mechanism under which CMS would analyze the group practice to determine whether the group practice has met the criteria for satisfactory reporting for the PQRS incentive and/or payment adjustment. We acknowledged that this proposal would depart from the way we analyze an individual eligible professional, as CMS analyzes an individual eligible professional (who is permitted to use multiple reporting mechanisms during a reporting period) under every reporting method the eligible professional uses. Unfortunately, due to the complexity of analyzing group practices under the GPRO, such as having to associate multiple NPIs under a single TIN, it is not technically feasible for us to allow group practices using the GPRO to use multiple reporting mechanisms or switch reporting mechanisms during the reporting period.

We solicited public comment on our proposal to lock-in a group practice's reporting mechanism choice at the time of self-nomination. The following is summary of the comments we received regarding this proposal.

Comment: One commenter stated that group practices should be allowed to change the reporting mechanisms through the calendar year in case a more advantageous reporting option is available later in the year. For example, a group practice may want to change its reporting mechanism during a given reporting period after the list of qualified registries becomes available.

Response: We agree that group practices should be provided with some flexibility to change their reporting mechanisms. We it is only fair to provide group practices with a window to switch their initially chosen reporting mechanisms, as individual eligible professionals are allowed to switch reporting mechanisms throughout the year. Therefore, we are allowing group practices to switch their chosen reporting mechanism until October 15 of the applicable reporting period. We believe this window provides eligible professionals with ample time to make an informed decision on which reporting mechanism to use and still provides CMS with advance notification of the group practices' chosen reporting mechanism. Based on the comments received, we are finalizing a deadline of October 15 of the applicable reporting period (that is, October 15, 2013 for reporting periods occurring in 2013) for group practices to elect (via its self-nomination statement) the reporting mechanism they will use to submit quality measures data for PQRS. Additionally, should a group practice wish to switch the reporting mechanism it chose when self-nominating, the group practice will be allowed to do so as long as the group practice switches its reporting mechanism prior to the October 15 deadline.

Please note that the ability to elect the administrative claims-based reporting mechanism will not be available until the summer of the applicable reporting period. Therefore, should a group practice self-nominate earlier, if the group practice elects to use the administrative claims-based reporting mechanism, the group practice would have to visit the Web page to elect the administrative claims-based reporting mechanism.

(3) Process To Participate in the GPRO

Please note that, for group practices participating in PQRS through other Medicare programs (such as but limited to those group practices participating as Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program), certain provisions in this section may not apply. For information on how to participate in PQRS through other Medicare programs, please refer to

the requirements for those respective programs.

Determining Group Practice Size. Please note that if a group practice participates in PQRS as a group practice, the eligible professionals in the selected group practice cannot participate in the PQRS individually. When selecting group practices to participate in the GPRO, CMS bases its decision on the information the group practice provides in its self-nomination statement. We believe that changes in a group practice's size or TIN constitute such a significant change in the group practice's composition that it would cause CMS to reconsider its decision to allow the group practice to participate in the GPRO for the applicable program year. Specifically, we understand that a group practice's size may vary throughout the program year. For example, we understand that eligible professionals enter into and leave group practices throughout the year. Similarly, we understand that group practices may undergo business reorganizations during the program year. We note that size fluctuations may affect the criteria under which a group practice would use to report after being selected to participate in the GPRO. We proposed that groups of varying sizes be subject to different criteria for satisfactory reporting for the 2013 and 2014 incentives, as well as for the payment adjustments (77 FR 44822–44833). Therefore, we proposed that, for analysis purposes, the size of the group practice must be established at the time the group practice is selected to participate in the GPRO. We invited but received no public comment on this proposal (77 FR 44807). Therefore, we are finalizing this proposal.

Changes in GPRO TIN. We also understand that, for various reasons, a group practice may change TINs within a program year. For example, a group practice may undergo a mid-year reorganization that leads to the group practice changing its TIN mid-year. We proposed that, if a group practice changes its TIN after the group practice is selected to participate in the GPRO, the group practice cannot continue to participate in PQRS as a group practice. We considered the changing of a group practice's TIN a significant change to the makeup of the group practice, as the group practice is evaluated under the TIN the group practice provided to CMS at the time the group is selected to participate in the GPRO for the applicable year (77 FR 44807). Therefore, we viewed a group practice that changes its TIN as an entirely new practice, associated with a new TIN. We noted that this proposal may pose a disadvantage for those group practices who find it beneficial to report PQRS quality measures using the GPRO. However, we noted that eligible professionals in a group practice that has changed its TIN within a year may instead participate as individuals.

We invited public comment on this proposal. The following is summary of the comments we received regarding this proposal not to allow group practices who change their TINs to continue to participate in the GPRO for the applicable program year.

Comment: Some commenters urged CMS to allow group practices using the GPRO that subsequently change their TIN within a program year to continue participating in PQRS as a group practice. One commenter noted that not allowing a group practice to continue to use the GPRO should the group practice change their TIN in a program year is a hindrance to practice mergers and reorganizations.

Response: We appreciate the commenters' feedback. It is not our intention to hinder group practices from merging with another practice or reorganizing. However, it is not operationally feasible to allow a group practice selected to participate in the GPRO that changes its TIN within a program year to continue to participate in PQRS under the GPRO. Therefore, we are finalizing our proposal to require that a group practice maintain the same TIN throughout a given program year to continue to participate in the GPRO. We note that group practices will now be given until October 15 to self-nominate and select its reporting mechanism for the GPRO, allowing more time within the program year for group practices to organize its composition and ultimately its reporting structure. We note that, should a group practice change its TIN, eligible professionals within the group practice have the option to participate in PQRS individually.

GPRO Opt-out Period. We understand that a group practice may decide not to participate in PQRS using the GPRO after being selected. Therefore, we proposed that group practices be provided with an opportunity to opt out of participation in the GPRO after selection (77 FR 44807). We noted that it is necessary for a group practice to indicate to CMS the group practice's intent not to use the GPRO because, once a group practice is selected to participate in the GPRO for the applicable reporting period, CMS will not separately assess the NPIs associated with the group practice's TIN to see if they meet the criteria for satisfactory reporting as individual eligible professionals. Therefore, we must be notified of the group practice's decision not to participate in the GPRO so the eligible professionals within the group practice could be assessed at the individual TIN/NPI level. We proposed that group practices would have until April 1 of the year of the applicable reporting period (for example, by April 1, 2013 for reporting periods occurring in 2013) to opt out of participating in the GPRO.

We invited public comment on the proposed selection process for group practices wishing to participate in the GPRO. The following is summary of the comments we received regarding this proposed opt-out period for group practices that have elected to participate in PQRS under the GPRO.

Comment: One commenter supported our proposal to provide an opt-out period for those group practices who self-nominated to participate in the GPRO but later decide to participate at the individual level.

Response: We appreciate the commenter's feedback. We have historically provided an opt-out period, because the deadline for a group practice to submit a self-nomination statement to participate in the GPRO has normally been on or about January 31 of the applicable program year. We believed it was necessary to provide an opt-out period for group practices, as we required group practices to submit a self-nomination statement indicating their intent to participate in the GPRO early in the year. However, since, as we discussed above, beginning in 2013, group practices will have until October 15 of the applicable program year to submit its self-nomination statement, we believe that this opt-out period is no longer necessary. Therefore, we are not finalizing an opt-out period for group practices that are selected to participate in the GPRO for the applicable program year. Once a group practice is selected and approved to participate in the GPRO, past the opt-out period, the group practice will be required to participate in the GPRO for the applicable program year.

c. Requirement for Eligible Professionals and Group Practices Electing To Use the Administrative Claims-Based Reporting Mechanism for the 2015 Payment Adjustment

Unlike using the traditional PQRS reporting mechanisms (that is, claims, registry, EHRs, GPRO web interface) to satisfy the reporting requirements for the 2015 and 2016 payment adjustments, we proposed that eligible professionals and group practices wishing to use the proposed administrative claims reporting

mechanism, available for the 2015 and/or 2016 payment adjustments, must elect to use the administrative claims reporting mechanism (77 FR 44805). We believed this election requirement is important because it is necessary for eligible professionals to actively engage in quality reporting. By requiring registration, eligible professionals and group practices are making an active choice in how they would like their quality performance measured. For eligible professionals, we proposed that this election process would consist of a registration statement that included: The eligible professional's name and practice name, the eligible professional's TIN and NPI for analytical purposes, and the eligible professional's contact information (77 FR 44806). For group practices, we proposed that this election process would also consist of a registration statement that included: The group practice's business name and contact information, the group practice's TIN, and contact information of the group practice's contact(s) who will be contacted for program, clinical, and/or technical purposes. For the method of submitting this registration statement, we proposed any of the following options:

- If technically feasible, submission of this statement via the web; and
- If technically feasible, submission of an eligible professional's or group practice's intent to register to use the administrative claims-based reporting mechanism by placing a G-code on at least 1 Medicare Part B claim.

In the event the two proposed options are not technically feasible, we also considered allowing for submission of the registration statement by submitting a mailed letter to CMS at Centers for Medicare & Medicaid Services, Center of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850. However, we noted that using this mailing option would be a more burdensome and time-intensive process for CMS.

The eligible professional would be required to complete this election process by January 31 of the applicable payment adjustment reporting period (for example, by January 31, 2013 for the 2015 payment adjustment). However, we noted that we proposed that we may extend this deadline based on the submission method that we finalized. For example, because processing mailed letters would take the longest to process (out of the 3 methods), we anticipated that if we were to include the option of mailed letters, the deadline for submitting a mailed registration letter would be January 31 of the applicable payment adjustment reporting period. Since it would be more efficient to process registration statements received via the web or via a G-code on a claim, we anticipated that we would be able to extend the registration deadline to as late as December 31 of the applicable payment adjustment reporting period. Once an eligible professional makes an election to participate in PQRS using the administrative claims-based reporting mechanism for the PQRS payment adjustments, the eligible professional would be assessed under the administrative claims-based reporting mechanism.

For group practices participating in the GPRO, we proposed that these group practices would use the 3 methods described above (mailed letter, web, or G-code submission) and have the same deadline as eligible professionals wishing to elect to use the administrative claims-based reporting mechanism for an applicable payment adjustment. In the alternative, we proposed that a group practice participating in the GPRO would be required to elect to use the administrative claims-based reporting mechanism in its self-nomination statement. We proposed to provide less time for group practices to elect to use the administrative claims-based reporting mechanism because it is necessary for CMS to receive this information in the beginning of the applicable reporting period to indicate to CMS how these group practices should be analyzed throughout the reporting period. This early notification is especially important for large group practices, which may have hundreds or thousands of eligible professionals to track as a group practice. Therefore, we felt it was appropriate to request that a group practice elect to use the administrative claims-based reporting mechanism when the group practice self-nominates.

We further proposed that an eligible professional or group practice would be required to make this election for each payment adjustment year the eligible professional or group practice seeks to be analyzed under this mechanism. For example, if the eligible professional seeks to report under the administrative claims mechanism for the 2015 and 2016 payment adjustments, the eligible professional would be required to make this election by the applicable deadline, for the 2015 payment adjustment and again by the applicable deadline, for the 2016 payment adjustment. We invited public comment on the proposed election requirement for eligible professionals and group practices electing to participate in the 2015 and 2016 payment adjustments using the administrative claims-based reporting mechanism.

We invited public comment on the process for electing the administrative claims-based reporting option for eligible professionals and group practices. The following is a summary of the comments received on this proposed process and on the proposed election requirement.

Comment: Some commenters requested that the deadline for electing the administrative claims-based reporting option be extended. The commenters believed eligible professionals and group practices needed more time to understand the different reporting options and determine whether the administrative claims-based reporting option would be appropriate for their respective practices.

Response: We agree with the commenters and would like to provide eligible professionals and group practices with sufficient time to make an informed decision as to whether to elect the administrative claims-based reporting option. Therefore, we are extending the timeframe that eligible professionals and group practices have for electing the administrative claims-based reporting mechanism. However, as we explain in greater detail below, we are not finalizing the administrative claims-based reporting option for the 2016 PQRS payment adjustment. For the 2015 payment adjustment, eligible professionals and group practices may begin to make an election in the summer of the applicable reporting period. The deadline for electing the administrative claims-based reporting mechanism will be October 15 of the applicable reporting period for both eligible professionals and group practices. For example, for the 2015 payment adjustment, eligible professionals and group practices will be able to elect the administrative claims-based reporting mechanism until October 15, 2013.

Therefore, based on the comments received, we are finalizing the following election process for eligible professionals and group practices wishing to use the administrative claims-based reporting option for the 2015 PQRS payment adjustment. We note that we are changing the name of this process from a registration to an election process. We believe using the term election process is more appropriate, as individuals and group practices would be electing to be analyzed under a reporting mechanism, not registering to participate in PQRS

(as registration is not a requirement to participate in PQRS). This election process is the same process as the registration process proposed, with the following exceptions:

• We proposed three methods of accepting this election: Via the web, a G-code on claims, or, if neither were technically feasible, via U.S. mail. We are finalizing submission of the administrative claims election statement via the web, because we believe that this is the most efficient method of accepting these elections. However, in the event that we experience issues with accepting election statements via the web, we are finalizing a back-up method of accepting elections via U.S. mail. In the event the we experience issues with accepting election statements via the web, eligible professionals and group practices may elect to be analyzed under the administrative claims-based reporting mechanism by submitting a mailed letter to CMS at Centers for Medicare & Medicaid Services, Center of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850.

• The final deadline for submitting the administrative claims election statement to participate using the administrative claims reporting mechanism for the 2015 PQRS payment adjustment for both individual eligible professionals, and group practices is October 15, 2013. Group practices will be able to make this election under its self-nomination statement. As we discussed above, we are finalizing a later deadline so that eligible professionals and group practices have more time to determine which reporting mechanism would be more advantageous for their respective practices. We note that, should we encounter issues with accepting election statements via the web, we may extend the deadline for submitting these administrative claims election statements to account for any time the web may not be properly functioning.

We are modifying newly created § 414.90(h) to indicate this election requirement for individual eligible professionals and group practices who wish to use the administrative claims-based reporting option for the 2015 PQRS payment adjustment.

Please note that, for group practices participating in PQRS through other Medicare programs, the administrative claims-based reporting mechanism may not be a reporting option for reporting PQRS measures. For example, under the Medicare Shared Savings Program, eligible professionals within Accountable Care Organizations (ACOs) must report for purposes of the PQRS using the GPRO web interface (77 FR 67870). Therefore, group practices participating within ACOs participating in the PQRS under the Medicare Shared Savings Program cannot participate in the traditional PQRS or report using the administrative claims-based reporting mechanism.

2. Reporting Periods for the PQRS Payment Adjustments

For the PQRS incentives, we previously established 12 and 6-month reporting periods for satisfactorily reporting PQRS quality measures at § 414.90(f)(1). Under section 1848(a)(8)(C)(iii) of the Act, we are authorized to specify the quality reporting period (reporting period) for a payment adjustment year. We proposed to modify the regulation to establish the reporting periods for the PQRS payment adjustments for 2015 and beyond (77 FR 44808). Please note that we are re-designating § 414.90(f) as § 414.90(g) and making technical changes to change the structure of the regulation and to improve the readability of the regulation. Newly designated § 414.90(g)(1) indicates the reporting periods available for the PQRS incentives.

Additional Reporting Periods for the 2015 and 2016 PQRS Payment Adjustments. For the 2015 payment adjustment, in the CY 2012 Medicare PFS final rule, we established CY 2013 (that is, January 1, 2013 through December 31, 2013) as the reporting period for the 2015 payment adjustment (76 FR 73392). We established a 12-month reporting period occurring 2 years prior to the application of the payment adjustments for group practices and for individual eligible professionals to allow time to perform all reporting analysis prior to applying payment adjustments on eligible professionals' Medicare Part B PFS claims. However, we noted that we might specify additional reporting periods for the 2015 payment adjustment. To coincide with the 6-month reporting period associated with the 2013 incentive for the reporting of measures groups via registry, we proposed to modify the regulation at newly designated § 414.90(h) to add a 6-month reporting period occurring July 1, 2013–December 31, 2013, for the 2015 payment adjustment for the reporting of measures groups via registry (77 FR 44808).

For the 2016 payment adjustment, to coincide with the reporting periods for the 2014 incentive, we proposed to modify the regulation at newly designated § 414.90(h) to specify a 12-month (January 1, 2014–December 31, 2014) and, for individual eligible professionals reporting measures groups via registry only, a 6-month (July 1, 2014–December 31, 2014) reporting period for the 2016 payment adjustments.

We invited public comment on our proposed reporting periods for the 2015 and 2016 payment adjustments. The following is a summary of the comments we received on our proposals.

Comment: Some commenters supported our proposal to establish a 6-month payment adjustment reporting period for the 2015 and 2016 PQRS payment adjustments to coincide with the 6-month reporting period for the 2013 and 2014 PQRS incentives. Some commenters also supported our proposal to establish a 12-month payment adjustment reporting period for the 2016 PQRS payment adjustment. One commenter believes that a 12-month reporting period provides a more accurate assessment of actions performed in a clinical setting than data collected based on a 6-month reporting period. Other commenters supported continuing to allow a 6-month and 12-month reporting period.

Response: Based on the comments received and to parallel the reporting periods for the 2013 and 2014 PQRS incentives, we are finalizing the addition of a 6-month reporting period for the 2015 and 2016 PQRS payment adjustments as proposed. We are also finalizing the 12-month reporting period for the 2016 PQRS payment adjustment. We are therefore finalizing newly created § 414.90(h) to specify 6- and 12-month reporting periods occurring 2 years prior to the 2015 and 2016 PQRS payment adjustments.

With respect to the commenter's concern that a 6-month reporting period may not provide as accurate of a picture of the quality of care provided than the 12-month period, we generally agree with the commenter. However, our desire to align the reporting periods of the 2013 and 2014 PQRS incentive and 2015 and 2016 PQRS payment adjustments, and afford additional reporting options, outweighs this interest. We also note that the 6-month reporting period will only be available for individual eligible professionals reporting measures groups via registry.

Reporting Periods for the 2017 PQRS Payment Adjustment and Beyond. We believe that data on quality measures collected based on 12 months provide a more accurate assessment of actions performed in a clinical setting than data collected based on a 6-month reporting period, as eligible professionals would

report on a larger set of patients. We stated that it was our intention to move towards using solely a 12-month reporting period once the reporting periods for the 2013 and 2014 incentives conclude. Therefore, for payment adjustments occurring in 2017 and beyond, we proposed to modify the regulation at newly designated § 414.90(h) to specify only a 12-month reporting period occurring January 1–December 31, that falls 2 years prior to the applicability of the respective payment adjustment (for example, January 1, 2015 through December 31, 2015, for the 2017 payment adjustment) (77 FR 44808).

We invited public comment on our proposal to establish a 12-month reporting period for payment adjustments occurring in 2017 and beyond. The following is a summary of the comments we received on this proposal.

Comment: One commenter supported our proposal to eliminate the 6-month reporting period for 2015 and beyond, because the commenter believes that data collected based on 12 months provides a more accurate assessment of actions performed in a clinical setting than data collected based on a 6-month reporting period.

Response: We agree with the point raised by the commenter and are therefore not finalizing a 6-month period for payment adjustments occurring in 2017 and beyond. However, we note that we did not propose to eliminate the 6-month reporting period for 2015 and beyond. Rather, we simply did not propose a 6-month reporting period for payment adjustments occurring in 2017 and beyond (77 FR 44808).

Comment: Several commenters opposed our proposal to base the PQRS payment adjustment year on a reporting period occurring 2 years prior to the payment adjustment year. The commenters believe that the reporting period should occur closer to the payment adjustment year. Some commenters urged that the implementation of the PQRS payment adjustment should be delayed until the PQRS participation rate increases.

Response: We understand the commenters' concerns on establishing a reporting period 2 years prior to the payment adjustment year. However, it is not operationally feasible to create a full calendar year reporting period for the PQRS payment adjustment any later than 2 years prior to the adjustment year and still avoid retroactive payments or the reprocessing of claims. Section 1848(a)(8) of the Act requires that a payment adjustment be applied to covered professional services furnished by an eligible professional in the particular payment adjustment year. Therefore, using 2017 as an example, we believe it is necessary to reduce the PFS amount concurrently for PFS allowed charges for covered professional services furnished in 2017. If we do not reduce the PFS amount concurrently with claims submissions in 2017, we would need to potentially recoup or provide added payments after the determination is made about whether the payment adjustment applies, or alternatively, hold claims until such a determination is made. In addition, we note that if such retroactive adjustments were made it may require a reconciliation of beneficiary copayments.

As a result, we need to determine whether eligible professionals have satisfactorily reported under the PQRS based on a reporting period that occurs prior to 2017. For the reasons stated above, for the PQRS payment adjustments occurring in 2017 and beyond, we are finalizing 12-month reporting periods that fall 2 years prior to the application of the respective payment adjustment year. For example, the reporting period for the 2017 PQRS payment adjustment will be CY 2015 (that is, January 1, 2015–December 31, 2015). We are finalizing newly created § 414.90(e) to specify a 12-month reporting period for the 2017 PQRS payment adjustments and beyond.

Comment: One commenter supported our proposal to move towards a 12-month reporting period, provided that we continue to offer the administrative claims-based reporting option to eligible professionals and group practices.

Response: We appreciate the commenter's feedback but reiterate that we view the administrative claims-based reporting option as a temporary option under PQRS. Therefore, as we discuss in section III.G.3, we are only finalizing use of the administrative claims-based reporting mechanism for the 2015 PQRS payment adjustment at this time.

Comment: One commenter opposed our proposal to eliminate the 6-month reporting period beginning with the 2017 PQRS payment adjustment, at least until such time as the PQRS achieves greater alignment with other CMS quality reporting programs. The commenter believes that this alternative reporting period should be maintained to offer greater flexibility in reporting. The commenter also noted that the late start of this 6-month reporting period has traditionally served as an alternative reporting option for eligible professionals who are new to PQRS.

Response: We appreciate the commenter's feedback. However, in an effort to streamline the satisfactory reporting requirements under PQRS and to align with programs such as the Value-based Payment Modifier which utilize a performance period of 12 months, we are not adding a 6-month reporting period for payment adjustments occurring in 2017 and beyond.

3. Requirements for the PQRS Reporting Mechanisms

This section addresses the following reporting mechanisms: Claims, registry, EHR (including direct EHR products and EHR data submission vendor), GPRO web interface, and administrative claims. We previously established at § 414.90(f)(2) that eligible professionals reporting individually may use the claims, registry, and EHR-based reporting mechanisms. We proposed to modify § 414.90 to allow group practices comprised of 2–99 eligible professionals to use the claims, registry, and EHR-based reporting mechanisms as well, because we recognized the need to provide varied reporting criteria for smaller group practices, particularly since we proposed to expand the definition of group practice (77 FR 44808). For example, we noted that a smaller group practice may not have a sufficiently varied practice to be able to meet the proposed satisfactory reporting criteria for the GPRO web interface that would require a smaller group practice to report on all of the PQRS quality measures we proposed. We proposed changes to § 414.90, which we proposed to re-designate § 414.90(g) and § 414.90(h).

We invited public comment on this proposal to make the claims, registry, and EHR-based reporting options applicable to group practices of 2–99 eligible professionals. The following is summary of the comments we received regarding this proposal.

Comment: Several commenters supported our proposal to expand the claims, registry, direct EHR, and EHR data submission vendor reporting mechanisms to group practices of 2–99 eligible professionals using the GPRO. Commenters were pleased that groups that are not able to use the GPRO web interface (such as specialty provider group practices for which GPRO measures typically do not apply) would still be able to participate in PQRS as a group practice in the GPRO. Most of these commenters suggested that we extend use of the claims, registry, direct EHR, and EHR data submission vendor reporting mechanisms to group practices of 100 or more eligible

professionals to allow greater flexibility in reporting for these larger group practices. These commenters noted that extending the claims, registry, and EHR-based reporting options would be especially beneficial to large specialty groups for which the GPRO measures do not apply.

Response: We appreciate the commenters' positive feedback regarding these proposals. Although we proposed to expand the claims-based reporting mechanism to group practices of 2–99 eligible professionals, we have discovered that it will not be technically feasible to accept group practice reporting data via the claims-based reporting mechanism at this time. Therefore, we are not finalizing that part of our proposal. However, we will work to provide group practice reporting via the claims-based reporting mechanism in the future.

As for the registry-based reporting mechanism, we are finalizing our proposal to extend the registry-based reporting mechanism to groups practices comprised of 2–99 eligible professionals participating in PQRS via the GPRO for 2013 and beyond.

For group practices of 2–99 eligible professionals using direct EHR and EHR data submission vendor products, we are delaying availability of this option until 2014 to coincide with when the EHR Incentive Program introduces its group practice reporting option for meeting the clinical quality measures (CQM) objective for achieving meaningful use (77 FR 54076 through 54078). Therefore, in this final rule, we are adopting the EHR-based reporting options for groups of 2–99 eligible professionals participating in PQRS via the GPRO for 2014 and beyond.

As for extending use of the registry and EHR-based reporting mechanisms for GPRO group practices of 100 of more eligible professionals, we agree with the commenters that extending the registry and EHR-based reporting mechanisms would provide more opportunities for large specialty group practices to participate in PQRS. Therefore, based on the comments received, we are finalizing the registry-based reporting mechanism for 2013 and beyond and the EHR-based reporting mechanisms for 2014 and beyond for groups of 100 or more eligible professionals under the GPRO as well as those group practices with 2–99 eligible professionals under the GPRO.

Therefore, we are finalizing § 414.90(g) and § 414.90(h) to indicate that the registry-based reporting mechanism will be available for use by eligible professionals and group practices beginning in 2013 and the EHR-based reporting mechanisms (direct EHR product and EHR data submission vendor) will be available for use by eligible professional and group practices beginning in 2014 to report for the PQRS incentives and payment adjustments.

a. Claims-Based Reporting: Requirements for Using Claims-Based Reporting for 2013 and Beyond

Eligible professionals that wish to report data on PQRS quality measures via claims for the incentives and for the payment adjustments must submit quality data codes (QDCs) on claims to CMS for analysis. QDCs for the eligible professional's selected PQRS (individual or measures groups) quality measures that are reported on claims may be submitted to CMS at any time during the reporting period for the respective program year. However, as required by section 1848(m)(1)(A) of the Act, all claims for services furnished during the reporting period, would need to be processed by no later than the last Friday occurring 2 months after the end of the reporting period, to be included in the program year's PQRS analysis. For example, all claims for services furnished during a reporting period that occur during calendar year 2013 would need to be processed by no later than the last Friday of the second month after the end of the reporting period, that is, processed by February 28, 2014 for the reporting periods that end December 31, 2013. In addition, after a claim has been submitted and processed, we proposed at re-designated § 414.90(g)(2)(i)(A) and newly added § 414.90(h)(2)(i)(A) to indicate that EPs cannot submit QDCs on claims that were previously submitted and processed (for example, for the sole purpose of adding a QDC for the PQRS).

We invited public comment on our proposed requirements for using the claims-based reporting mechanism for the incentives and for the payment adjustments for 2013 and beyond. The following is a summary of the comments we received regarding these proposals.

Comment: Some commenters disagreed with our proposal not to allow the resubmission of claims for the sole purpose of attaching a reporting code on a claim.

Response: We understand that there are instances where Medicare Part B claims are resubmitted and reprocessed. However, to avoid unnecessary reprocessing of claims for the sole purpose of reporting PQRS quality data, and because it is overly burdensome and costly to analyze claims that are resubmitted to identify the submission of additional codes for the PQRS, we are finalizing our proposal. We note that this has been a program policy since the inception of PQRS in 2007. Therefore, we are finalizing § 414.90(g)(2)(i)(A) and § 414.90(hg)(2)(i)(A), with some technical changes to the language we are making in this final rule, to indicate that if an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on individual Physician Quality Reporting System measures or measures groups.

b. Registry-Based Reporting

(1) Proposed Qualification Requirements for Registries for 2013 and Beyond

For 2013 and beyond, we proposed that registries wishing to submit data on PQRS quality measures for a particular reporting period would be required to be qualified for each reporting period the registries wish to submit quality measures data (77 FR 44808). This qualification process is necessary to verify that registries are able to submit data on PQRS quality measures on behalf of eligible professionals and group practices to CMS. Registries who wish to become qualified to report PQRS quality measures for a reporting period undergo (1) a self-nomination process and (2) a qualification process regardless of whether the registry was qualified the previous program year.

Registry Self-nomination Process. For the self-nomination process, we proposed that the self-nomination process would consist of the submission of a self-nomination statement submitted via the web by January 31 of each year in which the registry seeks to submit data on PQRS quality measures on behalf of eligible professionals and group practices (77 FR 44809). For example, registries that wish to become qualified to report data in 2013 under the program, that is, to report during all of the reporting periods for the 2013 incentive and the 2015 payment adjustment, would be required to submit its self-nomination statement by January 31, 2013. We proposed that the self-nomination statement contain all of the following information:

- The name of the registry.
- The reporting period start date the registry will cover.
- The measure numbers for the PQRS quality measures on which the registry is reporting.

We noted that CMS is currently developing the functionality to accept registry self-nomination statements via the web and anticipate development of this functionality to be complete for registries to submit their self-

nomination statements via the web in 2013. However, in the event that it is not technically feasible to collect this self-nomination statement via the web, we proposed that registry vendors would submit its self-nomination statement via a mailed letter to CMS (77 FR 44809). The self-nomination statement would be mailed to the following address: Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850. We proposed that these self-nomination statements must be received by CMS by 5:00 p.m. Eastern Standard Time on January 31 of the applicable year.

We invited public comment on our proposals related to the registry self-nomination process. The following is a summary of these comments.

Comment: One commenter suggested that we extend the proposed self-nomination deadline of January 31 for registries who wish to become qualified to submit PQRS measures data should we finalize the option to submit this self-nomination statement via U.S. mail.

Response: Based on our desire to streamline the self-nomination process, we are finalizing our proposal to accept the registry self-nomination statements via the web. However, we understand that issues may arise with respect to the web-based self-nomination process. Therefore, we are finalizing the proposed back-up submission method. Specifically, only in the event that we encounter issues accepting registry self-nomination statements via the web, we are finalizing our proposal to accept self-nomination statements from registries who wish to become qualified to submit PQRS measures data to CMS via U.S. mail. The self-nomination statement will be mailed to the following address: Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850.

We are also finalizing the deadline of January 31. Although we agree that submitting a self-nomination statement via U.S. mail would require more time to complete than submitting the self-nomination statement via the web, we do not believe an extended submission deadline is warranted since registries (such as those participating in PQRS in 2012) are familiar with submitting self-nomination statements by January 31 via U.S. mail. Beginning 2013, registries wishing to indicate their intent to submit PQRS measure data on behalf of eligible professionals are required to submit a self-nomination statement for each year in which the registry seeks to participate in PQRS. Please note that when submitting self-nomination statements via the web, registries are required to meet CMS' security and system requirements. Should a registry wishing to self-nominate encounter issues using the web, the registry may contact the QualityNet Help Desk for assistance in submitting a self-nomination statement.

Comment: One commenter suggested that we extend the proposed self-nomination deadline of January 31 for registries who wish to become qualified to submit PQRS measures data to CMS. The commenter believes that, since we are proposing new criteria for registries, the registries should be provided with more time to make any needed changes prior to submitting its self-nomination statement.

Response: We understand that registries need time to decide whether to undergo the qualification process to submit PQRS measures data to CMS. However, extending the self-nomination deadline would delay our ability to make the list of qualified registries available to eligible professionals and group practices for a particular reporting period. We note that the deadline for registries to submit a self-nomination statement has historically been January 31 of the year in which the registry seeks to become qualified. The January 31 deadline has provided registries with sufficient time to submit self-nomination statements in the past, even when new requirements were established for registries, so we do not believe it is necessary to extend the self-nomination deadline for registries past January 31 of the year in which the registry seeks to become qualified. In addition, as previously stated, beginning 2013, we are accepting registry self-nomination statements via the web. We believe this will provide registries with more time to submit their self-nomination statements, as registries will not have to account for the time it takes for CMS to receive its self-nomination statement via U.S. mail. Please note that the self-nomination statement simply indicates to CMS a registry's intent to participate in PQRS. The process to become a qualified registry, which follows this discussion, occurs after the deadline for registries to submit its self-nomination statement.

Registry Qualification Process. For the qualification process, we proposed that all registries, regardless of whether or not they have been qualified to report PQRS quality measures in a prior program year, undergo a qualification process to verify that the registry is prepared to submit data on PQRS quality measures for the reporting period in which the registry seeks to be qualified (77 FR 44809–44810). To become qualified for a particular reporting period, we proposed that a registry would be required to:

- Be in existence as of January 1 the year prior to the program year in which the registry seeks qualification (for example, January 1, 2012, to be qualified to submit data in 2013).
- Have at least 25 participants by January 1 the year prior to the program year in which the registry seeks qualification (for example, January 1, 2012, to be qualified for the reporting periods occurring in 2013).
- Provide at least 1 feedback report to participating eligible professionals and group practices for each program year in which the registry submits data on PQRS quality measures on behalf of eligible professionals and group practices. This feedback reporting would be based on the data submitted by the registry to CMS for the applicable reporting period or periods occurring during the program year. For example, if a registry was qualified for the reporting periods occurring in 2013, the registry would be required to provide a feedback report to all participating eligible professionals and group practices based on all 12 and 6-month reporting periods for the 2013 incentive and the 12-month reporting period for 2015 payment adjustment. Although we proposed to require that qualified registries provide at least 1 feedback report to all participating eligible professionals and group practices, we encouraged registries to provide an additional, interim feedback report, if feasible, so that an eligible professional may determine what steps, if any, are needed to meet the criteria for satisfactory reporting.
- For purposes of distributing feedback reports to its participating eligible professionals and group practices, the registry must collect each participating eligible professional's email address and have documentation from each participating eligible professional authorizing the release of his or her email address.
- Not be owned or managed by an individual, locally-owned, single-specialty group (for example, single-specialty practices with only 1 practice location or solo practitioner practices would be precluded from becoming a qualified PQRS registry).
- Participate in all ongoing PQRS mandatory support conference calls and meetings hosted by CMS for the

program year in which the registry seeks to be qualified. For example, a registry wishing to be qualified for reporting in 2013 would be required to participate in all mandatory support conference calls hosted by CMS related to reporting in 2013 under the PQRS.

• Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 3 measures.

• Be able to calculate and submit measure-level reporting rates and/or, upon request, the data elements needed to calculate the reporting rates by TIN/NPI.

• Be able to calculate and submit, by TIN/NPI, a performance rate (that is, the percentage of a defined population who receive a particular process of care or achieve a particular outcome based on a calculation of the measure's numerator and denominator specifications) for each measure on which the eligible professional (as identified by the TIN/NPI) or group practice reports and/or, upon request, the Medicare beneficiary data elements needed to calculate the reporting rates.

• Be able to separate out and report on Medicare Part B FFS patients.

• Report the number of eligible instances (reporting denominator).

• Report the number of instances a quality service is performed (reporting/performance numerator).

• Report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification.

• Report the number of reported instances, performance not met, meaning the quality action was not performed for any valid reason as defined by the measure specification. Please note that an eligible professional receives credit for reporting, not performance.

• Be able to transmit data on PQRS quality measures in a CMS-approved XML format.

• Comply with a CMS-specified secure method for data submission, such as submitting the registry's data in an XML file through an identity management system specified by CMS or another CMS-approved method, such as use of appropriate Nationwide Health Information Network specifications, if technically feasible.

• Submit an acceptable ''validation strategy'' to CMS by March 31 of the reporting year the registry seeks qualification (for example, if a registry wishes to become qualified for reporting in 2013, this validation strategy would be required to be submitted to CMS by March 31, 2013). A validation strategy details how the registry will determine whether eligible professionals and group practices have submitted accurately and on at least the minimum number (80 percent) of their eligible patients, visits, procedures, or episodes for a given measure. Acceptable validation strategies often include such provisions as the registry being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method.

• Perform the validation outlined in the strategy and send the results to CMS by June 30 of the year following the reporting period (for example, June 30, 2014, for data collected in the reporting periods occurring in 2013).

• Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the registry's receipt of patient-specific data from the eligible professionals and group practices, as well as the registry's disclosure of quality measure results and numerator and denominator data and/or patient-specific data on Medicare beneficiaries on behalf of eligible professionals and group practices who wish to participate in the PQRS.

• Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the registry has authorized the registry to submit quality measure results and numerator and denominator data and/or patient-specific data on Medicare beneficiaries to CMS for the purpose of PQRS participation. This documentation would be required to be obtained at the time the eligible professional signs up with the registry to submit PQRS quality measures data to the registry and would be required to meet any applicable laws, regulations, and contractual business associate agreements.

• Upon request and for oversight purposes, provide CMS access to review the Medicare beneficiary data on which PQRS registry-based submissions are founded or provide to CMS a copy of the actual data.

• Provide CMS a signed, written attestation statement via mail or email which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.

• Use PQRS measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. We will provide registries a standard set of logic to calculate each measure and/or measures group they intend to report for each reporting period.

• Provide a calculated result using the CMS-supplied measure calculation logic and XML file format for each measure that the registry intends to calculate. The registries may be required to show that they can calculate the proper measure results (that is, reporting and performance rates) using the CMS-supplied logic and send the calculated data back to CMS in the specified format. The registries will be required to send in test files with fictitious data in the designated file format.

• Describe to CMS the cost for eligible professionals and group practices that the registry charges to submit PQRS and/or eRx Incentive Program data to CMS.

• Agree to verify the information and qualifications for the registry prior to posting (includes names, contact, measures, cost, etc.) and furnish/support all of the services listed for the registry on the CMS Web site.

• Agree that the registry's data for Medicare beneficiaries may be inspected or a copy requested by CMS and provided to CMS under our oversight authority.

• Be able to report consistent with the satisfactory reporting criteria requirements for the PQRS incentives and payment adjustments.

In addition to meeting all the requirements specified previously for the reporting of individual quality measures via registry, for registries that intend to report on PQRS measures groups, we proposed that these registries, regardless of whether or not registries were qualified in previous years, would be required to:

• Indicate the reporting period chosen for each eligible professional who chooses to submit data on measures groups.

• Base reported information on measures groups only on patients to whom services were furnished during the relevant reporting period.

• If the registry is reporting using the measures group option for 20 patients, the registry on behalf of the eligible professional may include non-identifiable data for non-Medicare beneficiaries as long as these patients meet the denominator of the measure and the eligible professional includes a majority of Medicare Part B patients in their cohort of 20 patients for the measures group.

We intend to post the final list of registries qualified for each reporting period by the summer of each year in which the reporting periods occur on

the CMS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.* For example, we intend to post the list of registries qualified for 2013 reporting periods by summer 2013. For each reporting period, the list of qualified registries would contain the following information: The registry name, registry contact information, the measures and/or measures group(s) for which the registry is qualified and intends to report for the respective reporting period.

The registry qualification process we proposed was largely the same process we established to qualify registries for the reporting periods occurring in 2012. We proposed a similar process to the 2012 qualification process because, registries are already familiar with this qualification process, so we felt there would be a greater likelihood that registries wishing to be qualified to report quality measures data for a particular reporting period would be able to pass the qualification process. We felt this would provide eligible professionals with more qualified registry products from which to choose.

We invited public comment on our proposals related to the qualification process for registries. The following is a summary of the comments we received regarding these proposals.

Comment: One commenter asked for clarification on our proposal to have a validation strategy.

Response: Please note that we do not provide requirements or guidelines for a validation strategy. Registries must adopt a strategy in the manner the registry chooses. Therefore, the specifics of the validation strategy are dependent on the registry. However, we are finalizing the requirement that a registry seeking to be qualified to submit PQRS quality measures data have a validation strategy. As we discuss in further detail in the following response, although we strongly encourage registries to test their validation strategies with CMS, we are not finalizing this testing requirement.

Comment: One commenter requested that the requirement for registries to provide data to CMS should contain the stipulation that it be de-identified at the patient level.

Response: We have historically reserved the right to request patient identifiable data if we so choose. We understand the security concerns around patient-identified data and will work with the registry to receive the data in a secure manner.

Comment: One commenter recommended that the final list of qualified PQRS registries be available earlier than the summer of each reporting period.

Response: We realize that it may be challenging for eligible professionals to choose among the numerous registries. Due to the commenter's concerns as well as concerns we have heard from other stakeholders regarding the timing of the availability of the qualified registry list, we are not finalizing the following proposed registry qualification requirement: Perform the validation outlined in the strategy and send the results to CMS by June 30 of the year following the reporting period (for example, June 30, 2014, for data collected in the reporting periods occurring in 2013). We note that the delay in posting the list of qualified registries was mainly due to our desire to test a registry's validation strategy prior to qualifying the registry to report PQRS quality measures data for the applicable year. Since we are not requiring that this validation strategy be tested, we will be able to post the list of qualified registries sooner. We anticipate that we will post the list of qualified registries in the Spring of the applicable year the registries are qualified submit quality measures data on behalf of eligible professionals (for example, Spring 2013 for reporting periods occurring in 2013).

We note that, although we are not requiring that a registry's validation strategy be tested to become qualified to submit PQRS quality measures data on behalf of its eligible professionals, this testing process will still be available for registries to test their respective validation strategies. It is important for registries to undergo this testing process to check whether they will be able to submit quality measures data accurately to CMS after the applicable reporting period.

Comment: One commenter sought clarification on our proposal to, ''upon request and for oversight purposes, provide CMS access to review the Medicare beneficiary data on which PQRS registry-based submissions are founded or provide to CMS a copy of the actual data.'' Specifically, the commenter sought clarification as to whether this requirement would require that CMS have access to more data than is already required for PQRS.

Response: This requirement would not require that CMS have access to more data than is already required for PQRS. Rather, this requirement is necessary in order for CMS to verify the accuracy of the data submitted by the respective registry. As stated previously, CMS will work with registries to accept data in a secure manner.

Based on the comments received and for the reasons stated previously, we are finalizing the registry qualification process for 2014 and beyond, as proposed, with the exception that we are not finalizing the requirement that a registry perform the validation outlined in its strategy and send the results to CMS by June 30 of the year following the reporting period.

Registry Audit and Disqualification Process. Lastly, in the CY 2012 Medicare PFS proposed rule, we raised the issue of disqualifying registries that submit inaccurate data (76 FR 42845). We did not adopt a disqualification process but noted the importance of such a process, as well as our intention to provide detailed information regarding a disqualification process in future rulemaking (76 FR 73322). In an effort to ensure that registries provide accurate reporting of quality measures data, we proposed to modify § 414.90(b) to indicate that we would audit qualified registries (77 FR 45044–45045). If, during the audit process, we find that a qualified registry has submitted grossly inaccurate data, we proposed, under § 414.90(b), to indicate that we would disqualify such a registry from the subsequent year under the program, meaning that a registry would not be allowed to submit PQRS quality measures data on behalf of eligible professionals and group practices for the next year. Under this proposal, a disqualified registry would not be included in the list of qualified registries that is posted for the applicable reporting periods under which the registry attempted to qualify (77 FR 44810). We further proposed to post a registry's disqualification status on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.* For example, if a qualified registry submits quality measures data for the reporting periods occurring in 2013 but is then audited and later disqualified, the registry would not be allowed to submit PQRS quality measures data on behalf of participating eligible professionals and group practices to CMS for the reporting periods occurring in 2014 or later. One example of submitting grossly inaccurate data that CMS has encountered in the past is if a registry reports inaccurate TIN/NPIs on 5 percent or more of the registry's submissions. As CMS calculates data on a TIN/NPI level, it is important for registries to provide correct TIN/NPI information.

In proposing registry disqualification, we considered other alternatives, such as placing registries in a probationary

status. However, we believed it is important for registries to submit correct data once it is qualified to submit data on behalf of its eligible professionals and therefore, find that immediate disqualification to be appropriate. This becomes especially important particularly as the program moves from the use of incentives to payment adjustments (77 FR 44811).

We invited public comment as to the threshold of grossly inaccurate data for the purpose of disqualifying a registry. The following is a summary of the comments we received regarding this proposal.

Comment: One commenter generally supported the establishment of a process to audit qualified registries, but advised CMS to exercise caution when using their authority to disqualify registries, thereby preventing these registries from submitting data on PQRS measures.

Response: We understand the consequences of disqualifying a previously qualified registry and will therefore use this authority with caution. It is our intention that disqualification be used only for those registries submitting grossly inaccurate data. However, we stress the importance of having registries provide correct data to ensure that eligible professionals and group practices are correctly provided with incentive payments or payment adjustments.

Comment: Should CMS discover that a registry has submitted inaccurate data, one commenter requested that the registry be allowed an opportunity to correct their mistakes and rectify any processes leading to data submission errors.

Response: We appreciate the commenter's feedback. However, due to the time it takes to perform data analysis for payment determination, it is not technically feasible to allow registries to another opportunity resubmit data that is found to be inaccurate. We note that the registries have until the last Friday of February following the applicable reporting period (for example, February 28, 2014 for reporting periods occurring in 2013). After this data submission period, CMS must perform its analysis to determine whether eligible professionals have met the criteria for satisfactory reporting for the PQRS incentives or payment adjustments. In order to perform this analysis in time to issue payment adjustments beginning January 1 of the applicable payment adjustment year (for example, January 1, 2015 for the 2015 PQRS payment adjustment), CMS cannot provide for an additional opportunity to resubmit data that is found to be inaccurate.

We note that, although no longer required, registries have an opportunity during the year to test its validation and submission strategy with CMS prior to submitting the data that CMS will use to determine whether its eligible professionals or group practices have met the criteria for satisfactory reporting for the PQRS incentives and/or payment adjustments. We strongly encourage registries to undergo this testing process, as it will help to alleviate issues that may occur when submitting PQRS quality measures data to CMS.

Comment: Some commenters oppose disqualifying registries because of inaccuracies in TIN/NPI information provided to CMS by the registries. One commenter states that registries do not gather TIN/NPI information; rather, outside reporting sites provide TIN/NPI information. Since the registries do not have access to this information provided by these outside sites, registries have no way of verifying the accuracy of TIN/NPI information. Another commenter stated that submission of inaccurate data should be shared by those generating the data, that is, the responsibility of submitting inaccurate data should be shared with the registry, its eligible professionals and group practices, as well as other entities involved in submitting quality measures data to CMS via a qualified registry.

Response: We recognize that registries are limited to the data they receive from their eligible professionals. It is not our intention to seek to disqualify registries who, through no fault of their own, submit inaccurate data. However, we believe it is necessary to eliminate or, at a minimum, drastically reduce instances where mismatches in TIN/NPI information would result in nonpayment of an incentive or conversely the application of the payment adjustment when it appears that the eligible professional or group practice would otherwise be eligible to receive an incentive. While we understand that registries are reliant on the data they receive from their eligible professionals or group practices, CMS discovered numerous instances where registries have failed to correct data inaccuracies within the purview of a registry's calculations. We understand that registry vendors undergo costs associated with qualifying their products to submit data on PQRS measures. We also understand that it would place an added burden on registries who were previously qualified to repeat the qualification process should CMS disqualify the registry. Therefore, as proposed, it is our intention to limit disqualification of registries to those who submit grossly inaccurate data to CMS.

Comment: One commenter suggested that registries in their first year of PQRS participation be provided with leniency with regard to disqualification.

Response: We note that CMS typically works with registries during the data submission period following a PQRS reporting period to help avoid the reporting of inaccurate data. One example of this is providing the testing process whereby registries may test its validation and submission strategy. In addition, during the submission process occurring immediately after the PQRS reporting periods, CMS provides help and guidance to those registries who encounter issues submitting PQRS quality measures data to CMS. Therefore, we do not believe that registries participating in PQRS for the first time are disadvantaged to the point that they should be provided greater leniency. The need for CMS to receive accurate data to determine PQRS incentive and/or payment adjustment applicability outweighs the need to afford newly qualified registries leniency should these registries submit grossly inaccurate data.

Comment: One commenter sought clarification on the following questions: (1) What happens to the registry participants' respective data? Are their submissions also ''disqualified''? (2) Does a finding of a submission with ''grossly inaccurate data'' by a registry mean that all data collected and submitted by that registry is to be considered ''grossly inaccurate''?

Response: We appreciate the commenter's questions. With respect to the first question, if we find that a registry has submitted grossly inaccurate data, the data submitted by its registry participants those reporting periods will be disregarded. For example, if a registry submits grossly inaccurate data to CMS in 2014 for reporting periods occurring in 2013, the data submitted by the registry on behalf of its eligible professionals and group practices for reporting periods occurring in 2013 will not be accepted by CMS. With respect to the second question, should we find that a registry has submitted grossly inaccurate data, the data submitted will be considered inaccurate, and CMS will not accept the data provided.

Based on the comments received and for the reasons stated, we are modifying § 414.90(b) to indicate that we are finalizing the proposed disqualification process for registries. Should CMS decide to disqualify a registry, please note that our decision to disqualify a registry is final.

Collection of Registry Data via the NwHIN. The Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via a registry through NwHIN. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we solicited public comment on collecting data via registry for PQRS via NwHIN. We received no comments on this proposal. However, since we believe the NwHIN must be further developed in order to be able to collect registry data via the NwHIN, we are not finalizing any policy to collect data via the NwHIN at this time.

c. EHR-Based Reporting

(1) Requirements for a Vendor's Direct EHR Products for 2014 and Beyond

Definition of Direct EHR Product. We proposed to modify § 414.90(b) to define a direct electronic health record (EHR) product as ''an electronic health record vendor's product and version that submits data on Physician Quality Reporting System measures directly to CMS'' (77 FR 45053). Please note that the self-nomination and qualification requirements for a vendor's direct EHR products for 2012 and 2013 were established in the CY 2012 Medicare PFS final rule (76 FR 73323).

We did not receive public comment on our proposal to modify the definition of a direct electronic health record (EHR) product (77 FR 44811). Therefore, we are modifying § 414.90(b) to define a direct electronic health record (EHR) product as ''an electronic health record vendor's product and version that submits data on Physician Quality Reporting System measures directly to CMS,'' as proposed.

Discontinuation of the Qualification Process for Direct EHR Products. In the CY 2012 PFS final rule, we established the requirement that direct EHR products that submit PQRS quality measures data to CMS for reporting periods occurring in 2013 be qualified (77 FR 77323). We proposed to no longer require qualification of direct EHR products beginning in 2014 (77 FR 44811). Although we would still allow EHR vendors to submit test files to the PQRS and continue to provide support calls, we would no longer require vendors to undergo this testing process. Although vendors and their products would no longer be required to undergo this testing or qualification process, we proposed that CMS would only accept the data if the data are:

- Transmitted in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 and
- In compliance with a CMS-specified secure method for data submission, such as submitting the direct EHR vendor's data (for testing) through an identity management system specified by CMS or another approved method.

CMS would therefore no longer post a list of qualified EHR vendors and their products on the CMS Web site. Therefore, eligible professionals would need to work with their respective EHR vendor to determine whether their specific EHR product has undergone any testing with the PQRS and/or whether their EHR product can produce and transmit the data in the CMS-specified form and manner. While we no longer believe that this process is necessary, we invited public comment as to whether CMS should continue to require that direct EHR products undergo self-nomination and qualification processes prior to being authorized to submit quality measures data to CMS for PQRS reporting purposes.

We proposed to not continue the qualification requirement (that is, no longer propose this process for future years of the program) because we believe adequate checks are in place to ensure that a direct EHR product is able to submit quality measures data for the PQRS. For example, to the extent possible, we intend to align with the Medicare EHR Incentive Program for our criteria for satisfactory reporting and measures available for reporting under the EHR-based reporting mechanism. The Medicare EHR Incentive Program requires that an eligible professional submit clinical quality measures using EHR technology certified under the program established by the Office of the National Coordinator for Health Information Technology (ONC). We anticipated that ONC's certification process could include testing related to the reporting of the proposed PQRS EHR measures indicated in Tables 32 and 33, since we proposed to align the PQRS EHR-based measures with the measures available for reporting under the EHR Incentive Program. We invited public comment as to whether, in lieu of qualification, CMS should require that direct EHR products that would be used to submit data on PQRS quality measures for a respective reporting period be classified as certified under the program established by ONC.

The following is summary of the comments we received regarding our proposal to discontinue the qualification process for direct EHR products as well as our proposal to require CEHRT in lieu of PQRS qualification.

Comment: Several commenters supported our proposal to discontinue qualification of direct EHR products. The commenters believe that this proposal moves towards our goal of aligning PQRS and the EHR Incentive Program. The commenters also believe discontinuing qualification of direct EHR vendor products helps to encourage use of the EHR-based reporting mechanism for reporting under PQRS.

Response: We appreciate the commenters' feedback and, based on the support we received for this proposal and the reasons we discussed above, we are finalizing our proposal to discontinue qualifying direct EHR products beginning in 2014.

Comment: Should CMS discontinue the qualification process, one commenter requested that CMS continue to allow EHR vendors the opportunity to submit test files when needed.

Response: Although CMS is discontinuing qualifying EHR products, vendors will be able to continue to submit test files. We believe that allowing submission of test files is an important tool for providers and provides an adequate check to determine whether the vendor products are able to successfully submit data to CMS.

Comment: Some commenters opposed our proposal to discontinue qualification of direct EHR products. The commenters believed that discontinuing qualification will increase burden on providers, who will have no guide to determine whether a direct EHR product is qualified to report PQRS measures. One commenter therefore urged CMS to continue to qualify direct EHR products until the ONC's certification process can be used for PQRS in addition to the EHR Incentive Program. Another commenter expressed concern that, should CMS discontinue the qualification process for direct EHR products, eligible professionals and group practices would simply assume that their CEHRT are able to submit data on measures under PQRS.

Response: We understand that our decision to discontinue the qualification process for direct EHR products puts the onus on eligible professionals and group practices to determine whether a direct EHR product meets the requirements for reporting PQRS measures. However, we

have received much stakeholder feedback requested that we discontinue the requirement that an eligible professional select a ''qualified'' direct EHR product; the stakeholders believe that the qualified designation is confusing, because there is already certification process in place administered by ONC that tests EHR products. Therefore, we are finalizing our proposal to discontinue the qualification process for direct EHR products under the PQRS beginning in 2014.

Nonetheless, we share the commenter's concern to provide guidance to eligible professionals on choosing EHR products. Therefore, based on the comments received, we are also finalizing to the requirement that a direct EHR product be certified by ONC as Certified EHR Technology (CEHRT), and therefore meet the definition of CEHRT in ONC's regulations (see 45 CFR 170.102), to submit PQRS measures. (For the 2014 Edition EHR certification criteria, please refer to 77 FR 54163). While the process for certifying EHR technology may not be distinctly tailored for reporting PQRS quality measures, we note that we are making efforts to align, to the maximum extent possible, the measures and reporting criteria with the EHR Incentive Program, which requires eligible professionals to use CEHRT. For example, it is our intention to further align the EHR measures available for reporting by eligible professionals and group practices under PQRS and the EHR Incentive Program, so that the specifications of these measures will be the same. Therefore, beginning in 2014, ONC's certification process would test the submission of data on CQMs available for reporting under the EHR Incentive Program and, consequently, since the measures would be the same, data on PQRS quality measures that are reportable via an EHR.

We understand that CEHRT may provide more capabilities than needed to report PQRS quality measures. However, we note that most of these capabilities are intertwined with the direct EHR product's ability to capture data on quality measures and therefore necessary. The certified health information technology product list (CHPL) includes all EHR technology that has been certified, and it can be found at *http://oncchpl.force.com/ehrcert?q=CHPL*.

Comment: While one commenter generally supported requiring direct EHR products to be ONC certified as CEHRT to report PQRS measures, the commenter stated that the ONC certification process should only be used for the PQRS and EHR Incentive Programs if the measures are identical, particularly in specifications and reporting format.

Response: We note the commenter's concern regarding use of the ONC certification process and the alignment of EHR-based measures in PQRS and the EHR Incentive Program. As we noted in the previous response, it is our intention to align, to the maximum extent possible, the measures and reporting criteria for eligible professionals to meet the criteria for satisfactory reporting under PQRS and the criteria for meeting the CQM component of meaningful use under the EHR Incentive Program. By 2014, we expect that the measures and reporting criteria available under both programs will be sufficiently aligned to justify requiring that an EHR product used to report PQRS quality measures data undergo the ONC certification process. Therefore, we believe that requiring a direct EHR product to be CEHRT in order to be eligible to report measures under PQRS beginning in 2014 is appropriate.

Comment: One commenter recommended that a certified quality reporting module be considered as a direct EHR product for purposes of submitting PQRS measures to CMS.

Response: We are discontinuing the qualification process and requiring that a direct EHR product be CEHRT beginning in 2014. A certified quality reporting module may be part of CEHRT, but CEHRT as a whole is more comprehensive. Please refer to ONC's standards and certification criteria final rule for additional information on requirements for CEHRT (77 FR 54163). The Certified HIT Product List CHPL, which is the listing of all certified products, is available at *http://oncchpl.force.com/ehrcert?q=CHPL*.

Other Requirements for Direct EHR Products. Although we proposed that direct EHR products would no longer be required to undergo this testing or qualification process, we proposed that CMS would only accept the data if the data are:

- Transmitted in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 and
- In compliance with a CMS-specified secure method for data submission, such as submitting the direct EHR vendor's data (for testing) utilizing an identity management system specified by CMS or another approved method (77 FR 44811).

In addition, upon request and for oversight purposes, we proposed that the vendor would still be expected to provide CMS access to review the Medicare beneficiary data on which PQRS direct EHR-based submissions are founded or provide to CMS a copy of the actual data.

We invited public comment on these additional proposed requirements for direct EHR products. The following is a summary of comments we received on this proposal.

Comment: One commenter opposed our proposed requirement that direct EHR vendors would be expected to provide CMS access to review to Medicare beneficiary data on which PQRS direct EHR-based submissions are founded or provide to CMS a copy of the actual data. Under the direct EHR submission method, healthcare organizations are submitting data directly to CMS. The vendor does not come into possession of the data being submitted during this process and does not have a copy of the data to provide to CMS. Responsibility for providing access to such data must remain with the healthcare organization. Another commenter expressed HIPAA concerns regarding our proposed requirement that EHR vendors would be expected to provide CMS access to review to Medicare beneficiary data on which PQRS direct EHR-based submissions are founded or provide to CMS a copy of the actual data.

Response: We agree with the concerns the commenters have raised. Therefore, we are not finalizing the requirement that direct EHR products provide CMS access to review the Medicare beneficiary data upon which the direct vendor's submissions are founded or a copy of the actual data.

In summary, we are finalizing the requirements for submitting quality measures data via a direct EHR product, as proposed, with the following exception: We are not finalizing our proposal to allow CMS access to review the Medicare beneficiary data on which PQRS direct EHR-based submissions are founded or provide to CMS a copy of the actual data. In addition, we note that the EHR Incentive Program has provided an additional format for transmitting quality measures data to CMS from CEHRT. In addition to finalizing the submission of quality measures data using the QRDA Category I format, the EHR Incentive Program also finalized the QRDA Category III transmission format (77 FR 54075). In our proposal, we proposed to require that eligible professionals and group practices using CEHRT transmit quality measures data in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard, and used QRDA Category I as an example. Since

it was our intent to align with the EHR Incentive Program, who finalized transmission of quality measures data using the QRDA Category I and QRDA Category III formats, we are requiring that quality measures data submitted via CEHRT for purposes of reporting for PQRS beginning in 2014 be transmitted using the QRDA Category I and QRDA Category III formats. We note that, although we are requiring that products be able to transmit data using the QRDA Category I and III formats, for purposes of reporting PQRS quality measures data to CMS, eligible professionals need only submit data via their EHR using 1 (either QRDA Category I or III) of these formats. For those eligible professionals who wish to participate in both PQRS and the EHR Incentive Program using an EHR product that is CEHRT beginning in 2014, we refer readers to Option 2 for the submission of CQMs under the EHR Incentive Program (77 FR 54058).

Collection of EHR data via the NwHIN. The Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via a direct EHR product through NwHIN, but we would like to encourage this method with EHR-based reporting. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we solicited public comment on collecting data via an EHR for PQRS via NwHIN. The following is a summary of the comments we received.

Comment: One commenter opposed collection of data received via a direct EHR product through the Nationwide Health Information Network (NwHIN). The commenter believes collecting data through NwHIN is premature and believes that development of the NwHIN is necessary prior to collecting data through the NwHIN.

Response: We appreciate the commenter's feedback and agree with the commenter. Therefore, we are not finalizing any policy to collect data received via a direct EHR product through the NwHIN at this time.

(2) Requirements for a Vendor's EHR Data Submission Vendor Products for 2013 and Beyond

Definition of EHR Data Submission Vendors. The EHR data submission vendor product was a reporting mechanism that was newly established in the CY 2012 Medicare PFS final rule (76 FR 73324). EHR products from an EHR data submission vendor were products that are able to receive and transmit clinical quality data extracted from an EHR to CMS. We proposed to modify § 414.90(b) to define an electronic health record (EHR) data submission vendor product as ''an electronic health record vendor's product and version that acts as an intermediary to submit data on Physician Quality Reporting System measures on behalf of an eligible professional or group practice'' (77 FR 45053).

We invited public comment but received no comments on this proposed definition of EHR data submission vendor product. However, we are modifying this definition to indicate that a data submission vendor is not necessarily an EHR product. Rather, according to stakeholder feedback, an EHR data submission vendor is any entity that is able to receive and transmit to CMS quality measures data extracted from an EHR product on behalf of the eligible professional. Therefore, we are modifying § 414.90(b) to define an ''electronic health record (EHR) data submission vendor'' as ''an entity that receives and transmits data on Physician Quality Reporting System measures from an EHR product to CMS.''

Qualification process for EHR Data Submission Vendors for 2013. Please note that the qualification requirements for a vendor's EHR data submission vendor products for 2013 were established in the CY 2012 Medicare PFS final rule (76 FR 73327). Specifically, we established that a qualification and testing process would occur in 2012 to qualify EHR data submission vendor products to submit PQRS quality measures data for reporting periods occurring in CY 2013. Operationally, we were unable to establish a qualification and testing process in 2012 to qualify EHR data submission vendor products for reporting periods occurring in CY 2013. Therefore, we proposed to perform, in 2013, the qualification and testing process established in the CY 2012 Medicare PFS final rule (76 FR 73327) that was supposed to occur in 2012 (77 FR 44812). We invited but received no public comment on this proposal. Therefore, we are finalizing our proposal to perform this qualification and testing process for EHR data submission vendor products in 2013.

Discontinuation of Qualification Process for EHR Data Submission Vendors. For 2014 and beyond, we proposed to no longer qualify EHR data submission vendor products to use such products under the PQRS for the same reasons we have articulated in our proposal not to continue qualifying direct EHR products (77 FR 44812). Although we would still allow EHR data submission vendors to submit test files to the PQRS and continue to provide support calls, we would no longer require vendors to undergo this testing process. CMS, however, would no longer post a list of qualified EHR data submission vendors on the CMS Web site. Therefore, eligible professionals would need to work with their respective EHR data submission vendor to determine whether the vendor has undergone any testing with the PQRS and/or whether EHR data submission vendor can produce and transmit the data in the CMS-specified form and manner.

We invited public comment on our proposal to, beginning 2014, not require qualification of EHR data submission vendor products. We also invited public comment as to whether CMS should continue to require that EHR data submission vendors undergo these self-nomination and qualification processes prior to being authorized to submit quality measure data to CMS on an eligible professional's behalf for PQRS reporting purposes.

We proposed to not continue the qualification requirement (that is, no longer propose this process for 2014 and future years of the program) because we felt adequate checks were in place to ensure that an EHR data submission vendor is able to submit quality measures data for the PQRS. For example, to the extent possible, we intend to align with the Medicare EHR Incentive Program for our criteria for satisfactory reporting and measures available for reporting under the EHR-based reporting mechanism. The Medicare EHR Incentive Program requires that an eligible professional submit clinical quality measures using EHR technology certified under the program established by the Office of the National Coordinator for Health Information Technology (ONC). We anticipated that the ONC's certification process could include testing related to the reporting of the proposed PQRS EHR measures indicated in Table 95, since we proposed to align the PQRS EHR-based measures with the measures available for reporting under the EHR Incentive Program. We invited public comment as to whether, in lieu of qualification, CMS should require that direct EHR products that would be used to submit data on PQRS quality measures for a respective reporting period be classified as CEHRT under the program established by the ONC.

The following is a summary of comments we received regarding our

proposals to discontinue the qualification process for EHR data submission vendors and/or requiring that a vendor's EHR product be CEHRT.

Comment: Several commenters supported our proposal to discontinue qualification of EHR data submission vendors. The commenters believed that this proposal moves towards our goal of aligning PQRS and the EHR Incentive Program. The commenters also believed discontinuing qualification of EHR data submission vendors helps to encourage use of the EHR-based reporting mechanism for reporting under PQRS.

Response: Based on the comments received and for the reasons stated previously, we are finalizing our proposal to discontinue qualifying EHR data submission vendors beginning in 2014.

Comment: Some commenters opposed our proposal to discontinue qualification of EHR data submission vendors. The commenters believe that discontinuing qualification will increase burden on providers, who will have no guide to determine whether an EHR data submission vendor is qualified to report PQRS measures. One commenter therefore urged CMS to continue to qualify EHR data submission vendors until the Office of the National Coordinator (ONC) for Health Information Technology certification process can be used for PQRS to certify its EHR products in addition to the EHR Incentive Program. Another commenter expressed concern that, should CMS discontinue the qualification process for EHR data submission vendors, eligible professionals and group practices would simply assume that their CEHRT are able to submit data on measures under PQRS.

Response: We understand that our decision to discontinue the qualification process for an EHR data submission vendor's EHR products puts the onus on eligible professionals and group practices to determine whether a product meets the requirements for reporting PQRS measures. However, we have received much stakeholder feedback requested that we discontinue the requirement that an eligible professional select a ''qualified'' EHR product; the stakeholders believe that the qualified designation is confusing, because there is already a certification program in place established by ONC that tests and certifies certain EHR products. Therefore, we are finalizing our decision to discontinue the qualification process for EHR data submission vendor's EHR products under the PQRS beginning in 2014.

Nonetheless, we share the commenter's concern that discontinuing the qualification process would place additional burden on providers when trying to determine which EHR data submission vendor to enter into an agreement with. Therefore, based on the comments received and for the reasons we are requiring that direct EHR products be CEHRT beginning in 2014, we are also finalizing a requirement that a vendors EHR product be certified under the program established by ONC as Certified EHR Technology (CEHRT), and therefore meet the definition of CEHRT in ONC's regulations (see 45 CFR 170.102), to submit PQRS measures. We understand that CEHRT may provide more capabilities than needed to report PQRS quality measures. However, we note that most of these capabilities are intertwined with the EHR product's ability to capture data on quality measures and therefore necessary.

Comment: While one commenter generally supported requiring that EHR data submission vendor products be ONC certified as CEHRT to report PQRS measures, the commenter stated that the ONC certification process should only be used for the PQRS and EHR Incentive Programs if the measures are identical, particularly in specifications and reporting format.

Response: We note the commenter's concern regarding use of the ONC certification process and the alignment of EHR-based measures in PQRS and the EHR Incentive Program. As we noted in the response to this comment regarding requiring CEHRT and direct EHR products, it is our intention to align, to the maximum extent possible, the measures and reporting criteria for eligible professionals to meet the criteria for satisfactory reporting under PQRS and the criteria for meeting the CQM component of meaningful use under the EHR Incentive Program. By 2014, we expect that the measures and reporting criteria available under both programs will be sufficiently aligned to justify requiring that an EHR product undergo the ONC certification process. Therefore, we believe that requiring a direct EHR product to be CEHRT in order to be eligible to report measures under PQRS beginning in 2014 is appropriate.

Other Requirements for Data Submission Vendors' EHR Products. Although EHR data submission vendor products are no longer be required beginning in 2013 to undergo this testing or qualification process, we proposed that CMS would only accept the data if the data are:

- Transmitted in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 and for EHR data submission vendor products that intend to report for purposes of the proposed PQRS-Medicare EHR Incentive Program Pilot, if the aggregate data are transmitted in a CMS-approved XML format.
- In compliance with a CMS-specified secure method for data submission (77 FR 44812).

In addition, upon request and for oversight purposes, we proposed that the vendor would still be expected to provide CMS access to review the Medicare beneficiary data on which PQRS direct EHR-based submissions are founded or provide to CMS a copy of the actual data.

We invited public comment on these proposed requirements for EHR data submission vendors. The following is a summary of the comments we received on this proposal.

Comment: One commenter generally supported our proposal to require that data submitted follow the proposed format, regardless of whether the qualification process is discontinued. The commenter also specifically supported use of a standard reporting structure in XML. The commenter further believes that QRDA Level 1 should adequately capture measure information for patients and types of measures where the analysis is something other than the patient.

Response: We appreciate the commenter's support and are finalizing these proposed requirements, as proposed.

In addition, we note that in addition to finalizing the submission of quality measures data using the QRDA Category I format, the EHR Incentive Program also finalized the QRDA Category III transmission format (77 FR 54075). In our proposal, we proposed to require that eligible professionals and group practices using CEHRT transmit quality measures data in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard, and used QRDA Category I as an example. Since it was our intent to align with the EHR Incentive Program, who finalized transmission of quality measures data using the QRDA Category I and QRDA Category III formats, we are also requiring that quality measures data submitted via CEHRT for purposes of reporting for PQRS beginning in 2014 be transmitted using the QRDA Category I and QRDA Category III formats. We note that, although we are requiring that products be able to transmit data using the QRDA Category I and III formats, for purposes of reporting PQRS quality measures data to CMS, eligible

professionals need only submit data via their EHR using 1 (either QRDA Category I or III) of these formats. For those eligible professionals who wish to participate in both PQRS and the EHR Incentive Program using an EHR product that is CEHRT beginning in 2014, we refer readers to Option 2 for the submission of CQMs under the EHR Incentive Program (77 FR 54058).

Collection of EHR Data via the NwHIN. The Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via an EHR data submission vendor through NwHIN, but we would like to encourage this method with EHR-based reporting. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we solicited public comment on collecting data via an EHR for PQRS via NwHIN. The following is a summary of comments we received.

Comment: One commenter opposed collection data received via a direct EHR product through the Nationwide Health Information Network (NwHIN). The commenter believes collecting data through NwHIN is premature and believes that development of the NwHIN is necessary prior to collecting data through the NwHIN.

Response: We appreciate the commenter's feedback and agree with the commenter. Therefore, we are not finalizing any plan to collect data received via an EHR data submission vendor through the NwHIN at this time.

d. GPRO Web Interface: Requirements for Group Practices Using the GPRO Web Interface for 2013 and Beyond

The GPRO web interface is a reporting mechanism established by CMS that is used by group practices that are selected to participate in the GPRO. For 2013 and beyond, we proposed to modify newly designated § 414.90(g) and § 414.90(h) to identify the GPRO web interface as a reporting mechanism available for reporting under the PQRS by group practices comprised of 25 or more eligible professionals (77 FR 45055). Consistent with the GPRO satisfactory reporting criteria we established for the 2012 PQRS (76 FR 73338), as well as the GPRO satisfactory reporting criteria we proposed for 2013 and beyond, we proposed to limit reporting via the GPRO web interface during a respective reporting period to group practices composed of at least 25 eligible professionals (that is, this reporting option would not be available to group practices that contain 2–24 eligible professionals) and selected to participate in the GPRO for the year under which the reporting period occurs (77 FR 44812). For example, a group practice wishing to submit quality measure data via the GPRO web interface for 2013 must be a group practice selected to participate in the GPRO for the 2013 program year. We believe it is necessary to limit use of the GPRO web interface to group practices comprised of at least 25 eligible professionals selected to participate in the GPRO because the 18 measures (including 2 composite measures, for a total of 22 measures) that are proposed to be reportable via the GPRO web interface (as specified in Table 33 of the proposed rule) reflect a variety of disease modules: Patient/caregiver experience, care coordination/patient safety, preventive health, diabetes, hypertension, ischemic vascular disease, heart failure, and coronary artery disease.

We believe that the reporting of the 18 proposed measures spanning across various settings would lend this reporting mechanism to larger group practices that are more likely to be multi-specialty practices (which are typically group practices consisting of more than 24 eligible professionals). The GPRO web interface was modeled after the CMS Physician Group Practice (PGP) demonstration, and this demonstration was originally intended for large group practices. From our experience with the PGP demonstration, we believe a group practice comprised of 25 eligible professionals is the smallest group practice that could benefit from use of the GPRO web interface as a reporting mechanism. We also do not believe that excluding group practices comprised of 2–24 eligible professionals from using the GPRO web interface as a reporting mechanism would harm these smaller group practices because we proposed to expand the reporting options for small group practices by proposing to allow groups composed of 2–99 eligible professionals to report using the claims, qualified registry, EHR, and administrative claims-based reporting mechanisms.

We proposed to provide group practices that are selected to participate in the GPRO using GPRO web interface reporting option with access to the GPRO web interface by no later than the first quarter of the year following the end of the reporting period under which the group practice intends to report (77 FR 44813). For example, for group practices selected for the GPRO for the 2013 incentive using the GPRO web interface tool, we proposed to provide group practices selected to participate in the GPRO with access to the GPRO web interface by no later than the first quarter of 2014 for purposes of reporting for the applicable 2013 reporting period for the incentive. In addition, we noted that if CMS encountered operational issues with the use of the GPRO web interface, we reserved the right to use a similar tool for group practices to use in lieu of reporting via the GPRO web interface.

We invited public comment on our proposed requirements for group practices using the GPRO web interface for 2013 and beyond. We received the following comment on these proposals:

Comment: One commenter supported our proposal to limit availability of the GPRO web interface to group practices of 25 or more eligible professionals and agreed with our reasoning.

Response: We appreciate with the commenter's feedback and, therefore, we are finalizing our proposal to limit the availability of the GPRO web interface to group practices comprised of 25 or more eligible professionals. In the future, CMS will try to develop ways by which smaller group practices could be able to use the GPRO web interface.

Based on the comments received, we are finalizing, as proposed, requirements for group practices using the GPRO web interface for 2013 and beyond. We are also modifying § 414.90(g)(3) and § 414.90(h)(3) to indicate that the GPRO web interface will be a reporting mechanism available for use by group practices for the PQRS incentives and payment adjustments.

Collection of GPRO Web interface Data via the NwHIN. The Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via the GPRO web interface through NwHIN. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we solicited public comment on collecting data via the GPRO web interface for PQRS via NwHIN. We received no public comment on this proposal. However, since we believe collecting data via the NwHIN would be premature, we are not finalizing any policy to collect data received via the GPRO web interface in the NwHIN.

e. Administrative Claims

For purposes of reporting for the 2015 and 2016 PQRS payment adjustments only, we proposed to modify § 414.90(h) to allow eligible professionals and group practices to use an administrative claims reporting mechanism (77 FR 45056). The administrative claims reporting mechanism builds off of the traditional PQRS claims-based reporting mechanism. Under the traditional PQRS claims-based reporting mechanism, eligible professionals and group practices wishing to report data on PQRS quality measures via claims for the incentives and for the payment adjustments must submit quality data codes (QDCs) on claims to CMS for analysis. Under the proposed administrative claims reporting mechanism, unlike the traditional claims-based reporting option, an eligible professional or group practice would not be required to submit QDCs on claims to CMS for analysis (77 FR 44813). Rather, CMS would analyze every eligible professional's or group practice's patient's Medicare claims to determine whether the eligible professional or group practice has performed any of the clinical quality actions indicated in the proposed PQRS quality measures in Table 63 of the CY 2013 PFS proposed rule. We proposed that, for purposes of assessing claims for quality measures under this option, all claims for services furnished that occur during the 2015 and/or 2016 PQRS payment adjustment reporting period would need to be processed by no later than 60 days after the end of the respective 2015 and 2016 payment adjustment reporting periods (that is, December 31, 2013 and December 31, 2014).

We invited public comment on our proposed requirements for using the administrative claims-based reporting mechanism for the 2015 and 2016 payment adjustments. The following is summary of the comments we received regarding these proposals.

Comment: Several commenters supported the addition of the administrative claims-based reporting mechanism for the 2015 and 2016 PQRS payment adjustments. The commenters noted that this addition of the administrative claims-based reporting mechanism would relieve the reporting burden on eligible professionals.

Response: We appreciate the commenters' feedback and are finalizing the administrative claims-based reporting mechanism for the 2015 payment adjustment. Since it is our intention that this reporting option be temporary, we will consider having the administrative claims-based reporting mechanism available for the 2016 PQRS payment adjustment in the future, but we are not finalizing our proposal to have the administrative claims-based reporting option for eligible professionals and group practices for the 2016 PQRS payment adjustment at this time. As participation in PQRS increases and eligible professionals and group practices become more familiar with the traditional claims, registry, direct EHR, EHR data submission vendor-based, or GPRO web interface reporting mechanisms, it is our intention to move away from use of the administrative claims-based reporting mechanism to allow for more proactive reporting by eligible professionals and group practices.

Comment: One commenter suggested that eligible professionals be allowed to choose the administrative claims-based reporting option to meet the criteria for satisfactory reporting for the 2013 and 2014 PQRS incentives.

Response: We respectfully disagree. We believe that eligible professionals and group practices should be required to use the traditional reporting mechanisms (claims, registry, EHR, or GPRO web interface) to report for the PQRS incentive as we believe that reporting via these traditional reporting mechanisms produce more meaningful data. As noted previously, while the administrative claims-based reporting mechanism still satisfies PQRS requirements by submitting quality measures data to CMS, we agree with other commenters that the administrative claims-based reporting option may not provide data that is as meaningful as data collected through other mechanisms. We are finalizing the addition of the administrative claims-based reporting option only as a means to report for the 2015 PQRS payment adjustments to ease eligible professionals into reporting PQRS measures. Since we see this option as temporary, only a limited set of measures were proposed for use under the administrative claims-based reporting option. We believe that more meaningful data will be collected using the traditional claims, registry, EHR, or GPRO web interface reporting mechanisms, where eligible professionals or group practices may choose measures from a broad set that may be more relevant to their practice. Therefore, eligible professionals will not be able to use the administrative claims-based reporting mechanism for the 2013 and 2014 PQRS incentives.

Based on the comments received, we are finalizing, as proposed, the administrative claims-based reporting mechanism for reporting for the 2015 payment adjustment only. We are not finalizing the administrative claims-based reporting mechanism for the 2016 PQRS payment adjustment, as we will revisit the necessity of having this reporting option available for the 2016 PQRS payment adjustment next year. We are modifying § 414.90(h)(2) and § 414.90(h)(3) to indicate that the administrative claims-based reporting mechanism is available for use by eligible professionals and group practices for the 2015 PQRS payment adjustment.

4. Criteria for Satisfactory Reporting for the 2013 and 2014 Incentives

For 2013 and 2014, in accordance with § 414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. This section contains the criteria for satisfactory reporting for the 2013 and 2014 incentives, which are the last two incentives authorized under the PQRS.

a. Criteria for Satisfactory Reporting for Individual Eligible Professionals

(1) Criteria for Satisfactory Reporting on Individual PQRS Quality Measures via Claims

According to the ''2010 Physician Quality Reporting System and eRx Reporting Experience and Trends,'' available for viewing in the ''downloads'' section of the main page the PQRS Web site (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*), reporting via the claims-based reporting mechanism was the most commonly used reporting method. We believe that this trend would continue, so we anticipated that, for the 2013 and 2014 incentives, the criteria for satisfactory reporting for the claims-based reporting mechanism would be the method most widely used by individual eligible professionals. So as not to change reporting criteria that a large number of individual eligible professionals are familiar with using, we established the same reporting criteria for the 2011 and 2012 incentives (76 FR 73330). Therefore, for the respective 12-month reporting periods for the 2013 and 2014 incentives, based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for

satisfactory reporting specified under the statute and our desire to maintain the same reporting criteria we established for individual eligible professionals for the 2012 PQRS incentive (76 FR 73330), we proposed the following criteria for satisfactory reporting of PQRS individual measures for individual eligible professionals using the claims-based reporting mechanism: Report at least 3 measures, OR, if less than 3 measures apply to the eligible professional, report 1–2 measures, AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies (77 FR 44813). Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 3 measures via the claims-based reporting mechanism, we proposed that the eligible professional be subject to the Measures Applicability Validation (MAV) process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. We felt the MAV process was necessary to review whether there are other closely related measures (such as those that share a common diagnosis or those that are representative of services typically provided by a particular type of eligible professional). Under the MAV process, if an eligible professional who reports on fewer than 3 measures reports on a measure that is part of an identified cluster of closely related measures, then the eligible professional would not qualify as a satisfactory reporter for the 2013 and/or 2014 incentives. We proposed this MAV process for the claims-based reporting mechanism only because it is more likely for EPs to report on more than 3 measures under the registry and EHR-based reporting mechanisms, as a registry or EHR product will typically automatically report on all measures that apply to the eligible professional's practice. We note that, consistent with section 1848(m)(3)(A)(i) of the Act, this proposed claims-based reporting criteria would be the only proposed criteria where an eligible professional could report on fewer than 3 measures.

We invited public comment on the proposed criteria for satisfactory reporting of individual measures by individual eligible professionals via claims for the 2013 and 2014 incentives. The following is a summary of the comment we received regarding these proposed criteria:

Comment: One commenter supported our proposed criteria for satisfactory reporting for individual eligible professionals via claims. The commenter stated that the 3-measure threshold allows small practices that participate individually treating multi-morbid patients to participate in PQRS.

Response: Based on the comments received and for the reasons stated previously, we are finalizing, as proposed, the criteria for satisfactory reporting for individual eligible professionals via claims for the 2013 and 2014 PQRS incentives. These criteria are specified in Tables 25 and 26 below.

(2) Criteria for Satisfactory Reporting on Individual PQRS Quality Measures via Registry

We note that section 1848(m)(3)(A)(ii) of the Act provides that, to meet the criteria for satisfactory reporting under PQRS, an eligible professional would be required to report on at least 3 measures for at least 80 percent of the cases in which the respective measure is reportable under the system. Although we have the authority under section 1848(m)(3)(D) of the Act to revise the criteria for satisfactory reporting, for registry-based reporting, we have largely followed these reporting criteria for the PQRS incentives. According to the ''2010 Physician Quality Reporting System and eRx Reporting Experience and Trends,'' eligible professionals are more likely to meet the requirements for a PQRS incentive using the satisfactory reporting criteria for the registry-based reporting mechanism than claims. In fact, in 2010, approximately 87 percent of the eligible professionals reporting individual PQRS quality measures via registry were eligible and met the criteria for satisfactory reporting for the 2010 incentive. Since eligible professionals have had success with using these satisfactory reporting criteria, we believe such criteria are appropriate and see no reason to change the criteria for satisfactory reporting via registry that has been in place since 2010. Therefore, for those reasons and our desire to maintain the same reporting criteria we established for individual eligible professionals for the 2012 PQRS incentive (76 FR 73331), we proposed the following criteria for satisfactory reporting of PQRS individual measures for individual eligible professionals using the registry-based reporting mechanism for the 12-month reporting periods for the 2013 and 2014 incentives, respectively: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies (77 FR 44814). Measures with a zero percent performance rate will not be counted.

We invited but received no public comment on the proposed criteria for satisfactory reporting of individual measures by individual eligible professionals via a registry for the 2013 and 2014 incentives. Therefore, we are finalizing these criteria as proposed. These criteria are specified in Tables 25 and 26 below.

(3) Criteria for Satisfactory Reporting on Individual PQRS Quality Measures via EHR

Satisfactory Reporting Criteria of Individual PQRS Quality Measures via EHR for the 2013 PQRS Incentive. As stated previously, section 1848(m)(7) of the Act requires us to develop a plan to integrate reporting requirements for PQRS and the EHR Incentive Program. Therefore, for EHR-based reporting, it is our main goal to align our EHR reporting requirements with the reporting requirements an eligible professional must meet to satisfy the clinical quality measure (CQM) component of meaningful use (MU) under the EHR Incentive Program. To align with the EHR Incentive Program, we based our proposals on the EHR Incentive Program—Stage 2 NPRM (77 FR 13698). Also to align with the EHR Incentive Program, for the EHR reporting periods in CY 2013, we proposed (77 FR 13745) to continue the CQM reporting requirements that were established for eligible professionals for CYs 2011 and 2012 in the EHR Incentive Program—Stage 1 final rule (75 FR 44398–44411). Therefore, to align with the reporting requirements for meeting the CQM component of meaningful use, and based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting identified under the statute, we proposed the following criteria for the 12-month reporting period for the 2013 incentive (77 FR 44814):

- As required by the Stage 1 final rule, eligible professionals must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program's core, alternate core, and additional measures can be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of the CY 2013 PFS proposed rule. We referred readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those CQMs (75 FR 44398 through 44411).

Under this proposal, eligible professionals using these reporting

criteria would be required to report on 6 measures. For the proposed PQRS EHR measures that are also Medicare EHR Incentive Program core, alternate core, or additional measures that the eligible professional reports (75 FR 44398 through 44411), an eligible professional would be required to report the applicable measure for 100 percent of the eligible professionals Medicare Part B FFS patients.

In addition, we noted that section 1848(m)(3)(A)(ii) of the Act provides that, to meet the criteria for satisfactory reporting under PQRS, an eligible professional would be required to report on at least 3 measures for at least 80 percent of the cases in which the respective measure is reportable under the system. Although we have the authority under section 1848(m)(3)(D) of the Act to revise the criteria for satisfactory reporting, for EHR-based reporting, we noted that we have largely kept these reporting criteria for the 2010–2012 incentives. As some eligible professionals succeeded with these criteria, we proposed the following similar criteria for the 12-month reporting period for the 2013 incentive: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies (77 FR 44814). Measures with a zero percent performance rate will not be counted.

We received no public comment on the satisfactory reporting criterion we proposed for individual PQRS measures using a direct EHR or EHR data submission vendor product for the 2013 PQRS incentive: Report at least 3 measures for at least 80 percent of the cases in which the respective measure is reportable under the system. Therefore, for the reasons previously stated, we are finalizing the criterion.

We invited public comment on the proposed criteria for the satisfactory reporting of individual PQRS measures using a direct EHR or EHR data submission vendor product for the 2013 PQRS incentive. The following is a summary of those comments.

Comment: Several commenters generally supported our proposals to align the EHR reporting criteria with the criteria established for meeting the CQM component of achieving meaningful use under the EHR Incentive Program.

Response: We appreciate the commenters' positive feedback.

Comment: Several commenters supported our proposed criteria for the satisfactory reporting of PQRS measures via direct EHR or EHR data submission vendor products for the 2013 PQRS incentive, as the proposed criteria aligns with the CQM criteria of meaningful use for the EHR Incentive Program.

Response: We appreciate the commenters' feedback. Based on the support received for this proposed criterion and for the reasons we discussed above, we are finalizing the following criterion for the satisfactory reporting of individual PQRS measures using a direct EHR or EHR data submission vendor product for the 2013 PQRS incentive: As required by the Stage 1 final rule, eligible professionals must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program's core, alternate core, and additional measures can be found in Tables 6 and 7 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398 through 44411) or in Table 95 of this section. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those CQMs (75 FR 44398 through 44411).

Comment: Several commenters encouraged us to accept the reporting of measures with a zero percent performance rate using the EHR-based satisfactory reporting criteria that aligns with the EHR Incentive Program. Under Stage 1, many of the core and alternate core measures are not applicable to specialties. The commenter believes that allowing the reporting of measures with a zero percent performance rate will achieve our goal of having eligible professionals report one set of data for PQRS and the EHR Incentive Program.

Response: We understand the commenter's concerns. We have stressed the importance of collecting data that is applicable to the eligible professional's practice. Therefore, or PQRS, we are only concerned with the reporting of measures that are relevant to an eligible professional's practice. An eligible professional may still report on the same number of measures he/she is reporting for the EHR Incentive Program. However, for purposes of PQRS, we will only analyze the measures that are applicable to the eligible professional's practice. If using this reporting criterion, an eligible professional should be able to report on at least one applicable measure.

Satisfactory Reporting Criteria of Individual PQRS Quality Measures via EHR for the 2014 PQRS Incentive. At the time of the CY 2013 PFS proposed rule, we noted that we had proposed under the Medicare EHR Incentive Program options for meeting the CQM component of achieving meaningful use beginning with CY 2014 (77 FR 13746—13748). To align our EHR-based reporting requirements with those proposed under the Medicare EHR Incentive Program, we proposed the following criteria for satisfactory reporting using the EHR-based reporting mechanism for the 12-month reporting period for the 2014 incentive:

- Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33 of the proposed rule, including at least 1 measure from each of the following 6 domains—(1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness.
- Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Table 95 plus 1 menu clinical quality measure from Tables 32 and 33 of the proposed rule. We noted it was our intention to finalize the reporting criteria that aligns with the criteria that would be established for meeting the CQM component of meaningful use beginning with CY 2014 for the Medicare EHR Incentive Program. Furthermore, to the extent that the final criteria for meeting the CQM component of achieving meaningful use differ from what was proposed, we noted that our intention was to align with the reporting criteria the EHR Incentive Program ultimately established (77 FR 44814). Therefore, eligible professionals who participate in both PQRS and the EHR Incentive Program would be able to use one reporting criterion, during overlapping reporting periods, to satisfy the satisfactory reporting criteria under PQRS and the CQM component of meaningful use under the Medicare EHR Incentive Program.

In addition to this proposed criterion, we had proposed under the Medicare EHR Incentive Program that, beginning with CY 2014, eligible professionals who participate in both the Physician Quality Reporting System and the Medicare EHR Incentive Program may satisfy the CQM component of meaningful use if they submit and satisfactorily report PQRS clinical quality measures under the PQRS EHR reporting option using Certified EHR Technology (77 FR 13748). Since this language suggested that the Medicare EHR Incentive Program may defer to the satisfactory reporting criteria for the EHR-based reporting mechanism that we will establish for 2014, we proposed the following reporting criteria for the 12-month reporting period for the 2014 incentive that largely conform to the criteria set forth under section

1848(m)(3)(A)(ii) of the Act that we established for the 2012 incentive and that we proposed for the 2013 incentive: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

We received no comments regarding the following proposed criteria using a direct EHR or EHR data submission vendor product for the 2014 incentive: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. However, in an effort to streamline reporting requirements for the 2014 PQRS incentives, we only wish to finalize one reporting criterion to meet the criteria for satisfactory reporting for the 2014 PQRS incentive using an EHR-based reporting mechanism. Therefore, since the EHR Incentive Program did not finalize this proposed reporting criterion, we are not finalizing this proposed criterion. We understand that not finalizing this criterion would eliminate a reporting option previously available to eligible professionals. We note however, that this EHR-based reporting criterion was not widely used by eligible professionals. In fact, according to the 2010 PQRS and eRx Experience Report, less than 1% of eligible professionals participating in PQRS did so using the EHR-based reporting mechanism. Therefore, we do not believe eligible professionals will be harmed by our decision not to finalize this criterion. Furthermore, we believe that eligible professionals that have used the EHR-based reporting mechanism in the past will gravitate towards using reporting criterion that aligns with the EHR Incentive Program, as eligible professionals using aligned criterion will have the ability to submit one set of quality measures data to achieve the requirements under both PQRS and the EHR Incentive Program. Nonetheless, we are streamlining the criteria in 2014, and not 2013, in order to give eligible professionals an additional year to adjust their practice workflows to account for this change.

We invited public comment on the proposed criteria for satisfactory reporting on PQRS measures via EHR for the 2014 PQRS incentive that were proposed under the EHR Incentive Program for 2014. The following is summary of the comments we received regarding these proposals.

Comment: Several commenters generally supported our proposals to align the EHR reporting criteria with the criteria established for meeting the CQM component of achieving meaningful use under the EHR Incentive Program.

Response: We appreciate the commenters' positive feedback.

Comment: Some commenters suggested an alternative criterion for the satisfactory reporting of individual PQRS measures via EHR: For the 2014 PQRS incentive, report six measures, covering at least two domains. If no individual measures available for EHR-based reporting are relevant to the eligible professional, the eligible professional may submit measures with a zero percent performance rate.

Response: We appreciate the commenter's suggestion. However, as previously stated, it is our intention to adopt satisfactory reporting criteria that closely aligns with the criteria established for achieving meaningful use for the EHR Incentive Program. Since the alternative criterion proposed by the commenter does not align with the criteria established for the EHR Incentive Program, we respectfully decline to establish this alternative criterion for the satisfactory reporting of individual measures via EHR for the 2014 PQRS incentive.

Comment: For the proposed option 1a for EHR-based reporting for the 2014 PQRS incentive, one commenter believed that the requirement to report 12 CQMs is too high. The commenter believed that because many measures are focused towards primary care and preventive medicine, it may be difficult for sub-specialists to meet the 12 CQM threshold, leading these eligible professionals to potentially report a zero percent performance rate on most measures. Commenters were also concerned that the proposal to report at least 1 measure from each of the six proposed domains would add to difficulty in reporting, as some of the domains have limited measure sets.

Response: We understand and agree with the commenter's arguments against option 1a. Indeed, the EHR Incentive Program did not finalize these criteria for reporting CQMs to achieve meaningful use under the EHR Incentive Program. Therefore, we are not finalizing this proposal for the PQRS.

Comment: For the proposed option 1b for EHR-based reporting for the 2014 PQRS incentive, one commenter believed that the requirement to report 12 CQMs is too high. Because many measures are focused towards primary care and preventive medicine, the commenter was concerned that it may be difficult for sub-specialists to meet the 12 CQM threshold, leading these eligible professionals to potentially report a zero percent performance rate on most measures. Commenters also believed that the additional proposed requirement to reporting on 11 core CQM measures may have the negative consequence of forcing eligible professionals to report on measures that are not fully relevant to their respective practice, as there may not be 12 CQMs relevant to their practice.

Response: We understand and agree with the commenter's arguments against option 1b. Indeed, the EHR Incentive Program did not finalize these criteria for reporting CQMs to achieve meaningful use under the EHR Incentive Program. Therefore, we are not finalizing this proposal for the PQRS.

Comment: Several commenters encouraged us to accept the reporting of measures with a zero percent performance rate using the EHR-based satisfactory reporting criteria that aligns with the EHR Incentive Program. The commenter believes that allowing the reporting of measures with a zero percent performance rate will achieve our goal of having eligible professionals report one set of data for PQRS and the EHR Incentive Program.

Response: We understand the commenter's concerns. For PQRS, we are only concerned with the reporting of measures that are relevant to an eligible professional's practice. Therefore, we will only analyze the measures for which there is Medicare patient data.

We note that, despite this distinction in the way the eligible professional's submitted data is analyzed, we are still achieving our goal of aligning the criteria for satisfactory reporting under PQRS with the criteria for meeting the CQM component of achieving meaningful use under the EHR Incentive Program. Eligible professionals will still be able to report the same set of data in the same form and manner to satisfy the requirements for both programs. The only distinction lies in the analysis performed by the two programs. For example, let's pretend an eligible professional, in 2014, uses CEHRT to report 9 measures covering 3 domains, and only 1 measure applies to the eligible professional's practice (that is, the eligible professional has patients that are eligible for inclusion in only 1 measure's denominator). The eligible professional will have met the criteria for meeting the CQM component of achieving meaningful use in 2014, because the eligible professional would have reported 9 measures covering at least 3 domains and reported the measures (1 measure, in this example) for which there is patient data and the remaining required measures as ''zero denominators'' as displayed by the

eligible professional's CEHRT. The eligible professional will have also met the criteria for satisfactory reporting under PQRS for the 2014 PQRS incentive, because we will assume that by receiving data for only 1 measure with a denominator greater than zero that the eligible professional did not have any other applicable measures on which to report.

We understand that there may be instances where no measures apply to an eligible professional. For those eligible professionals for which no measures available for reporting used the EHR-based reporting mechanisms apply, for 2014, we strongly encourage those eligible professionals to meet the criteria for satisfactory reporting using an alternative reporting option.

Based on the comments received and for the reasons we stated above, we are finalizing the following criteria for satisfactory reporting of individual PQRS measures using direct EHR or EHR data submission vendor products for the 2014 PQRS incentive: Report 9 measures covering at least 3 domains, as specified in Table 95. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is patient data.

We note that the EHR Incentive Program established the requirements, should an eligible professional's CEHRT not contain patient data for at least 9 measures covering at least 3 domains, the eligible professional must report the measures for which there is patient data and report the remaining required measures as ''zero denominators'' as displayed by the eligible professional's CEHRT. If there are no measures applicable to the eligible professional's scope of practice and patient population, eligible professionals must still report 9 measures even if zero is the result in either the numerator or denominator of the measure. If all applicable measures have a value of zero from their CEHRT, then eligible professional must report any 9 measures (77 FR 54058). For PQRS, we are only concerned with the reporting of measures that are relevant to an eligible professional's practice. Therefore, we are not accepting the reporting of ''zero denominators.'' Therefore, to meet the criteria for satisfactory reporting for the 2014 PQRS incentive using this criterion, an eligible professional must report on at least 1 applicable measure (that is, at least 1 of the 9 measures that the eligible professional reports using an EHR-based reporting mechanism must not have a ''zero denominator'').

(4) Criteria for Satisfactory Reporting on PQRS Measures Groups via Claims

In the CY 2012 Medicare PFS final rule, we established the following criteria for satisfactorily reporting PQRS measures groups for the 12-month reporting period for the 2012 incentive (76 FR 73335):

- Report at least 1 PQRS measures group, AND report each measures group for at least 30 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted; OR
- Report at least 1 PQRS measures group, AND report each measures group for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT report each measures group on no less than 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0 percent performance rate will not be counted.

We received stakeholder feedback that it is difficult for some specialties to meet the 30 Medicare Part B FFS patient threshold. Therefore, based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting, we proposed the following criteria for the satisfactorily reporting PQRS measures groups for individual eligible professionals using the claims-based reporting mechanism for the 12-month reporting periods for the 2013 and 2014 incentives: Report at least 1 measures group AND report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a zero percent performance rate will not be counted (77 FR 44815).

We invited public comment on the proposed criterion for satisfactory reporting of measures groups via claims for the 2013 and 2014 incentives. The following is summary of the comments we received regarding this proposal.

Comment: Several commenters supported our proposal to lower the minimum patient count for reporting measures groups from 30 to 20. Commenters noted that lowering the reporting threshold would ease the reporting burden of reporting measures groups for eligible professionals.

Response: We appreciate the commenters' feedback and are finalizing our proposed criteria for individual eligible professionals reporting measures groups via claims for the 2013 and 2014 PQRS incentives. The criteria are specified in Tables 25 and 26 below.

(5) Criteria for Satisfactory Reporting on PQRS Measures Groups via Registry

In the CY 2012 Medicare PFS final rule, we established the following criteria for satisfactorily reporting PQRS measures groups for the 12-month reporting period for the 2012 incentive (76 FR 73337):

- Report at least 1 PQRS measures group AND report each measures group for at least 30 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted; OR
- Report at least 1 PQRS measures group, AND report each measures group for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT report each measures group on no less than 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0 percent performance rate will not be counted.

In addition, we established the following criteria for satisfactorily reporting PQRS measures groups for the 6-month reporting period for the 2012 incentive (76 FR 73337): Report at least 1 PQRS measures group, AND report each measures group for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT report each measures group on no less than 8 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0 percent performance rate will not be counted.

We received stakeholder feedback that it is difficult for some specialties to meet the 30 Medicare Part B FFS patient threshold. Therefore, based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting, we proposed the following criteria for satisfactory reporting of PQRS measures groups for individual eligible professionals using the registry-based reporting mechanism for the 2013 and 2014 incentives:

(1) For the 12-month reporting periods for the respective 2013 and 2014 incentives, report at least 1 measures group, AND report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate would not be counted.

(2) For the 6-month reporting period for the respective 2013 and 2014

incentives, report at least 1 measures group, AND report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures group containing a measure with a zero percent performance rate will not be counted. We noted that this is the same criterion established for the 12-month reporting period. We proposed the same criterion for both reporting periods in an effort to simplify the reporting criteria for satisfactory reporting (77 FR 44815).

We noted that, while we still proposed to require that an eligible professional report on at least 20 patients, we understood that a patient's personal identification information may be stripped when data is collected via a qualified registry. Therefore, we understood that it may be difficult to distinguish Medicare and non-Medicare patients. Given this difficulty and that the eligible professionals generally would be attempting to report data on Medicare patients, we felt the reporting of some non-Medicare patients could serve as a proxy for the reporting of Medicare patients whose data is not easily distinguishable as data on Medicare patients under this reporting mechanism.

Finally, we noted that our proposals would satisfy the requirement under section 1848(m)(5)(F) of the Act that we provide for alternative reporting periods and criteria for satisfactory reporting with regard to measures groups and registry-based reporting.

We invited public comment on the proposed criteria for satisfactory reporting of measures groups by individual eligible professionals via registry for the 2013 and 2014 incentives. The following is summary of the comments we received regarding these proposals.

Comment: One commenter opposed our proposed satisfactory reporting criteria for reporting measures groups via registry for the 6-month reporting period for the 2013 and/or 2014 PQRS incentives because the commenter was concerned that eligible professionals who are satisfactory reporters using this criteria would only receive half the allowed amount for the 2013 and/or 2014 PQRS incentives.

Response: We appreciate the commenter's feedback. Please note that all eligible professionals who satisfactorily report PQRS measures under the criteria for satisfactory reporting via registry for the 6-month reporting period for the 2013 and/or 2014 PQRS incentives will receive the 2013 and/or 2014 incentive of 0.5% of our estimate of the group practice's PFS allowed charges furnished during the applicable reporting period. Therefore, an eligible professional would earn the same incentive amount regardless of which reporting period the eligible professional chooses to use. In an effort to streamline our criteria for satisfactory reporting, this satisfactory reporting criterion is identical to the satisfactory reporting criterion for the 12-month reporting period.

Comment: Several commenters supported our proposal to lower the minimum patient count for reporting measures groups from 30 to 20. Commenters noted that lowering the reporting threshold would ease the reporting burden of reporting measures groups for eligible professionals. Several commenters also supported our proposal to allow for the reporting of data on non-Medicare patients.

Response: We appreciate the commenters' feedback and are finalizing, as proposed, the criteria for satisfactory reporting of measures groups by individual eligible professionals via registry for the 2013 and 2014 incentives. We note that, with respect to the requirement that an eligible professional report on at least a majority (11) of the 20 patients on which the eligible professionals report, to the extent that an eligible professional reports on more than 20 patients, for purposes of the 2013 and 2014 PQRS incentives, an eligible professional need only ensure that he/she has reported on 11 Medicare patients.

Tables 90 and 91 provide a summary of the final criteria for the satisfactory reporting of PQRS quality measures for the 2013 and 2014 incentives.

TABLE 90—SUMMARY OF CRITERIA FOR SATISFACTORY REPORTING BY INDIVIDUAL ELIGIBLE PROFESSIONALS OF DATA ON PQRS QUALITY MEASURES FOR THE 2013 INCENTIVE

Reporting period	Measure type	Reporting mechanism	Proposed reporting criteria
Jan 1, 2013–Dec 31, 2013*.	Individual Measures ...	Claims	Report at least 3 measures, OR, If less than 3 measures apply to the eligible professional, report 1–2 measures*; AND Report each measure for at least 50 percent of the eligible professio al's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2013–Dec 31, 2013.	Individual Measures ...	Qualified Registry	Report at least 3 measures, AND Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2013–Dec 31, 2013.	Individual Measures ...	Qualified Direct EHR Product.	Option 1: Report on ALL three PQRS EHR measures that are also Medicare EHR Incentive Program core measures. If the denominator for one or more of the Medicare EHR Incentive Program core measures is 0, report on up to three PQRS EHR measures that are also Medicare EHR Incentive Program alternate core measures; AND Report on three additional PQRS EHR measures that are also measures available for the Medicare EHR Incentive Program. Option 2: Report at least 3 measures, AND Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.

TABLE 90—SUMMARY OF CRITERIA FOR SATISFACTORY REPORTING BY INDIVIDUAL ELIGIBLE PROFESSIONALS OF DATA ON PQRS QUALITY MEASURES FOR THE 2013 INCENTIVE—Continued

Reporting period	Measure type	Reporting mechanism	Proposed reporting criteria
Jan 1, 2013–Dec 31, 2013.	Individual Measures ...	Qualified EHR Data Submission Vendor.	Option 1: Report on ALL three PQRS EHR measures that are also Medicare EHR Incentive Program core measures. If the denominator for one or more of the Medicare EHR Incentive Program core measures is 0, report on up to three PQRS EHR measures that are also Medicare EHR Incentive Program alternate core measures; AND Report on three additional PQRS EHR measures that are also measures available for the Medicare EHR Incentive Program. Option 2: Report at least 3 measures, AND Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2013–Dec 31, 2013.	Measures Groups	Claims	Report at least 1 measures group, AND Report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
Jan 1, 2013–Dec 31, 2013.	Measures Groups	Qualified Registry	Report at least 1 measures group, AND Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
Jul 1, 2013–Dec 31, 2013.	Measures Groups	Qualified Registry	Report at least 1 measures group, AND Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

* Subject to the measure applicability validation (MAV) process.

TABLE 91—SUMMARY OF CRITERIA FOR SATISFACTORY REPORTING BY INDIVIDUAL ELIGIBLE PROFESSIONALS OF DATA ON PQRS QUALITY MEASURES FOR THE 2014 INCENTIVE

Reporting period	Measure type	Reporting mechanism	Proposed reporting criteria
Jan 1, 2014–Dec 31, 2014*.	Individual Measures ...	Claims	Report at least 3 measures, OR, If less than 3 measures apply to the eligible professional, report 1–2 measures*; AND Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2014–Dec 31, 2014.	Individual Measures ...	Qualified Registry	Report at least 3 measures, AND Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2014–Dec 31, 2014.	Individual Measures ...	Direct EHR product that is CEHRT.	Report 9 measures covering at least 3 domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is patient data.
Jan 1, 2014–Dec 31, 2014.	Individual Measures ...	EHR data submission vendor's product that is CEHRT.	Report 9 measures covering at least 3 domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is patient data.
Jan 1, 2014–Dec 31, 2014.	Measures Groups	Claims	Report at least 1 measures group, AND Report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
Jan 1, 2014–Dec 31, 2014.	Measures Groups	Qualified Registry	Report at least 1 measures group, AND Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
Jul 1, 2014–Dec 31, 2014.	Measures Groups	Qualified Registry	Report at least 1 measures group, AND Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients.

TABLE 91—SUMMARY OF CRITERIA FOR SATISFACTORY REPORTING BY INDIVIDUAL ELIGIBLE PROFESSIONALS OF DATA ON PQRS QUALITY MEASURES FOR THE 2014 INCENTIVE—Continued

Reporting period	Measure type	Reporting mechanism	Proposed reporting criteria
			Measures groups containing a measure with a 0 percent performance rate will not be counted.

* Subject to the measure applicability validation (MAV) process.

b. Criteria for Satisfactory Reporting for Group Practices Participating in the GPRO

This section addresses the criteria for satisfactory reporting for group practices participating in the GPRO for the 2013 and 2014 incentives, which are the last two incentives authorized under the Physician Quality Reporting System. Please note that, in addition to offering the GPRO web interface that we've previously included under the program, we proposed new criteria for group practices under the GPRO that allow group practices to use the claims, registry, and EHR-based reporting mechanisms (77 FR 44819). In prior program years, large group practices have been successful in reporting quality measures data via the GPRO web interface. We proposed new criteria under the claims, qualified registry, and EHR-based reporting mechanisms because we felt that smaller groups may benefit from different reporting criteria and also other reporting mechanisms. Since the introduction of smaller group practices composed of 25–99 eligible professionals under the GPRO was fairly recent, and given that we proposed to modify the definition for group practice such that the PQRS GPRO would include, beginning in 2013, group practices composed of 2–24 eligible professionals, we proposed additional criteria for reporting because we felt it might be more practicable for smaller group practices to report on PQRS quality measures via claims, qualified registry, or direct EHR or EHR data submission vendor versus the GPRO web interface, which was designed for use by larger group practices.

(1) Beneficiary Assignment Methodology and Criteria for Satisfactory Reporting on PQRS Quality Measures via the GPRO Web Interface

GPRO Beneficiary Assignment Methodology. To populate the GPRO web interface, we must first assign beneficiaries to each group practice and then from those assigned beneficiaries draw a sample of beneficiaries for the disease and patient care modules in the GPRO web interface.

In the proposed rule we discussed how we are assigning beneficiaries in 2012 to group practices for purposes of reporting on the PQRS quality measures via the GPRO web interface. We proposed to continue using this same assignment methodology for 2013 and subsequent years because it is already in place operationally.

However, as an alternative way to assign beneficiaries to groups for the GPRO web interface, in the proposed rule we also discussed and invited comments on using the assignment and sampling methodology utilized under the more recently implemented Medicare Shared Savings Program (76 FR 6700). The Medicare Shared Savings Program uses an approach that is generally similar to and is based on the approach previously used by the PGP Transition demonstration, but that was revised to reflect both our experiences under the demonstration and specific statutory requirements for the Medicare Shared Savings Program. In particular, the attribution method used by the Medicare Shared Savings Program emphasizes primary care services furnished by physicians. More information regarding the assignment methodology that is used in the Shared Savings Program can be found on the program Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/*. To more closely align with the Medicare Shared Savings Program, we invited comments on whether it would be preferable to modify the assignment method PQRS uses to assign beneficiaries to a group practice to be more consistent with the two-step assignment method specified in § 425.402 that is used under the Medicare Shared Savings Program to assign beneficiaries to an ACO.

Consistent with that two-step methodology, in order for a beneficiary to be eligible for assignment to a group practice, the beneficiary must have received at least one primary care service from a physician within the group practice during the reporting period. Accordingly, we would identify beneficiaries who received at least one primary care service from any group practice physician (regardless of specialty) participating in the group practice during the reporting period. Under the first assignment step, we would assign the beneficiary to the group practice if the beneficiary had at least one primary care service furnished by a primary care physician at the participating group practice, and more primary care services (measured by Medicare allowed charges) furnished by primary care physicians in the participating group practice than furnished by primary care physicians at any other group or solo practice.

The second step applies only for those beneficiaries who do not receive any primary care services from a primary care physician during the reporting period. We would assign the beneficiary to the participating group practice in this step if the beneficiary had at least one primary care service furnished by a group practice physician regardless of specialty, and more primary care services were furnished by group practice eligible professionals (measured by Medicare allowed charges) at the participating group practice than at any other group or solo practice We would then pull samples of beneficiaries for the relevant measures/modules from this population of assigned beneficiaries to populate the GPRO web interface. In other words, the GPRO web interface would be populated based on a sample of the group practice assigned beneficiary population. Group practices would need to complete the tool for the first 411 or 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each domain, measures set, or individual measure if a separate denominator is required such as in the case of preventive care measures which may be specific to one sex. If the pool of eligible assigned beneficiaries is less than 411 or 218, the group practice would report on 100 percent of assigned beneficiaries for the domain, measure set, or individual measure. The GPRO web interface would need to be completed for all domains, measure sets, and measures described in Table 96.

We considered making this change to the assignment method beginning with the 2013 PQRS GPRO web interface so that the rules used to assign

beneficiaries to group practices participating in PQRS and ACOs participating in the Medicare Shared Savings Program would be more consistent. Since both group practices that are participating in the PQRS GPRO and ACOs participating in the Medicare Shared Savings Program would be using the same GPRO web interface to report the same set of quality measures to CMS, we believe that applying consistent assignment methods across the two programs would allow us to streamline our processes and could potentially reduce confusion among group practices considering participation in the PQRS GPRO or ACOs considering participation in the Medicare Shared Savings Program.

We invited public comment whether to continue to use the PQRS-established methodology for assigning beneficiaries, or, in the alternative, to use the assignment and sampling methodology utilized under the Medicare Shared Savings Program. The following is summary of the comments we received regarding these proposals.

Comment: One commenter supported our proposal to continue the assignment and sampling methodology currently being used to populate the GPRO web interface. However, another commenter urged CMS to adopt an assignment and sampling methodology that is more focused on primary care, as the commenter believes that medical colleges participating in the GPRO will experience more success in reporting via the GPRO web interface with this change.

Response: We appreciate the commenters' feedback. We appreciate the commenters' feedback. In an effort to align with the Medicare Shared Savings Program, we are adopting the beneficiary assignment and sampling methodology used under the Medicare Shared Savings Program, which, unlike the current methodology to populate the GPRO web interface, requires that the beneficiary being assigned had at least one primary care service furnished by a group practice physician. We understand that as a result of this requirement, there could be some group practices (such as groups consisting only of non-physician practitioners) that would not be able to report PQRS quality measures using the GPRO web interface because no beneficiaries would be assigned to them. However, we do not expect this would affect many group practices reporting PQRS quality measures using the GPRO web interface. We offer a number of other options for participating in PQRS. We note that the assignment and sampling methodology does not depart drastically from the assignment and sampling methodology currently used to populate the GPRO web interface as both methods were based off of the assignment and sampling methodology used under the PGP demonstration. Therefore, we are modifying 414.1240 to reflect the final decision to apply the same assignment and sampling methodology as is currently used under the Medicare Shared Savings Program.

Criteria for Satisfactory Reporting on PQRS Quality Measures via the GPRO Web interface. Consistent with the group practice reporting requirements under section 1848(m)(3)(C) of the Act, we proposed the following criteria for the satisfactory reporting of PQRS quality measures for group practices participating- in the GPRO for the 12-month reporting periods for the 2013 and 2014 incentives, respectively, using the GPRO web interface for groups practices of 25–99 eligible professionals: Report on all measures included in the web interface; AND populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each disease module or preventive care measure (77 FR 44820). If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology CMS provides will not be able to assign at least 218 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 eligible professionals. If the group practice is assigned less than 218 Medicare beneficiaries, then the group practice would report on 100 percent of its assigned beneficiaries. In addition, we proposed the following criteria for the satisfactory reporting of PQRS quality measures for group practices participating in the GPRO for the 2013 and 2014 incentives, respectively, using group practices of 100 or more eligible professionals: Report on all measures included in the web interface; AND populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each disease module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries.

The satisfactory reporting criteria we proposed for the GPRO web interface for groups of 25–99 eligible professionals and for large group practices for the 2013 and 2014 incentives were consistent with the reporting criteria we established for the 2012 PQRS incentive (76 FR 73339). We proposed these same criteria because the thresholds proposed for these criteria were based on analysis performed on group reporting based on the Medicare Care Management Performance (MCMP) and PGP demonstrations used to determine reasonable thresholds for group practice reporting. We also note that there are the same criteria used for ACOs participating in the Medicare Shared Savings Program. Therefore, we believed the satisfactory reporting criteria that for the GPRO web interface for the 2013 and 2014 incentives were appropriate criteria and reasonable for groups to meet.

Furthermore, we proposed using Medicare Part B claims data for dates of service on or after January 1 and submitted and processed by approximately the last Friday in October of the applicable 12-month reporting period under which the group practice participates in the GPRO to assign Medicare beneficiaries to each group practice. For example, for a group practice participating under the GPRO for the reporting periods occurring in 2013, for the sampling model, we proposed that we would assign beneficiaries on which to report based on Medicare Part B claims with dates of service beginning January 1, 2013 and processed by October 25, 2013 (77 FR 44820).

We invited but received no public comment on the proposed satisfactory reporting criteria on PQRS quality measures via the GPRO web interface. Therefore, we are finalizing these proposals as proposed. These criteria are specified in Tables 27 and 28.

(2) Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Participating in the GPRO via Claims, Registry, and EHR

We proposed to have the claims, registry, and EHR reporting mechanisms available for group practices of 2–99 eligible professionals to use to report PQRS quality measures (77 FR 44820). For these group practices, we proposed alternative criteria to those proposed under the GPRO web interface for satisfactory reporting for the 2013 and 2014 incentives using the claims, registry, and EHR-based reporting mechanisms that mirror the criteria we proposed for individual reporting for the claims, registry, and EHR-based reporting mechanisms from the 2013 and 2014 incentives. We noted that the criteria we proposed for the 2013 and 2014 incentives using the claims, registry, and EHR-based reporting mechanisms are similar to the criteria

for individual reporting, because we believe smaller group practices are more akin to individuals for practice scope. We believed that the larger the group practice, the more likely that the group practice would benefit using the reporting options under the GPRO web interface.

Therefore, based on our authority under section 1848(m)(3)(C) of the Act, we proposed the following satisfactory reporting criteria via claims for group practices comprised of 2–99 eligible professionals under the GPRO for the 2013 and 2014 incentives via claims: Report at least 3 measures AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

For those group practices that chose to report using a qualified registry, we proposed the following satisfactory reporting criteria via qualified registry for group practices comprised of 2–99 eligible professionals under the GPRO for the 2013 and 2014 incentives: Report at least 3 measures AND report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

For group practices comprised of 2–99 eligible professionals that chose to report PQRS quality measures via EHR, we proposed the following 2 options for the satisfactory reporting criteria via a direct EHR product or EHR data submission vendor for group practices comprised of 2–99 eligible professionals under the GPRO for the 2013 incentive:

Option 1: Eligible professionals in a group practice must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. We noted that the EHR Incentive Program's core, alternate core, and additional measures could be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of the proposed rule (77 FR 44821). We also referred readers to the discussion in the Stage 1 final rule for further explanation of the requirements for eligible professionals reporting those CQMs (75 FR 44398 through 44411).

Option 2: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

We noted that at the time of the CY 2013 PFS proposed rule, that we had proposed under the Medicare EHR Incentive Program 2 options for meeting the CQM component of achieving meaningful use beginning with CY 2014 (see 77 FR 13746–13748). To align our EHR-based reporting requirements with those proposed under the Medicare EHR Incentive Program at the time, we proposed the following criteria for satisfactory reporting using the EHR-based reporting mechanism for the 12-month reporting period for the 2014 incentive:

- *Option 1a:* Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains—(1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness (77 FR 44821).
- *Option 1b:* Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33 of the proposed rule plus 1 menu clinical quality measure from Tables 32 and 33 of the proposed rule. We proposed to adopt the group reporting criteria that aligns with the criteria that would be established for meeting the CQM component under CY 2014 for the Medicare EHR Incentive Program. Furthermore, to the extent that the final group reporting criteria for meeting the CQM component of achieving meaningful use differ from what was proposed, our intention was to align with the group reporting criteria the EHR Incentive Program ultimately established. We invited public comment on this proposal.

We also considered proposing the following satisfactory reporting criteria for the 2014 PQRS incentive for groups of 2–99 that was similar to the satisfactory reporting criteria being proposed for the 2013 PQRS incentive via EHR: report at least 3 measures, AND report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted (77 FR 44821). We invited public comment on this alternative considered.

We invited public comment on the proposed criteria for satisfactory reporting of individual measures by group practices via claims, registry, or EHR for the 2013 and 2014 incentives. The following is a summary of general comments we received.

Comment: Several commenters supported our proposal to expand the reporting mechanisms and satisfactory reporting criteria for group practices participating in the GPRO.

The commenters believe that establishing these proposals would lead to greater overall program participation.

Response: We appreciate the commenters' positive feedback. We are finalizing all proposed criteria for the satisfactory reporting of PQRS quality measures via the GPRO using the registry-based reporting mechanisms for groups of 2–99 eligible professionals for the 2013 and 2014 PQRS incentives, as proposed. In addition, to align with the EHR Incentive Program, which will introduce a group practice reporting option in 2014, we are delaying implementing criteria for satisfactory reporting for group practices of 2–99 eligible professionals to 2014. The details of the EHR reporting criterion for group practices are discussed in greater detail below. However, since we have determined that it is not technically feasible to accept group reporting via the claims-based reporting mechanism at this time, we are not finalizing our proposed reporting criteria for group practices using the claims-based reporting mechanism for the 2013 and 2014 PQRS incentives at this time.

Comment: One commenter opposes offering varying reporting criteria, depending on group size and reporting method. The commenter believes that these varying methods of reporting unnecessarily complicates the program and provide a strong disincentive for participation.

Response: We understand the commenter's concern regarding the complexity of reporting under PQRS. Therefore, we have made an effort to streamline reporting criteria wherever possible. For example, the criteria we are establishing for satisfactory reporting using the registry and EHR-based reporting mechanisms are similar whether an eligible professional is reporting PQRS measures as part of a group in a GPRO or as an individual. However, we believe it is necessary to offer different reporting options and varying criteria to provide flexibility in reporting as well as ensure that the reporting threshold we are establishing is appropriate given a particular group practice's size and resources. We also note that it is not necessary for eligible professionals and group practices to meet the criteria for satisfactory reporting for the PQRS incentives or payment adjustments using multiple criteria and reporting mechanisms.

Eligible professionals and group practices need only chose one criterion under which to report.

Comment: One commenter sought clarification on how many eligible professionals within the group practice would be required to report PQRS measures using the proposed GPRO satisfactory reporting criteria for the claims, registry, and EHR-based reporting mechanisms for the 2013 and 2014 PQRS incentives. The commenter suggests that CMS not focus on requiring a certain amount of eligible professionals within the group practice to report but, instead, focus on a group practice's aggregate patients.

Response: We clarify that the criteria we establish for reporting using the registry and EHR-based reporting mechanisms does not require every eligible professional in the group practice to report PQRS measures. Rather, we note that the criteria we establish focuses on the group reporting on a certain percentage of its applicable patients, regardless of how many of the group practice's eligible professionals participate in reporting the PQRS measures. For example, if a group practice comprised of 10 eligible professionals participating in the GPRO chooses to report PQRS measures using the registry-based reporting mechanism, the group practice must report on at least 3 measures for 80 percent of the group practice's aggregate applicable patients. A measure is applicable to a patient if the service provided to the patient and billed to Medicare under the Physician Fee Schedule is contained in the denominator of a measure. For more information on the PQRS measures, including what types of services are contained in the denominator of certain measures, please visit the PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html* to view the PQRS Measures List and Implementation Guide for the relevant year. It is irrelevant whether 5 or all 10 of the group practice's eligible professionals report. We would imagine, however, that a group practice would have to report on a larger set of patients the larger the group size.

Comment: One commenter urged CMS to expand the proposed satisfactory reporting criteria of individual PQRS measures under the GPRO using the claims, registry, and EHR based reporting mechanisms to groups of 100 or more eligible professionals. The commenter notes that the measures available for reporting using the GPRO web interface are limited, so expanding the proposed claims, registry, and EHR-based reporting options under the GPRO would allow greater flexibility for large specialty practices to report on PQRS measures.

Response: We agree with the commenter's feedback. Our desire to encourage specialties to submit meaningful measure data outweighs our desire to restrict the GPRO registry and EHR-based reporting options to smaller groups of 2–99 eligible professionals. We provided our reasons for limiting our proposal to restrict the registry and EHR-based reporting mechanisms to groups of 2–99 eligible professionals in the CY 2012 PFS proposed rule (76 FR 44821). Specifically, we stated that the reporting behavior of these smaller group practices would be more akin to individual reporting. However, we have received stakeholder feedback, such as the commenter's, that large groups (mainly large single specialty groups) find it more beneficial to report via registry or EHR as the measures available under these reporting mechanisms are more applicable to the group's practice. Stakeholders have also expressed concern that it is difficult for their billing departments to keep track of the reporting activities of each individual eligible professional. Providing a group practice reporting option for these groups would reduce the administrative burden these large single specialty practices incur from having to keep track of the group practice's reporting activity by each individual TIN/NPI combination. Therefore, we will expand the GPRO qualified registry and EHR-based reporting options to groups of 100 or more eligible professionals.

Comment: One commenter stressed the importance of allowing eligible professionals to still report as individuals despite these newly proposed group reporting options under the GPRO. The commenter noted that requiring eligible professionals to participate in PQRS under their respective group practices would have a negative impact on registries. The commenter noted that, historically, eligible professionals choosing to participate in PQRS independent of their group practice have used the registry-based reporting mechanism. The commenter believed that the registries have been particularly successful in collecting data relevant for measuring quality of care furnished to patients.

Response: CMS understands the need to establish reporting criteria for eligible professionals who wish to participate in PQRS independent of the other eligible professionals in their group practice. We note that the proposal to establish satisfactory reporting criteria using the claims, registry, and EHR-based reporting mechanisms for group practices using the GPRO was not intended to eliminate reporting options for eligible professionals who wish to participate in PQRS as individuals. These options are still available for individual reporting. Please note, however, that should an eligible professional fall under a TIN that elects to participate in PQRS using the GPRO, the eligible professional must participate in PQRS as part of the group practice. The eligible professional can no longer participate as an individual.

Comment: With regard to the satisfactory reporting criteria we proposed for groups in the GPRO using direct EHR products or EHR data submission vendor, one commenter noted that, should we finalize these proposed reporting criteria, the PQRS would be out of sync with Stage 1 of the Medicare EHR Incentive Program, which did not establish a group practice reporting option. The commenter did note, however, that the EHR Incentive Program established an EHR-based reporting option for group practices under Stage 2, which begins in 2014.

Response: We agree with the commenter that our proposed Options 1 and 2 for the satisfactory reporting of measures using the EHR-based reporting mechanism under the GPRO for the 2013 PQRS Incentive do not align with the requirements for meeting the CQM component of meaningful use in 2013 of the EHR Incentive Program, as there is no group reporting option for CQMs for the Medicare EHR Incentive Program until 2014. Therefore, we are not finalizing the following proposed satisfactory reporting criteria for the 2013 PQRS Incentive: (1) Option 1: Eligible professionals in a group practice must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures and (2) Option 2: Report at least 3 measures, AND report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

However, we finalized for the EHR Incentive Program two group reporting options beginning in 2014 for the CQM component of achieving meaningful use, one of which is the following: Medicare EPs who satisfactorily report PQRS CQMs using CEHRT under the PQRS GPRO would be considered to have satisfied their CQM reporting requirement as a group for the Medicare EHR Incentive Program (77 FR 54076

through 54078). In the proposed rule, we proposed 3 GPRO options for the satisfactory reporting of PQRS individual measures. However, we also indicated that it was our intent to finalize reporting criterion that aligns with the CQM requirements for achieving meaningful use in the EHR Incentive Program. Following the criteria we finalized for the satisfactory reporting of individual PQRS quality measures using a direct EHR product or EHR data submission vendor for individual eligible professionals, we are finalizing the following criteria for the satisfactory reporting of data on PQRS quality measures via the GPRO for the 2014 Incentive: Report 9 measures covering at least 3 domains specified in Table 95. If the group practice's CEHRT does not contain Medicare patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

Although we proposed three reporting criteria for the satisfactory reporting of PQRS measures via an EHR-based reporting mechanism under the GPRO for the 2014 PQRS incentive, we are only finalizing one GPRO EHR reporting criterion. Similar to the reasoning we provided to streamline the reporting criteria for reporting measures groups via registry for the 2013 and 2014 PQRS incentives, it is our desire to provide one streamlined reporting option via EHR for group practices participating in the GPRO.

We note that we believe these proposed criteria meet the requirements for group practice reporting specified in section 1848(m)(3)(C) of the Act. Section 1848(m)(3)(C) requires that the criterion for group reporting use a statistical sampling model, such as the model used in the PGP demonstration. We note that, although these criteria depart from the model used in the PGP demonstration, we believe that these criteria still meet the statistical sampling model requirement in that the group practices would still be required to report the measures on a sample of their patients. Rather than CMS choosing which sample of patients the group practice must report, with these criteria, the group practice decides to submit quality measures data on a sample of 100 percent of its patients. We note that although reporting on 100 percent of patients is not a sample, for data collection purposes, CMS would only collect data on the group practice's patients to which the EHR measures apply. Therefore, even though a group practice would report on 100 percent of patients to which the measure applies, not all of the EHR measures would necessarily apply to all of the group practice's patients. Since the group practice is then only providing information on its patients to whom the measure is applicable, we believe the proposed EHR reporting criteria would still meet the statistical sampling model requirement.

A summary of the final criteria for satisfactory reporting for group practices selected to participate in the GPRO for the 2013 and 2014 incentives is specified in Tables 92 and 93:

TABLE 92—CRITERIA FOR SATISFACTORY REPORTING OF DATA ON PQRS QUALITY MEASURES VIA THE GPRO FOR THE 2013 INCENTIVE

Reporting period	Reporting mechanism	Group practice size	Proposed reporting criterion
12-month (Jan 1–Dec 31).	GPRO Web interface	25–99 eligible professionals.	Report on all measures included in the web interface in Table 96; AND Populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.
12-month (Jan 1–Dec 31).	GPRO Web interface	100+ eligible professionals.	Report on all measures included in the web interface in Table 96; AND Populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries.
12-month (Jan 1–Dec 31).	Qualified Registry	2+ eligible professionals.	Report at least 3 measures, AND Report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.

* Subject to the measure applicability validation (MAV) process.

TABLE 93—CRITERIA FOR SATISFACTORY REPORTING OF DATA ON PQRS QUALITY MEASURES VIA THE GPRO FOR THE 2014 INCENTIVE

Reporting period	Reporting mechanism	Group practice size	Proposed reporting criterion
12-month (Jan 1–Dec 31).	GPRO Web interface	25–99 eligible professionals.	Report on all measures included in the web interface in Table 96; AND Populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.
12-month (Jan 1–Dec 31).	GPRO Web interface	100+ eligible professionals.	Report on all measures included in the web interface in Table 96; AND

TABLE 93—CRITERIA FOR SATISFACTORY REPORTING OF DATA ON PQRS QUALITY MEASURES VIA THE GPRO FOR THE 2014 INCENTIVE—Continued

Reporting period	Reporting mechanism	Group practice size	Proposed reporting criterion
			Populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries.
12-month (Jan 1–Dec 31).	Qualified Registry	2+ eligible professionals.	Report at least 3 measures, AND Report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1–Dec 31).	Direct EHR product that is CEHRT or EHR Data Submission Vendor's Product that is CEHRT.	2+ eligible professionals.	Report 9 measures covering at least 3 domains. If the group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is patient data.

* Subject to the measure applicability validation (MAV) process.

c. Analysis of the Criteria for Satisfactory Reporting for the 2013 and 2014 Incentives

For the proposed criteria for satisfactory reporting for the 2013 and 2014 incentives described in this section, we proposed that eligible professionals and group practices may not combine different satisfactory reporting criteria under different reporting mechanisms to meet the requirements of satisfactory reporting for the 2013 and 2014 incentives (77 FR 44824). For example, an eligible professional may not meet the requirements for the 2013 incentive by reporting on 2 applicable PQRS quality measures via EHR and 1 applicable PQRS quality measure via qualified registry, because the eligible professional did not meet the criteria for satisfactory reporting under at least one reporting mechanism. Similarly, a group practice would be required to select a single reporting mechanism for the entire group practice. For example, for a group practice consisting of 4 eligible professionals, the group practice would not be able to meet the requirements for the 2014 incentive by reporting 2 individual measures via qualified registry and 1 measure via the direct EHR submission method.

For individual eligible professionals and group practices reporting on individual measures and/or measures groups, we noted that, although an eligible professional or group practice could meet more than one criterion for satisfactory reporting, only one incentive payment will be made to the eligible professional or group practice. For example, if an eligible professional meets the criteria for satisfactory reporting of individual measures via claims and measures groups via claims for the 2013 incentive, the eligible professional would nonetheless only be entitled to one incentive payment. CMS would consider the eligible professional to be incentive eligible under whichever reporting criterion yields the greatest bonus.

We invited but received no public comment on our proposed analysis of the criteria for satisfactory reporting for the 2013 and 2014 incentives. Therefore, we are finalizing this analysis rule.

5. Criteria for Satisfactory Reporting for the Payment Adjustments

Section 1848(a)(8) of the Social Security Act, as added by section 3002(b) of the Affordable Care Act, provides that for covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. The applicable percent for 2015 is 98.5 percent. For 2016 and subsequent years, the applicable percent is 98.0 percent.

This section contains the final criteria for satisfactory reporting for purposes of the 2015 and 2016 payment adjustments for eligible professionals and group practices, as well as some discussion of what we are considering for the payment adjustments for 2017 and beyond.

As stated previously, the majority of eligible professionals currently are not participating in the PQRS. Yet, the payment adjustment will apply to all eligible professionals who are not satisfactory reporters during the reporting period for the year. Therefore, we noted that in implementing the PQRS payment adjustment, we seek to achieve two overarching policy goals. First, and foremost, we sought to increase participation in the PQRS and to implement the payment adjustment in a manner that will allow eligible professionals who have never participated in the program to familiarize themselves with the program. Second, we sought to align the reporting requirements under the PQRS with the quality reporting requirements of various CMS programs, such as the physician value-based payment modifier discussed in section III.K of this final rule with comment period.

a. Criteria for Satisfactory Reporting for the 2015 and 2016 Payment Adjustments for Eligible Professionals and Group Practices using the Claims, Registry, EHR, and GPRO web interface Reporting Mechanisms

This section addresses the criteria for satisfactory reporting for the 2015 and 2016 payment adjustments using the claims, registry, EHR-based, and GPRO web interface reporting mechanisms. First, we proposed that for purposes of the 2015 and 2016 payment adjustments (which would be based on data reported during 12 and 6-month reporting periods that fall within 2013 and 2014, respectively), an eligible professional or group practice would meet the requirement to satisfactorily report data on quality measures for covered professional services for the 2015 and 2016 payment adjustments by meeting the requirement for satisfactory reporting for the 2013 and 2014 incentives respectively (77 FR 44824). That is, we proposed the exact same

criteria for satisfactory reporting for the 2015 and 2016 payment adjustments that we proposed for the 2013 and 2014 incentives, described in Tables 25 and 26 of the proposed rule, with the exception of two additional alternative criteria. Since we had already proposed satisfactory reporting criteria for the 2013 and 2014 incentives and the reporting periods for the respective 2013 and 2014 incentives and 2015 and 2016 payment adjustments coincide, we felt it was appropriate that the proposed criteria for the 2013 and 2014 incentives apply to satisfy the satisfactory reporting requirements for the 2015 and 2016 payment adjustments, respectively. We noted that these proposed criteria for the 2013 and 2014 PQRS incentives were the only criteria we proposed to establish for the respective 2015 and 2016 PQRS payment adjustments for group practices using the GPRO web interface.

For individual eligible professionals also participating in the EHR Incentive Program, we noted that it is our intention to align our proposed criteria for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments with the criteria for meeting the CQM component of meaningful use applicable during the 2015 and 2016 PQRS payment adjustment reporting periods. For eligible professionals participating in PQRS and the EHR Incentive Program using a direct EHR product or EHR data submission vendor that is CEHRT, we noted that since we proposed to align our proposed EHR criteria for satisfactory reporting for the 2013 and 2014 PQRS incentives with the proposed criteria for meeting the CQM component of meaningful use for CYs 2013 and 2014 if these proposals were established and we meet our goal of aligning the two programs, an eligible professional that met the CQM component of meaningful use during the PQRS 2015 and 2016 payment adjustment reporting periods occurring in CYs 2013 and 2014 respectively using a direct EHR product or EHR data submission vendor that is CEHRT would meet the requirements for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments by submitting a single set of data.

We invited public comment on our proposals related to applying the satisfactory reporting criteria established for the 2013 and 2014 PQRS incentives for eligible professionals and group practices using the GPRO to the respective 2015 and 2016 PQRS payment adjustments. The following is a summary of the comments we received on these proposals.

Comment: Several commenters supported applying the satisfactory reporting criteria established for the 2013 and 2014 PQRS incentives for eligible professionals and group practices using the GPRO to the respective 2015 and 2016 PQRS payment adjustments.

Response: We appreciate the commenters' support for these proposals and are, therefore, finalizing these proposals, as proposed.

In addition, as a result of the overarching goals we have articulated above about encouraging participation and concern about eligible professionals' familiarity and experience with the program, we proposed the following alternative criteria for satisfactory reporting during the 12-month reporting periods for the 2015 and 2016 payment adjustments for eligible professionals and group practices: Report 1 (applicable) measure or measures group using the claims, registry or EHR-based reporting mechanisms. We noted that this particular proposed alternative criterion for satisfactory reporting was significantly less stringent than the satisfactory reporting criteria we have proposed for the 2013 and 2014 incentives. However, we stressed that we were proposing less stringent criteria only to ease eligible professionals and group practices who have not previously participated in PQRS into reporting into the mechanics of reporting quality measures under PQRS. As indicated in the proposed rule, for the 2017 PQRS payment adjustment and beyond, we anticipate eliminating these alternative proposed criteria and establishing criteria that more closely resemble the proposed satisfactory reporting criteria for the 2013 and 2014 incentives (77 FR 44826).

For group practices, section 1848(m)(3)(C) requires that the criterion for group reporting use a statistical sampling model, such as the model used in the PGP demonstration, we noted that we believed that the proposed reporting criteria met this standard, as the group practice would decide on which sample of patients to report (77 FR 44825). Under the proposed criteria, the group practice would select the sample number, meaning the group could choose to report on all applicable patients or a certain number of patients to which the particular measure applied. We noted that, although the group practice could choose the sample, we expected that the sample the group practice selects would represent a sufficient picture of the beneficiaries the group practice sees.

We invited public comments on these proposed criteria for satisfactory reporting for the 2015 and 2016 payment adjustments for eligible professionals and group practices using the claims, registry, EHR-based reporting mechanisms. The following is a summary of the comments we received regarding these proposed criteria.

Comment: Realizing the need to increase participation in PQRS, several commenters generally supported our proposed phased approach of introducing more lenient satisfactory reporting criteria for the 2015 and 2016 PQRS payment adjustments with the intention of moving towards more stringent satisfactory reporting criteria, such as the satisfactory reporting criteria established for the 2013 and 2014 PQRS incentives, for future payment adjustments.

Response: We appreciate the commenters' positive feedback on our proposals for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments.

Comment: Several commenters supported our proposed criteria for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments: Reporting 1 measure or measures group. These commenters believed that these proposed criteria would help ensure that an eligible professional who makes a good faith effort to report PQRS measures would avoid the 2015 and 2016 PQRS payment adjustments. In fact, some commenters suggested that we establish these criteria for the 2017 PQRS payment adjustment and beyond.

Response: We are not finalizing these reporting criteria for the 2017 PQRS payment adjustment and beyond. We note that we proposed these criteria to help eligible professionals and group practices who are participating in PQRS for the first time to become familiar with the PQRS reporting requirements. We believe that, by the reporting period for the 2017 PQRS payment adjustment, eligible professionals and group practices should be held to satisfactory reporting criteria that are identical or similar to the satisfactory reporting criteria we are establishing for the 2013 and 2014 PQRS incentives.

Based on the comments received and for the reasons previously stated, we are finalizing the proposed criteria for satisfactory reporting for the 2015 PQRS payment adjustment—Report 1 measure or measures group during the applicable payment adjustment reporting period. Therefore, an individual eligible professional will meet the criteria for satisfactory reporting for the 2015 payment adjustment if the eligible

professional reports 1 measure or, for eligible professionals only, measures group using a claims, qualified registry, or EHR-based reporting mechanism during the applicable payment adjustment reporting period. Unlike the criteria for satisfactory reporting for the 2013 and 2014 PQRS incentives, which requires an eligible professional to report on measures based on a percentage of applicable patients or patient count, this criterion only requires that an eligible professional or group practice report on 1 measure or, for individual eligible professionals only, 1 measures group for at least 1 applicable patient. However, we strongly encourage eligible professionals and group practices to report on as many applicable patients as possible. For group practices, please note that since we are not finalizing the claims-based reporting option for group practices, we are not finalizing this reporting criterion for satisfactory reporting for the claims-based reporting mechanism for group practices.

Although we did not propose using the GPRO web interface as a reporting mechanism to report 1 measure to meet the criteria for satisfactory reporting for the 2015 PQRS payment adjustment, we did propose this criterion for the other three traditional reporting mechanisms (claims, registry, and EHR). We anticipated that it would be sufficient to establish this criterion for these three other reporting mechanisms (claims, registry, and EHR) for the 2015 PQRS payment adjustment. However, as we previously stated, we are not finalizing the claims-based reporting mechanism for group practices participating in the GPRO. We are also not finalizing the EHR-based reporting mechanism for group practices participating in the GPRO until 2014. Therefore, since the registry-based reporting mechanism will be the only reporting mechanism under which group practices would be able to use this criterion, we are expanding this criterion for use under the GPRO web interface. Therefore, a group practice will not be subject to the 2015 payment adjustment if the group practice meets the criteria for satisfactory reporting by reporting 1 applicable measure using a qualified registry or the GPRO web interface reporting mechanism during the CY 2013 payment adjustment reporting period.

We are not finalizing these proposed criteria for the 2016 payment adjustment at this time, as we intend to revisit whether we should establish more stringent satisfactory reporting criteria beginning with the 2016 payment adjustment. We believe that, rather than maintaining this criterion for the 2016 PQRS payment adjustment, it may be more preferable to adopt a phased approach to moving towards reporting criteria that is identical to or similar to the criteria for satisfactory reporting for the 2013 and 2014 PQRS incentives. However, as we explained above, we are finalizing one criterion for satisfactory reporting for the 2016 PQRS payment adjustment: Meet the criteria for satisfactory reporting for the 2014 PQRS incentive.

Comment: Some commenters sought clarification on how the PQRS payment adjustment will be applied to specialties for which little to no relevant measures exist in the PQRS measures set, such as audiologists and endocrinologists. One commenter is concerned that endocrinologists who specialize in thyroid conditions will be unable to meet the proposed criteria for satisfactory reporting, as the commenter believes there are no proposed PQRS measures specific to the treatment of thyroid disease.

Response: Although the proposed PQRS measures set contains a broad set of measures, we understand that, in rare cases, there remains certain sub-specialties that may not be able to find relevant PQRS measures on which to report. However, please note that the PQRS measure set contains a broad set of measures that may in fact be applicable to these sub-specialties and relevant to their specific practice area. Many measures have broad denominator codes and code sets that apply to the majority of eligible professionals. Therefore, we urge these eligible professionals and group practices to contact our QualityNet Help Desk for advice on reporting and determining whether applicable measures can be found in the PQRS measure set. Meanwhile, to the extent possible, we will continue to work with stakeholders to ensure that the PQRS measure set addresses gaps for future program years.

b. Criteria for Satisfactory Reporting for the 2015 Payment Adjustment for Eligible Professionals and Group Practices Using the Administrative Claims-Based Reporting Mechanism

(1) Criteria for Satisfactory Reporting for the 2015 Payment Adjustment for Eligible Professionals and Group Practices Using the Administrative Claims-Based Reporting Mechanism

Unlike the traditional PQRS claims-based reporting mechanism, the administrative claims-based reporting mechanism we proposed does not require an eligible professional to submit quality data codes (QDCs) on Medicare Part B claims (77 FR 44825). Rather, using the administrative claims-based reporting mechanism only requires that an eligible professional or group practice submit Medicare claims to CMS. Since CMS, rather than the eligible professional or group practice, is performing the analysis and collecting the data provided in an eligible professional's or group practice's Medicare claims for an eligible professional's or group practice's Medicare beneficiaries, we believe it is appropriate to propose a reporting threshold that is more stringent than that proposed for the 2013 and 2014 incentives that use traditional PQRS reporting mechanisms. Therefore, we proposed the following criteria for satisfactory reporting for the 12-month reporting periods for the 2015 and 2016 payment adjustments (that occur in 2013 and 2014 respectively) for eligible professionals and group practices using the administrative claims-based reporting mechanism: Report ALL measures in Table 63 of the proposed rule for 100 percent of the cases in which the measures apply.

Section 1848(m)(3)(C) requires that the criterion for group reporting use a statistical sampling model, such as the model used in the PGP demonstration. We noted that, although these criteria depart from the model used in the PGP demonstration, similar to our arguments for the satisfactory reporting criteria we proposed for group practices using the claims, registry, and EHR-based reporting mechanisms, we believe that these criteria would still meet the statistical sampling model requirement in that the group practices would still be required to report the measures on a sample of their patients. We noted that, with these proposed criteria, the group practice would provide claims data to CMS on 100 percent of its patients for which the measure applies. We note that although reporting on 100 percent of patients is not a sample, for data collection purposes, CMS would only collect data on the group practice's patients to which the administrative claims measures apply. Therefore, the applicable measures will determine the sample size for which the group would report. Since the group practice is then only providing information on its applicable patients, we believe these reporting criteria would still meet the statistical sampling model requirement.

We invited public comment on these proposed criteria for eligible professionals and group practices using the administrative claims-based reporting mechanism. The following is a summary of comments received on these proposed criteria.

Comment: Several commenters supported our proposed criteria for the administrative claims-based reporting option for the 2015 and 2016 PQRS payment adjustments.

Response: We thank the commenters for their feedback. For the reasons we stated for not finalizing availability of the administrative claims-based reporting mechanism for the 2016 PQRS payment adjustment, we are finalizing the satisfactory reporting criteria for the administrative claims-based reporting option for the 2015 PQRS payment adjustment only.

Comment: One commenter sought clarification on the reporting threshold for eligible professionals and group practices using the administrative claims-based reporting option. Specifically, the commenter sought clarification on how eligible professionals and group practices would be assessed under the proposed requirement to report on all measures available under the administrative claims-based reporting option, particularly for those patients for whom not all of the administrative claims measures apply.

Response: Unlike the traditional claims, registry, EHR, or GPRO web interface reporting mechanisms, where an eligible professional or group practice is not required to submit reporting G-codes to submit data on quality measures, CMS will calculate the administrative claims measures on behalf of the eligible professional or group practice, therefore reducing the chance that a reporting error would occur. For those eligible professionals and group practices for which not all of the administrative claims measures apply to the patients of the eligible professionals or group practices, CMS would report zero percent performance rates for these measures, meaning that a certain clinical quality action was not performed because it did not apply to a certain patient. Please note that this administrative claims reporting option will be analyzed in the same manner as it will be analyzed under the Value-based Payment Modifier.

Comment: One commenter recommended that eligible professionals be allowed to choose the administrative claims-based reporting option to meet the criteria for satisfactory reporting for the 2013 and 2014 PQRS incentives.

Response: We respectfully disagree. We believe that eligible professionals and group practices should be held to a higher standard of reporting for the PQRS incentive vs. the PQRS payment adjustment. As noted previously, we agree with other commenters that the administrative claims-based reporting option may not always provide data that is as relevant to a practice as the data that would otherwise be provided from reporting measures using the traditional reporting mechanisms. We proposed the administrative claims-based reporting option primarily as a means to report for the 2015 and 2016 PQRS payment adjustments to ease eligible professionals into reporting PQRS measures. In fact, we are not finalizing the administration claims-based reporting option for the 2016 PQRS payment adjustment at this time. Since we see this option as temporary, only a limited set of measures were proposed for use under the administrative claims-based reporting option. We believe that more meaningful data will be collected using the traditional claims, registry, EHR, or GPRO web interface reporting mechanisms, where eligible professionals or group practices may choose measures from a broad set that may be more relevant to their practice and where we are able to collect richer data than what is routinely submitted for billing purposes. Therefore, eligible professionals and group practices will not be able to use the administrative claims-based reporting mechanism for the 2013 and 2014 PQRS incentives. However, should an eligible professional or group practice elect to use the administrative claims-based reporting mechanism for the 2015 PQRS payment adjustment, please note the eligible professional or group practice may use the traditional reporting mechanisms for the 2013 PQRS incentive.

Comment: One commenter stated that the administrative claims-based reporting option may not produce meaningful data. However, the commenter understands the need to balance our goal of increasing participation with our goal to collect meaningful data.

Response: We agree with the commenter that data collected using our traditional PQRS reporting options (using the claims, registry, EHR, and GPRO web interface reporting mechanisms) would provide more meaningful data. As such, we believe the administrative claims-based reporting option should be temporary, and we intend to move away from the administrative claims-based reporting option. Therefore, we are only finalizing it for the 2015 PQRS payment adjustment. We believe that providing this option for eligible professionals during the first year of the implementation of the PQRS payment adjustment will provide eligible professionals with enough time to transition into using a traditional PQRS reporting mechanism.

In addition, when developing proposals for reporting criteria for the 2015 and 2016 PQRS payment adjustments, we considered satisfactory reporting options that would encourage eligible professionals and group practices to report for the 2013 and/or 2014 incentives but, should eligible professionals or group practices come up shy of meeting the 2013 and/or 2014 incentive reporting criteria, would still allow an eligible professional to meet the criteria for satisfactory reporting for the 2015 and/or 2016 payment adjustments (77 FR 44825). In lieu of more lenient satisfactory reporting criteria we proposed for the 2015 and 2016 payment adjustment, for example, to report at least 1 measure or measures group or to elect the administrative claims-based reporting option, we considered the option of defaulting those eligible professionals who report but fail to meet the criteria for satisfactory reporting using the proposed criteria for the 2013 and/or 2014 incentives to the administrative claims-based reporting option. We would therefore analyze the claims of all eligible professionals who report at least 1 measure under a traditional reporting method during the respective 2015 and 2016 payment adjustment reporting periods under the administrative claims-based reporting option. We considered this proposal because it is our intention to encourage eligible professionals to report PQRS measures using the proposed reporting criteria for the 2013 and 2014 PQRS incentives. However, given our concern about new eligible professionals' familiarity and experience with the program, we stated that we felt it was necessary to propose an alternative, less stringent reporting option.

We invite public comment on this alternative, and the following is a summary of the comments we received.

Comment: One commenter opposed defaulting eligible professionals who do not meet the criteria for satisfactory reporting for the 2013 and/or 2014 PQRS incentives to the administrative claims-based reporting option. The commenter notes that the proposed measures under the administrative claims-based reporting option are not broadly applicable to all medical specialties and do not encourage the reporting of PQRS measures that are applicable to their patients.

Response: We understand the limitations of the proposed administrative claims-based reporting option, particularly as it applies to certain specialties. Based on the

comments received and our desire to encourage eligible professionals to report measures applicable to the eligible professionals' practice, we are not finalizing a policy to default eligible professionals who do not meet the criteria for satisfactory reporting for the 2013 and/or 2014 PQRS incentives to the administrative claims-based reporting option.

Comment: One commenter supported defaulting eligible professionals who do not meet the criteria for satisfactory reporting for the 2013 and/or 2014 PQRS incentives to the administrative claims-based reporting option. The commenter noted that should CMS default eligible professionals to the administrative claims-based reporting option, registration would not be necessary.

Response: Although we disagree, we appreciate the commenter's feedback. As eligible professionals and group practices choose the traditional reporting mechanisms under which they report PQRS quality measures, we are requiring eligible professionals to affirmatively choose whether or not to elect the administrative claims reporting option. We emphasize our preference towards the traditional claims, registry, EHR, and GPRO web interface PQRS reporting mechanisms.

In summary, eligible professionals and group practices have 3 options for meeting the criteria for satisfactory reporting for the 2015 PQRS payment adjustment:

- Meet the criteria for the 2013 PQRS incentive;
- Report 1 applicable measure or, for eligible professionals only, measures group; or
- Elect to be analyzed under the administrative claims-based reporting mechanism.

Eligible professionals and group practices have 1 option for meeting the criteria for satisfactory reporting for the 2016 PQRS payment adjustment: Meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment.

c. Analysis of Eligible Professionals and Group Practices Who Will Be Assessed a PQRS Payment Adjustment

As noted in § 414.90(b), an eligible professional is assessed at the TIN/NPI level and a group practice selected to participate in the GPRO is assessed at the TIN level. As there is a 1-year lapse in time between the end of a proposed respective payment adjustment reporting period and when an eligible professional is expected to receive a PQRS payment adjustment for not meeting the requirements for satisfactory reporting for the respective payment adjustment, we understand that an eligible professional may change his or her TIN/NPIs during this lapse of time. Likewise, a group practice selected to participate in the GPRO may change its TIN during this lapse in time. In the proposed rule (77 FR 44825–44826). We noted that we believed this could raise issues with regard to the subsequent application of the payment adjustment and concerns about the potential for abuse (for example, ''gaming the system'').

Accordingly, we invited public comment this issue, including what parameters, if any, CMS should impose regarding the changes in TIN/NPIs and compositions of group practices with regard to the payment adjustment. We received the following comment regarding this issue.

Comment: One commenter disagreed with our concern for potential abuse for allowing changes in an eligible professional's TIN/NPI composition for applying the PQRS payment adjustment. The commenter stated that actual reporting of PQRS measures is typically documented by the practice's administrative staff, not the eligible professional. Therefore, should an eligible professional decide to enter a new practice, the eligible professional should not be held accountable for errors that occurred in his or her previous practice. The commenter stated that having a PQRS payment follow the eligible professional into a potential new practice could affect the eligible professional's ability to seek new employment.

Response: It is not CMS' intention to affect the employment opportunities of eligible professionals by establishing parameters concerning changes in an eligible professional's TIN/NPI composition for applying the PQRS payment adjustment. Rather, CMS' concern regarding changes in an eligible professionals TIN/NPI combination lie in the potential that an eligible professional may change his/her TIN/NPI composition solely for the purpose of avoiding application of the PQRS payment adjustment. After taking into consideration the comment received, at this point, we are not placing any parameters around the changing of an eligible professional's TIN/NPI composition for purposes of the payment adjustment. However, we may place such parameters in the future should the need arise.

6. PQRS Quality Measures for 2013 and Beyond

This section focuses on the PQRS quality measures we are making available for reporting under PQRS using the claims, registry, EHR (direct EHR or EHR data submission vendor product), GPRO web interface, and/or administrative claims-based reporting mechanisms. Below, we address the comments we received regarding these measures. We note, however, that many commenters provided comments related to measure specifications and suggestions for additional measures. For the measure specifications for these proposed PQRS measures, please note that we do not use the rulemaking process to change measure specifications. Measure specifications are determined by the measure developers and owners. Therefore, suggestions on changes to measure specifications should be addressed to the respective measure developer and/or owner.

In addition, we note that we received some comments in which commenters suggested additional measures. However, as we have noted in prior program years, we do not generally adopt measures in the final measure set that were not proposed in the proposed rule (though we do take them in consideration for possible use in future years of the program). In addition, we note that we undergo a pre-rulemaking process—including the requirement that measure owners and developers submit these measures for inclusion in the PQRS measure set in our annual PQRS Call for Measures and have these measures subsequently reviewed by the MAP—prior to proposing measures in rulemaking. Since these proposed measures have not gone through our various vetting channels, we cannot include these newly suggested measures that arise from the comments provided.

We also received comments asking whether PQRS measures applied to certain specialties. Please note that these questions are not typically addressed in rulemaking. We urge the commenters to contact the QualityNet Help Desk for assistance with finding applicable measures.

a. Statutory Requirements for the Selection of PQRS Quality Measures for 2013 and Beyond

Under section 1848(k)(2)(C)(i) of the Act, the PQRS quality measures shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under subsection 1890(a) of the Act (currently, that is the National Quality Forum, or NQF). However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the NQF, section 1848(k)(2)(C)(ii) of

the Act authorizes the Secretary to specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the AQA alliance. In light of these statutory requirements, we believe that, except in the circumstances specified in the statute, each PQRS quality measure must be endorsed by the NQF. Additionally, section 1848(k)(2)(D) of the Act requires that for each PQRS quality measure, ''the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.''

The statutory requirements under section 1848(k)(2)(C) of the Act, subject to the exception noted previously, require only that the measures be selected from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) (that is, the NQF) and are silent for how the measures that are submitted to the NQF for endorsement were developed. The basic steps for developing measures applicable to physicians and other eligible professionals prior to submission of the measures for endorsement may be carried out by a variety of different organizations. We do not believe there needs to be any special restrictions on the type or make-up of the organizations carrying out this basic process of development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic development of quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards for purposes of the PQRS.

In addition to section 1848(k)(2)(C) of the Act, section 1890A of the Act, which was added by section 3014(b) of the Affordable Care Act, requires that the entity with a contract with the Secretary under subsection 1890(a) of the Act (currently that, is the NQF) convene multi-stakeholder groups to provide input to the Secretary on the selection of certain categories of quality and efficiency measures. These categories are described in section 1890(b)(7)(B) of the Act, and include such measures as the quality measures selected for reporting under the PQRS. Pursuant to section 3014 of Affordable Care Act, the NQF convened multi-stakeholder groups by creating the Measure Applications Partnership (MAP). Section 1890(A)(a) of the Act requires that the Secretary establish a pre-rulemaking process in which the Secretary must make publicly available by December 1st of each year a list of the quality and efficiency measures that the Secretary is considering for selection through rulemaking for use in the Medicare program. Once we have made this list available to the public, the NQF must provide CMS with the MAP's input on selecting measures by February 1st of each year. The list of measures under consideration for 2012 is available at *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.*

We received the following comments regarding these statutory requirements for the selection of PQRS quality measures:

Comment: One commenter was concerned with the requirement that all measures included in PQRS be NQF-endorsed.

Response: As we discussed above, section 1848(k)(2)(C)(i) of the Act generally requires that the PQRS quality measures be NQF endorsed. However, we note that section 1848(k)(2)(C)(ii) of the Act authorizes CMS to include measures in PQRS that are not NQF-endorsed. PQRS gives preference to measures that have been endorsed by NQF. However, there are cases where no NQF measures exist which address an identified quality area. Additionally, PQRS measures undergo yearly revisions based on NQF and measure owner direction, which incorporate new evidence and clinical recommendations.

Comment: Some commenters believed that only measures that are NQF-endorsed should be available for reporting in PQRS.

Response: We understand the importance of NQF endorsement. While we appreciate the commenters' feedback, we believe there are circumstances (such as when a measure addresses a gap in the PQRS measure set) where we may believe that it is important to include a non-NQF endorsed measure to be available for reporting under PQRS. Section 1848(k)(2)(C)(ii) of the Act authorizes the Secretary to include measures available for reporting under PQRS that are not NQF endorsed. We believe that the measures we finalize under PQRS undergo a vetting process. For example, prior to rule making, CMS reviews input from the Measure Applications Partnership (MAP). Among other factors, utility, feasibility, and analytics are assessed during this process. The Secretary has contracted with the National Quality Forum (NQF), as the consensus-based entity for a number of reasons, as described in section 1890 of the Act, including for the specific purpose of convening multi-stakeholder groups to provide input to CMS on the identification of the best available performance measures and the selection of these measures for PQRS (amongst other purposes).

Comment: One commenter stressed its concern with prioritizing measures that are NQF-endorsed. The commenter notes that NQF endorsement is not achievable for all measures as staff and financial resources are limited for many measure developers, both of which are needed to deploy large testing projects to support reliability and validity. Moreover, the commenter believed the method of measure development for primary care differs vastly from that of specialty care due to dissimilarities in patient populations and target diseases which may be more amenable to qualitative vs. quantitative research.

Response: We understand the commenter's concerns regarding the limitations of NQF-endorsement and have historically included measures that are not NQF-endorsed for inclusion in the PQRS measure set based on our exception authority under section 1848(k)(2)(C)(ii) of the Act. We continue to include measures that are not NQF-endorsed to address gaps in the PQRS measure set when appropriate.

Comment: One commenter requested that, in the future, CMS include more information regarding measure recommendations from the Measure Applications Partnership (MAP) to allow the public to more meaningfully comment on proposed PQRS measures.

Response: We understand the need to provide the public with adequate information to meaningfully comment on our proposals. Therefore, in the future, we will seek to provide more information regarding measure recommendations from the MAP.

b. Other Considerations for the Selection of Proposed PQRS Quality Measures for 2013 and Beyond

As we noted above, section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). We may select measures under this exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed by the entity. Under this exception, aside from NQF endorsement, we requested that stakeholders apply the following considerations when submitting measures for possible inclusion in the PQRS measure set:

- High impact on healthcare.
- Measures that are high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.
- Measures that address gaps in the quality of care delivered to Medicare beneficiaries.
- Address Gaps in the PQRS measure set.
- Measures impacting chronic conditions (chronic kidney disease, diabetes mellitus, heart failure, hypertension and musculoskeletal).
- Measures applicable across care settings (such as, outpatient, nursing facilities, domiciliary, etc.).
- Broadly applicable measures that could be used to create a core measure set required of all participating eligible professionals.
- Measures groups that reflect the services furnished to beneficiaries by a particular specialty.

On October 7, 2011, we ended a Call for Measures that solicited new measures for possible inclusion in the PQRS for 2013 and beyond. During the Call for Measures, we solicited measures that were either NQF-endorsed or fell under the exception specified in section 1848(k)(2)(C)(ii) of the Act.

Although the deadline to submit measures for consideration for the 2013 PQRS program year has ended, we invited public comment on future considerations related to the selection of new PQRS quality measures. The following is a summary of the comments received.

Comment: One commenter emphasized the need that measures selected for reporting under PQRS be vetted by multi-stakeholder entities from development to endorsement, particularly by physicians who are ultimately the end-users of the measures. Another commenter stressed the importance of providing a better review and vetting process of measures.

Response: We appreciate the commenter's feedback and understand the importance of ensuring that stakeholders review measures prior to being included in PQRS, particularly during our annual PQRS Call for Measures and subsequently through use of the MAP's input.

Comment: One commenter strongly supports the continued development of risk-adjusted measures versus process measures as true measures of physician quality.

Response: CMS agrees and will strive to include and implement robust outcomes measures in the PQRS measure set as appropriate measures.

Comment: One commenter urges CMS to bolster the current PQRS requirements, which rely too heavily on measures of basic competencies and other processes that are not necessarily close to or related to an outcome. The commenter believes that many measure gaps (particularly in the area of outcomes) must be filled for PQRS to effectively and accurately assess physician performance. Therefore, the commenter urges CMS to fill these gaps at the earliest opportunity by working with medical societies and other measure developers.

Response: We agree with the commenter's feedback and are actively working with stakeholders to address measure gaps in the PQRS measure set.

Comment: One commenter urged CMS to continue to develop risk adjustment methodologies as there is not a clear method to adjust many quality measures. The commenter asked CMS to support the development of measures that better address multi-morbidity and patient centeredness.

Response: We appreciate the commenter's feedback and encourage the submission of risk adjusted measures for consideration for inclusion in the PQRS measures set.

c. PQRS Quality Measures

This section focuses on the proposed PQRS individual Measures available for reporting via claims, registry, and/or EHR-based reporting for 2013 and beyond. To align with the proposed measure domains provided in the EHR Incentive Program (77 FR 13743), we classify all proposed measures against six domains based on the National Quality Strategy's six priorities, as follows (77 FR 44827):

(1) *Patient and Family Engagement.* These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level as well as the population level through greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

(2) *Patient Safety.* These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.

(3) *Care Coordination.* These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication.

(4) *Population and Public Health.* These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served and are especially focused on the leading causes of mortality. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the U.S. population.

(5) *Efficient Use of Healthcare Resources.* These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.

(6) *Clinical Processes/Effectiveness.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

We invited but received no public comment on these domains.

Please note that the PQRS quality measure specifications for any given proposed PQRS individual quality measure may differ from specifications for the same quality measure used in prior years. For example, for the proposed PQRS quality measures that were selected for reporting in 2012, please note that detailed measure specifications, including the measure's title, for the proposed individual PQRS quality measures for 2013 and beyond may have been updated or modified during the NQF endorsement process or for other reasons. In addition, due to our desire to align measure titles with the measure titles that were proposed for 2013, 2014, 2015, and potentially subsequent years of the EHR Incentive Program, we note that the measure titles for measures available for reporting via EHR may change. To the extent that the EHR Incentive Program updates its measure titles to include version numbers (77 FR 13744), we intend to use these version numbers to describe the PQRS EHR measures that will also be available for reporting for the EHR Incentive Program. We will continue to work toward complete alignment of measure specifications across programs whenever possible.

Through NQF's measure maintenance process, NQF endorsed measures are

sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. We proposed that if the NQF updates an endorsed measure that we have adopted for the PQRS 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 (77 FR 44822). Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on the CMS QualityNet Web site at *https://www.QualityNet.org.* We would provide sufficient lead time for implementing the changes where changes to the data collection systems would be necessary.

We would 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 this proposal adequately balances our need to incorporate NQF updates to NQF-endorsed measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted.

We invite public comment on this proposal. The following is a summary of comments we received on this proposal to allow for altering of a measure that has been finalized in rulemaking, provided that the updates do not substantially change the nature of the measure.

Comment: Some commenters opposed our proposal to handle changes to a measure through a subregulatory process.

Response: We understand the need for transparency when effectuating changes to a measure. However, we note that the measure changes we envision making outside of rulemaking are relatively minor, such as minor changes to the measure specifications. Other examples of minor changes include: Adding the NQF endorsement number to a measure, correcting faulty logic, adding or deleting codes as well as providing additional implementation guidance for a measure. These changes do not substantively change the measures we finalize in rulemaking. We believe it is necessary to be able to make non-substantive changes to PQRS measures, so that we may quickly address issues that arise with the reporting of measures. Therefore, we are finalizing our proposal to make non-substantive measure changes outside of rulemaking.

We note that CMS does not usually make unilateral changes to measures. These minor changes are usually addressed in collaboration with stakeholder feedback—measure developers, measure owners, eligible professionals reporting the respective measures, etc. Therefore, to the extent that we received comments related to minor changes to the proposed PQRS measures, we did not address these comments in this final rule. Commenters are encouraged to contact the respective measures owners regarding these issues.

To receive more information on the proposed measures contained in this section, including the measure specifications for these proposed measures, please contact the respective measure owners. Contact information for the measure owners of these proposed PQRS measures is available at the PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.*

(1) HHS Million Hearts Individual Measures Available for Claims, Qualified Registry, and EHR-Based Reporting for 2013 and Beyond

In 2011, the Department of Health and Human Services (HHS) started the Million Hearts Initiative, which is an initiative to prevent 1 million heart attacks and strokes in 5 years. We are dedicated to this initiative and seek to encourage eligible professionals to join in this endeavor. Therefore, based on our desire to support the Million Hearts Initiative and maintain our focus on cardiovascular disease prevention, we proposed individual PQRS Core Measures that were specified in Table 94 of the CY 2013 MPFS proposed rule for 2013 and beyond (77 FR 44827). These measures were the same measures we finalized under the 2012 PQRS in the CY 2012 Medicare PFS final rule (76 FR 73345). Please note that, although we proposed that certain measures serve as core PQRS quality measures, we did not propose to require that eligible professionals report on these proposed PQRS core measures. We invited public comment on the proposed PQRS core measures for 2013 and beyond. We did not receive public comment on the majority of measures we proposed to classify as PQRS core measures.

The following is a summary of the comments we received on the proposed PQRS core measures for 2013 and beyond and our proposal regarding the ''core'' designation.

Comment: One commenter recommended that we avoid classifying the proposed PQRS core measures as ''core measures,'' because the EHR Incentive Program uses the term ''core measures'' differently. Therefore, the commenter stated that classifying these PQRS measures as ''core measures'' may cause confusion.

Response: We agree with the commenter that the term ''core measures'' is used differently under PQRS and the EHR Incentive Program. Therefore, we will refer to these measures as HHS Million Hearts Measures.

Comment: One commenter supports CMS' dedication to view the treatment of cardiovascular conditions as a top priority.

Response: We appreciate the commenter's feedback. Indeed, aside from finalizing our measures related to cardiovascular conditions, we are finalizing this proposed measure set. However, rather than referring to this measure set as PQRS core measures, we will refer to this measure set as the measure set containing the HHS Million Hearts Measures.

Comment: One commenter opposed classifying the following measure as a PQRS core measure:

- Preventive Care and Screening: Cholesterol-Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL

The commenter does not believe that this measure should be a core measure because it is only available for reporting using the EHR-based reporting mechanism.

Response: While this measure is only available for reporting using the EHR-based reporting mechanism, the measure addresses important quality actions related to the Million Hearts Initiative. Therefore, we are finalizing these proposed measures as part of the HHS Million Hearts measure set available for reporting under PQRS for 2013 and beyond.

Table 94 provides a summary of the HHS Million Hearts measures we are finalizing for 2013 and beyond. Please note that, although we strongly encourage that eligible professionals report these measures, eligible professionals are not required to report these specific measures for the purposes of meeting the criteria for satisfactory reporting for the PQRS incentives or payment adjustments.

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Table 94: HHS Million Hearts Measures for 2013 and Beyond*

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0064/ 2		Clinical Process/ Effectiveness	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA	X	X	X		X	HITECH Million Hearts
0068/ 204		Clinical Process/ Effectiveness	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) with documented use of aspirin or another antithrombotic	NCQA	X	X	X	X	X	HITECH ACO Million Hearts
0028/ 226		Population /Public Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI	X	X	X	X	X	HITECH ACO Million Hearts
0018/ 236		Clinical Process/ Effectiveness	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)	NCQA	X	X	X	X	X	HITECH ACO Million Hearts
0075/ 241		Clinical Process/ Effectiveness	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control:** Percentage of patients	NCQA	X	X	X	X	X	HITECH ACO Million Hearts

			aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)							
N/A/ 316		Clinical Process/ Effectiveness	**Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL:** Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed *There are three criteria for this measure based on the patient's risk category. 1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent 2. Moderate Level of Risk: Multiple (2+) Risk Factors 3. Lowest Level of Risk: 0 or 1 Risk Factor	CMS/ QIP			X			HITECH Million Hearts
N/A/ 317		Population /Public Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated	CMS/ QIP	X	X	X	X	X	HITECH ACO Million Hearts

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(2) PQRS Quality Measures Available for Reporting via the Claims, Qualified Registry, EHR, and GPRO Web Interface Reporting Mechanisms for 2013 and Beyond

This section contains individual PQRS quality measures we proposed for 2013 and beyond (77 FR 44830) and the final measure set we are adopting in this final rule with comment period. Please note that, in large part, we proposed to retain most of the quality measures we finalized for reporting for the 2012 PQRS (76 FR 42865 through 42872). However, in 2013 and 2014, we proposed to include new measures, as well as remove measures that were available for reporting under the 2012 PQRS (not re-propose certain measures for 2013 and beyond). Table 97 of the CY 2013 PFS proposed rule contains the list of measures we proposed to be available for reporting under the PQRS for 2013 and beyond that were available under the 2012 PQRS (77 FR 44841). Tables 30 and 33 of the CY 2013 PFS proposed rule contains the list of new measures we proposed to be available for reporting under the PQRS beginning in 2013 and 2014 respective that were not available under the 2012 PQRS (77 FR 44831 and 77 FR 44942). Tables 31 and 34 of the CY 2013 PFS proposed rule contains the list of measures we did not propose for reporting under PQRS beginning in 2013 and 2014 respectively that are available for reporting under the 2012 PQRS (77 FR 44837 and 77 FR 44953).

General Comments on Proposed Individual Measures for Reporting for 2013/2014 and Beyond. We received the following general comments related to the individual measures we proposed for reporting under PQRS beginning in 2013 or 2014:

Comment: Several commenters appreciate CMS' efforts to align the PQRS measures available for reporting under the EHR-based reporting mechanisms with the measures available for reporting under the EHR Incentive Program. The commenters believe this alignment will reduce the administrative burden on eligible professionals while harmonizing the two programs.

Response: We appreciate the commenter's feedback and note that we are working to completely align the measures available for reporting via EHR under PQRS and the EHR Incentive Program. For the 2012 PQRS, we have attempted to align the PQRS measures available for EHR-based reporting with the EHR measures available for reporting under the EHR Incentive Program (76 FR 73364) and we are retaining those measures for 2013 and beyond. In fact, we are adding or removing measures available for EHR-based reporting that align with what has been finalized for reporting under the EHR Incentive Program for beginning in CY 2014 (77 FR 54060).

Comment: Some commenters were pleased that the proposed PQRS measure set provided a variety of measures for which certain specialties may report, such as vascular surgeons.

Response: We appreciate the commenters' feedback. It is our goal to ensure that specialties are able to report under PQRS. Therefore, as our final set of measures specified in Table 95 indicates, we allow for a broad variety of measures in the PQRS measure set.

We note that we received several comments related to the addition of measures we did not propose for inclusion in PQRS. We note the need to be transparent and provide the public with an opportunity to provide comment on the measures we include in PQRS prior to finalizing these measures in the PQRS measure set. Since we did not propose including these measures for reporting under PQRS, we are not addressing these comments in this final rule. However, we will use the comments we have received when selecting measures to be included in PQRS for future program years.

Prior Measures Not Proposed for Reporting under PQRS. We did not propose to retain 14 measures in 2013 that were previously established for reporting under the 2012 PQRS (see Table 96 of the CY 2013 PFS proposed rule, 77 FR 44837). We did not propose to retain 9 measures in 2014 that were previously established for reporting under the 2012 PQRS (see Table 34 of the CY 2013 proposed rule, 77 FR 44953). The public comments we received did not address the majority of the measures identified from prior PQRS program years that we did not propose to include from reporting under PQRS in 2013 and 2014.

The following is a summary of the comments we did receive regarding prior program measures we did not propose to include under PQRS in 2013 or 2014:

Comment: Some commenters opposed our decision not to propose for the 2013 PQRS and beyond:

- Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers. One commenter states that the MAP recommended that the measure be submitted for NQF endorsement.

Response: We are not retaining this measure for reporting under PQRS beginning in 2013. Indeed, as the commenter stated, the MAP recommended that this measure be submitted for NQF endorsement. Currently, this measure is not-NQF endorsed. We interpret the MAPs recommendation that this measure be submitted for NQF endorsement as the MAP not recommending this measure until the measure is NQF endorsed. As such, according to the MAP recommendation, we are not retaining this measure for reporting under PQRS. However, we may consider including this measure for reporting under PQRS in future years should this measure later receive NQF endorsement. We note that it is the responsibility of the respective measure owners and developers to submit measures for NQF endorsement.

Comment: Some commenters opposed our proposal not to retain the following measure for reporting under PQRS:

- Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR).

One commenter suggested that this measure be retained until a majority of eligible professionals have adopted EHR systems. Another commenter disagreed with CMS' contention that this measure is redundant to have an eligible professional report on whether or not s/he has adopted an EHR. The commenter believed that the measure is only redundant in the instances where the eligible professional is using direct EHR reporting. The commenter suggested that CMS follow the same protocol as other PQRS measures by designating measure #124 available only to those eligible professional who report using claims or registry reporting.

Response: We appreciate the commenter's feedback, but we are not retaining this measure for reporting under PQRS. It is our intention to align the measures available for EHR-based reporting under PQRS with the measures available for reporting under the Medicare EHR Incentive Program. Since this measure is not available for reporting under the EHR Incentive Program, we do not believe it is appropriate to include in the final PQRS measure set.

With respect to the commenter's request that this measure be retained until a majority of eligible professionals have adopted EHR systems, we do not believe we need to retain this measure for reporting for this purpose as we are encouraging eligible professionals to adopt EHR systems in other ways. For example, we are aligning our EHR reporting criteria with the criteria for meeting the CQM component of meaningful use such that eligible professionals reporting quality measures data via an EHR may satisfy the requirements for satisfactory reporting under PQRS and achieving meaningful use under the EHR Incentive Program by submitting one set of data.

With respect to the commenter who disagreed that the measure is redundant, we respectfully disagree with the commenter. Measures in PQRS generally provide that the eligible professional perform some sort of clinical quality action. For example, with respect to the HHS Million Hearts measure set that we are finalizing, the measure set indicates that an eligible professional asks certain questions of beneficiaries and perform certain procedures that we believe would help prevent heart disease. This measure does not do this; rather, the measure merely asks the eligible professional in indicate to CMS whether or not the eligible professional has adopted an EHR system. We do not believe this measure provides meaningful information to CMS anymore, as there are other PQRS requirements and CMS programs that more appropriately address the adoption and use of EHR systems. For these reasons, we will not extend the reporting of this measure for claims or registry-based reporting as the commenter requested.

Comment: One commenter opposed our decision not to include the following measure for reporting under PQRS:

- Stroke and Stroke Rehabilitation: Computed Tomography (CT) and Magnetic Resonance Imaging (MRI).

Response: We respectfully disagree with the commenter. This measure was reviewed by the MAP and not recommended for inclusion in the PQRS measure set beginning 2013. Therefore, we are following the MAP's recommendation and excluding this

measure from reporting in PQRS beginning in 2013.

Comment: One commenter opposed our decision not to retain the following measure from reporting under PQRS:

• Coronary Artery Disease (CAD): Symptom and Activity Assessment.

The commenter is concerned that this measure is paired with PQRS Measure #242 (CAD: Symptom Management), and therefore should be remain in PQRS for reporting to coincide with the reporting of measure #242.

Response: This measure was part of a two-part measure paired with Measure #242 for the 2012 PQRS. The two measures were intended to reflect the quality of services provided for the primary management of patients with CAD who are seen in the ambulatory setting. For 2012, the PQRS measure specifications (available on the PQRS Web site at *http://www.cms.gov/apps/ama/license.asp?file=/PQRS/downloads/2012_PhysQualRptg_IndividualClaimsRegistry_Specs_SupportingDocs_01162012.zip*) note that, should an eligible professional assess angina symptoms and patient activity under this measure, then Measure #242 should also be reported. As such, this measure triggered the reporting of Measure #242.

We prioritize the recommendation the MAP provides for the inclusion of measures in the PQRS measure set over our desire to retain the manner we have suggested that eligible professionals reporting these CAD measures in 2012. Since this measure was reviewed by the MAP and not recommended for inclusion in the PQRS measure set beginning 2013, we are not retaining this measure for reporting in PQRS. Measure #242 will therefore be reportable as a standalone measure. The description on how to report Measure #242 will be found in the Measures Specifications Manual that will be published for 2013 that will be available on the PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*.

Comment: One commenter opposed our proposal to remove the following measure from reporting under PQRS:

• Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Oxygen Saturation.

Response: The MAP recommended that this measure be ''removed'' from the PQRS measure set. Although we are not bound by the recommendations of the MAP, we find no reason to oppose the MAP's recommendation and retain this measure for reporting in PQRS. Therefore, we are not retaining this measure for reporting in PQRS beginning in 2013.

Comment: One commenter opposed our proposal to remove the following measure from the PQRS measure set:

• Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness.

The commenter urged CMS to consider retiring Measure 188: Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear in lieu of retiring Measure 190: Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness, because Measure 100 relates to a relatively uncommon condition seen in audiology practices.

Response: Although we are not bound by the MAP's recommendation, we note that the MAP recommended that this measure be ''removed'' from reporting under PQRS. We agree with the MAP's recommendation. We believe that this measure is too low bar as it is not a high impact measure that provides analysis on the patient or provider level. Rather, the measure simply asks whether a beneficiary has been referred for an evaluation. Therefore, we are not retaining this measure for reporting in PQRS. However, we encourage the development of a similar, more robust measure related to Otologic services.

Comment: Commenters supported our decision not to retain the following measure from reporting under PQRS:

• Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Mental Status.
• Heart Failure: Patient Education.
• Hypertension (HTN): Plan of Care.
• Hypertension (HTN): Blood Pressure Measurement.
• Prostate Cancer: Three Dimensional (3D) Radiotherapy.
• Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation.
• Preventive Care and Screening: Unhealthy Alcohol Use—Screening.

Response: We appreciate the commenter's feedback. These measures will not be included in the PQRS measure set for 2013 or 2014 and beyond.

Individual Measures Available for Reporting Under PQRS. Table 97 of the CY 2013 PFS proposed rule contains the list of measures we proposed to be available for reporting under the PQRS for 2013 and beyond that were available under the 2012 PQRS (77 FR 44841). Tables 30 and 33 of the CY 2013 PFS proposed rule contains the list of new measures we proposed to be available for reporting under the PQRS beginning in 2013 and 2014 respective that were not available under the 2012 PQRS (77 FR 44831 and 77 FR 44942). We proposed a total of 212 measures for available for reporting beginning in 2013. Beginning 2014, we proposed that 210 measures be available for reporting under PQRS. As indicated previously, these proposed measures are classified under 6 domains: (1) Patient safety, (2) patient and family engagement, (3) care coordination, (4) clinical process/effectiveness, (5) population/public health, and (6) efficiency.

With respect to the individual measures we proposed to include for reporting in PQRS beginning in 2013 or 2014, we did not receive public comments on a majority of the measures we proposed for inclusion in PQRS (specific measures we did receive comments on are addressed below). Therefore, based on the reasons previously stated in the CY 2013 PFS proposed rule, we are finalizing these measures, as proposed. These measures either meet the requirement that the measures available in the PQRS measure set be NQF endorsed or address an exception to NQF endorsement, such as filling a gap in the PQRS measure set. The following is a summary of the comments we did receive on certain proposed individual measures:

Comment: Commenters provided general support for the following measures that are available for reporting in PQRS in 2012:

• Melanoma: Coordination of Care—The inclusion of this measure would expand the number of measures relevant to dermatologists.
• Melanoma: Continuity of Care—Recall System—The inclusion of this measure would expand the number of measures relevant to dermatologists.
• Melanoma: Overutilization of Imaging Studies in Melanoma—The inclusion of this measure would expand the number of measures relevant to dermatologists.

For the following measures, one commenter supported the following proposed measures for inclusion in PQRS as they are relevant to ophthalmologists:

• Age-Related Macular Degeneration (AMD): Dilated Macular Examination.
• Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy.
• Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care.

One commenter applauds the decision to incorporate the following measures for reporting in PQRS:

• Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluative in Low-Risk Surgery Patients.

• Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI).

• Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients.

The commenter believes these measures collect data on three most common areas on inappropriate imaging, allowing CMS to more accurately capture information on the overall value of cardiac diagnostic imaging for beneficiaries. Another commenter specifically supported the measure titled ''Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients.''

Response: We agree with the commenters' feedback and are therefore finalizing these individual measures for reporting in PQRS beginning in 2013 or 2014. Since these measures were available for reporting in 2012, we are retaining these measures so that eligible professionals may continue to report on these measures.

Comment: Commenters provided support for the following measures that we proposed to add to the PQRS measure set beginning in 2013:

• Participation by a Hospital, Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality.

• Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy—The commenter also requested that the measure owner information on this measure should be updated to indicate that AMA–PCPI/ACCF/AHA is the current measure owner.

• Pediatric Kidney Disease: Adequacy of Volume Management—The commenter also requested that the measure owner information on this measure should be updated to indicate that AMA–PCPI is the current measure owner.

Response: We appreciate the commenters' support for adding these measure and, for the reasons stated in the CY 2012 PFS proposed rule (76 FR 44956), are finalizing these measures for reporting under PQRS for 2013 and beyond. For the measure ''Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy,'' we will reflect that the measure owner for this measure is currently AMA–PCPI/ACCF/AHA. For the measure ''Pediatric Kidney Disease: Adequacy of Volume Management,'' we will reflect that the measure owner for this measure is currently AMA–PCPI.

Comment: One commenter supported our proposal to include the following measure:

• Adult Major Depressive Disorder (MDD): Coordination of Care of Patients With Co-morbid Conditions.

However, the commenter opposed our proposal that this measure be paired, since the measure owner did not support the following second part of the measure: ''who have a follow-up attempt within 60 days of original communication by the physician treating MDD to elicit a response from the other physician.''

Response: We appreciate the commenter's feedback. However, this measure was submitted for consideration for inclusion in the PQRS measure set as a paired measure. Since we usually defer to the respective measures owners and developers on how a particular measure should be reported, we are finalizing this measure, as proposed.

Comment: One commenter urged CMS to consider retiring the following measure:

• Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear.

The commenter requests retiring this measure in lieu of retiring Measure 190: Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness, because Measure 100 relates to a relatively uncommon condition seen in audiology practices.

Response: We appreciate the commenter's feedback. According to the 2012 PQRS and eRx Experience Report, we note that no eligible professionals satisfactorily reported this measure. Since eligible professionals attempting to report this measure have had difficulty historically with reporting this measure, we are finalizing our decision not to retain this measure for reporting under PQRS.

Comment: Some commenters requested that the following measure be reclassified from the NCQA domain ''Clinical Process/Effectiveness'' to the ''Care Coordination'' domain:

• Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care

Since the activity addressed in the measure relates to communication and coordination with diabetes patients, the measure is more appropriately classified in the Care Coordination domain.

Response: We appreciate the commenters' feedback. We agree with the commenters that the actions indicated in this measure involve coordination between patients and physicians. We understand that measures may pertain to multiple domains. However, as the EHR Incentive Program has also classified this as a clinical process/effectiveness measure (77 FR 54071), we are retaining the classifying this measure as a clinical process/effectiveness measure. We will, however, consider changing the classification of this measure in the future.

Comment: One commenter supported our proposal to include an Osteoporosis composite measure but suggested that a sub-measure (''Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older'') be added to the Osteoporosis composite measure owned by ABIM.

Response: We appreciate the commenter's feedback and are finalizing the Osteoporosis composite measure for inclusion in the PQRS measures set. However, we are not finalizing this measure under the individual measures set. Rather, this composite measure is being finalized as a measures group as specified in Table 119 because we believe that composite measures are reported more similarly to measures groups under which an eligible professional must report on a group of interrelated measures. Please note that the addition of sub-measures is determined by the measure owner, ABIM. The sub-measure suggested for inclusion under the Osteoporosis measure (''Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older'') is owned by AMA. While we agree that post-fracture care is an important component of quality related to Osteoporosis care, we are unable to add components to composite measures owned by outside entities.

Comment: One commenter opposed our proposal to include the following measures for reporting in PQRS, as the measure owners will no longer support these measures:

- Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered (Paired Measure)
- Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Administered Initiated (Paired Measure)
- Coordination of Care of Patients with Co-Morbid Conditions—Timely Follow-Up (Paired Measure)

Response: We agree with the commenter and are therefore not finalizing these measures for reporting under PQRS.

Please note that we are making the following changes to certain proposed measures for the following reasons:

- Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy—The measure owner updated the threshold of an FEV1/FVC less than 70 percent to 60 percent based on scientific evidence/clinical trials
- Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients—The measure owner updated the age criteria for this measure to 18 to 80
- Adult Major Depressive Disorder (MDD): Comprehensive Depression Evaluation: Diagnosis and Severity—The measure owner has added an assessment of depression severity to this measure
- Oncology: Cancer Stage Documented—The measure owner has broadened the denominator for this measure
- Melanoma: Overutilization of Imaging Studies in Melanoma—The measure owner has incorporated cancer staging into this measure
- Radiation Dose Optimization—The measure owner has updated this measure title to ''Optimizing Patient Exposure to Ionizing Radiation''

A list of the measures we are finalizing for PQRS beginning in 2013 or 2014 is contained in Table 95. Please note that the titles of the measures may change slightly from CMS program and/or CMS program year based on specifications updates. We intend to continue to work toward complete alignment of measure specifications across programs whenever possible.

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Table 95: Individual Quality Measures for the Physician Quality Reporting System Proposed to be Available for Reporting via Claims, Registry, EHR, or GRPO Web Interface Beginning in 2013 or 2014*

NQF/ PQRS	Measures to be added/deleted	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0059/ 1		Clinical Process/ Effective ness	**Diabetes Mellitus: Hemoglobin A1c Poor Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%	NCQ A	X	X	X	X	X	MU1/ MU2 ACO
0064/ 2		Clinical Process/ Effective ness	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQ A	X	X	X		X	MU1/ MU2 Million Hearts
0061/ 3		Clinical Process/ Effective ness	**Diabetes Mellitus: High Blood Pressure Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg)	NCQ A	X	X	X		X	MU1
0081/ 5		Clinical Process/ Effective ness	**Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at **each** hospital discharge	AMA - PCPI/ ACC F/AH A		X	X		X	MU1/ MU2
0067/ 6		Clinical Process/ Effective ness	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen	AMA - PCPI/ ACC	X	X	X		X	MU1

			within a 12 month period who were prescribed aspirin or clopidogrel	F/AHA						
0070/7		Clinical Process/ Effectiveness	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) :** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have prior MI OR a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy	AMA - PCPI/ ACC F/AHA		X	X			MU1/ MU2
0083/8		Clinical Process/ Effectiveness	**Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at **each** hospital discharge	AMA - PCPI/ ACC F/AHA		X	X	X	X	MU1/ MU2 ACO
0105/9		Clinical Process/ Effectiveness	**Major Depressive Disorder (MDD): Antidepressant Medication During Acute Phase for Patients with MDD:** Percentage of patients aged 18 years and older diagnosed with a new episode of MDD and documented as treated with antidepressant medication during the entire 84-day (12-week) acute treatment phase	NCQA	X	X	X			MU1/ MU2
0086/12		Clinical Process/ Effectiveness	**Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma who have an optic nerve head evaluation during one or more office visits within 12 months	AMA - PCPI/ NCQA	X	X	X			MU1/ MU2
0087/14		Clinical Process/ Effectiveness	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of AMD who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months	AMA - PCPI/ NCQA	X	X				
0088/		Clinical	**Diabetic Retinopathy: Documentation**	AMA	X	X	X			MU1/

18		Process/ Effective ness	**of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months	- PCPI/ NCQ A						MU2
0089/ 19		Care Coordinat ion	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months	AMA - PCPI/ NCQ A	X	X	X			MU1/ MU2
0270/ 20		Patient Safety	**Perioperative Care: Timing of Prophylactic Parenteral Antibiotic – Ordering Physician:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or vancomycin, 2 hours), prior to the surgical incision (or start of procedure when no incision is required)	AMA - PCPI/ NCQ A	X	X			X	
0268/ 21		Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin OR cefuroxime for antimicrobial prophylaxis	AMA - PCPI/ NCQ A	X	X			X	
0271/ 22		Patient Safety	**Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures):** Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures	AMA - PCPI/ NCQ A	X	X			X	

			with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time							
0239/23		Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	AMA - PCPI/NCQA	X	X			X	
0045/24		Care Coordination	**Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a hip, spine or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis	AMA - PCPI/NCQA	X	X				
0092/28		Clinical Process/Effectiveness	**Aspirin at Arrival for Acute Myocardial Infarction (AMI):** Percentage of patients, regardless of age, with an emergency department discharge diagnosis of AMI who had documentation of receiving aspirin within 24 hours before emergency department arrival or during emergency department stay	AMA - PCPI/NCQA	X	X				
0269/30		Patient Safety	**Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics:** Percentage of surgical patients aged 18 years and older who receive an anesthetic when undergoing procedures with the indications for prophylactic parenteral antibiotics for whom administration of the prophylactic parenteral antibiotic ordered has been initiated within one	AMA - PCPI/NCQA	X	X				

			hour (if fluoroquinolone or vancomycin, 2 hours) prior to the surgical incision (or start of procedure when no incision is required)							
0240/31		Clinical Process/Effectiveness	**Stroke and Stroke Rehabilitation: Deep Vein Thrombosis (DVT) Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who were administered DVT prophylaxis by end of hospital day 2	AMA - PCPI/NCQA	X	X				
0325/32		Clinical Process/Effectiveness	**Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) who were prescribed antithrombotic therapy at discharge	AMA - PCPI/NCQA	X	X				
0241/33		Clinical Process/Effectiveness	**Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge	AMA - PCPI/NCQA		X				
0243/35		Clinical Process/Effectiveness	**Stroke and Stroke Rehabilitation: Screening for Dysphagia:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who receive any food, fluids or medication by mouth (PO) for whom a dysphagia screening was performed prior to PO intake in accordance with a dysphagia screening tool approved by the institution in which the patient is receiving care	AMA - PCPI/NCQA	X	X				
0244/36		Clinical Process/Effectiveness	**Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage for whom occupational, physical, or speech rehabilitation services were ordered at or prior to inpatient discharge OR documentation that no rehabilitation services are indicated at or prior to inpatient discharge	AMA - PCPI/NCQA	X	X				
0046/		Clinical	**Screening or Therapy for**	AMA	X	X	X		X	

39		Process/ Effective ness	**Osteoporosis for Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who have a central dual-energy X- ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months	- PCPI/ NCQ A						
0048/ 40		Clinical Process/ Effective ness	**Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with fracture of the hip, spine, or distal radius who had a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed or pharmacologic therapy prescribed	AMA - PCPI/ NCQ A	X	X				
0049/ 41		Clinical Process/ Effective ness	**Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months	AMA - PCPI/ NCQ A	X	X				
0134/ 43		Clinical Process/ Effective ness	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft	STS	X	X			X	
0236/ 44		Clinical Process/ Effective ness	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision	CMS/ QIP	X	X			X	
0637/ 45		Patient Safety	**Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Cardiac Procedures):** Percentage of cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 48 hours of surgical end time	AMA - PCPI/ NCQ A	X	X				
0097/ 46		Patient Safety	**Medication Reconciliation:** Percentage of patients aged 65 years and older	AMA -	X	X		X		ACO

			discharged from any inpatient facility (e.g., hospital, skilled nursing facility, or rehabilitation facility) and **seen within 30 days following discharge** in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented	PCPI/ NCQ A						
0326/ 47		Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	AMA - PCPI/ NCQ A	X	X	X			
0098/ 48		Clinical Process/ Effectiveness	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months	AMA - PCPI/ NCQ A	X	X	X		X	
0099/ 49		Clinical Process/ Effectiveness	**Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence whose urinary incontinence was characterized at least once within 12 months	AMA - PCPI/ NCQ A	X	X				
0100/ 50		Patient and Family Engagement	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months	AMA - PCPI/ NCQ A	X	X				
0091/ 51		Clinical Process/ Effectiveness	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented	AMA -PCPI	X	X			X	
0102/ 52		Clinical Process/	**Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator**	AMA -PCPI	X	X			X	

		Effective ness	**Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV_1/FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator							
0047/ 53		Clinical Process/ Effective ness	**Asthma: Pharmacologic Therapy for Persistent Asthma - Ambulatory Care Setting:** Percentage of patients aged 5 through 50 years with a diagnosis of persistent asthma and at least one medical encounter for asthma during the measurement year who were prescribed long-term control medication	AMA - PCPI/ NCQ A	X	X	X		X	MU1
0090/ 54		Clinical Process/ Effective ness	**Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non- Traumatic Chest Pain:** Percentage of patients aged 40 years and older with an emergency department discharge diagnosis of non-traumatic chest pain who had a 12-lead ECG performed	AMA - PCPI/ NCQ A	X	X				
0093/ 55		Clinical Process/ Effective ness	**Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Syncope:** Percentage of patients aged 60 years and older with an emergency department discharge diagnosis of syncope who had a 12-lead ECG performed	AMA - PCPI/ NCQ A	X	X				
0232/ 56		Clinical Process/ Effective ness	**Emergency Medicine: Community-Acquired Pneumonia (CAP): Vital Signs:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia with vital signs documented and reviewed	AMA - PCPI/ NCQ A	X	X				
0096/ 59		Clinical Process/ Effective ness	**Emergency Medicine: Community-Acquired Pneumonia (CAP): Empiric Antibiotic:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia with an appropriate empiric antibiotic prescribed	AMA - PCPI/ NCQ A	X	X				
0001/ 64		Clinical Process/ Effective ness	**Asthma: Assessment of Asthma Control – Ambulatory Care Setting:** Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated at least once for asthma control (comprising asthma impairment and asthma risk)	AMA - PCPI/ NCQ A	X	X	X		X	MU1
0069/ 65		Efficient Use of	**Appropriate Treatment for Children with Upper Respiratory Infection**	NCQ A	X	X				MU2

		Healthcare Resources	**(URI):** Percentage of children aged 3 months through 18 years with a diagnosis of URI who were **not prescribed or dispensed** an antibiotic prescription on or within 3 days of the initial date of service							
0002/66		Efficient Use of Healthcare Resources	**Appropriate Testing for Children with Pharyngitis:** Percentage of children aged 2 through 18 years with a diagnosis of pharyngitis, who were prescribed an antibiotic and who received a group A streptococcus (strep) test for the episode. A higher rate represents better performance (i.e. appropriate testing).	NCQA	X	X	X			MU1/MU2
0377/67		Clinical Process/Effectiveness	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of MDS or an acute leukemia who had baseline cytogenetic testing performed on bone marrow	AMA-PCPI/ASH	X	X				
0378/68		Clinical Process/Effectiveness	**Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy:** Percentage of patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy	AMA-PCPI/ASH	X	X				
0380/69		Clinical Process/Effectiveness	**Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period	AMA-PCPI/ASH	X	X				
0379/70		Clinical Process/Effectiveness	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry:** Percentage of patients aged 18 years and older seen within a 12 month reporting period with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart	AMA-PCPI/ASH	X	X				

0387/71		Clinical Process/Effectiveness	**Breast Cancer: Hormonal Therapy for Stage IC - IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer:** Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period	AMA-PCPI/ASCO/NCCN	X	X	X		X	MU1/MU2
0385/72		Clinical Process/Effectiveness	**Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients:** Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period	AMA-PCPI/ASCO/NCCN	X	X	X		X	MU1/MU2
0464/76		Patient Safety	**Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol:** Percentage of patients, regardless of age, who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique [cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis (or acceptable alternative antiseptics per current guideline)] followed	AMA-PCPI	X	X				
0323/81		Care Coordination	**Adult Kidney Disease: Hemodialysis Adequacy: Solute:** Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week for ≥ 90 days who have a spKt/V ≥ 1.2	AMA-PCPI		X				
0321/82		Care Coordination	**Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute:** Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a total Kt/V ≥ 1.7 per week measured once every 4 months	AMA-PCPI		X				
0393/83		Clinical Process/Effective	**Hepatitis C: Testing for Chronic Hepatitis C – Confirmation of Hepatitis C Viremia:** Percentage of	AMA-PCPI		X				

		ness	patients aged 18 years and older with a diagnosis of hepatitis C seen for an initial evaluation who had HCV RNA testing ordered or previously performed							
0395/84		Clinical Process/Effectiveness	**Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment	AMA-PCPI	X	X			X	
0396/85		Clinical Process/Effectiveness	**Hepatitis C: HCV Genotype Testing Prior to Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment	AMA-PCPI	X	X			X	
0397/86		Clinical Process/Effectiveness	**Hepatitis C: Antiviral Treatment Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12-month reporting period	AMA-PCPI	X	X			X	
0398/87		Clinical Process/Effectiveness	**Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment	AMA-PCPI	X	X			X	
0401/89		Clinical Process/Effectiveness	**Hepatitis C: Counseling Regarding Risk of Alcohol Consumption:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12-months	AMA-PCPI	X	X			X	
0394/90		Clinical Process/Effectiveness	**Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy:** Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment	AMA-PCPI	X	X			X	

0653/91		Clinical Process/ Effectiveness	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	AMA-PCPI	X	X				
0654/93		Care Coordination	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were **not prescribed** systemic antimicrobial therapy	AMA-PCPI	X	X				
0391/99		Clinical Process/ Effectiveness	**Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade	AMA-PCPI/CAP	X	X				
0392/100		Clinical Process/ Effectiveness	**Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	AMA-PCPI/CAP	X	X				
0389/102		Efficient Use of Healthcare Resources	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did **not** have a bone scan performed at any time since diagnosis of prostate cancer	AMA-PCPI	X	X	X			MU1/MU2
0390/104		Clinical Process/ Effectiveness	**Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH	AMA-PCPI	X	X				

			agonist or antagonist)							
0103/ 106		Clinical Process/ Effective ness	**Adult Major Depressive Disorder (MDD): Comprehensive Depression Evaluation: Diagnosis and Severity:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with evidence that they met the DSM-IV-TR criteria for MDD AND for whom there is an assessment of depression severity during the visit in which a new diagnosis or recurrent episode was identified	AMA -PCPI	X	X				
0104/ 107		Clinical Process/ Effective ness	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified	AMA -PCPI	X	X				MU2
0054/ 108		Clinical Process/ Effective ness	**Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy:** Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a DMARD	NCQ A	X	X			X	
0050/ 109		Patient and Family Engagem ent	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with assessment for function and pain	AMA -PCPI	X	X				
0041/ 110		Populatio n/Public Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA -PCPI	X	X	X	X	X	MU1/ MU2 ACO
0043/ 111		Clinical Process/ Effective ness	**Preventive Care and Screening: Pneumococcal Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQ A	X	X	X	X	X	MU1/ MU2 ACO
0031/ 112		Clinical Process/ Effective ness	**Preventive Care and Screening: Breast Cancer Screening:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer within 24 months	NCQ A	X	X	X	X	X	MU1/ MU2 ACO

0034/ 113		Clinical Process/ Effective ness	**Preventive Care and Screening: Colorectal Cancer Screening:** Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening	NCQ A	X	X	X	X	X	MU1/ MU2 ACO
0058/ 116		Efficient Use of Healthcar e Resource s	**Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use:** Percentage of adults aged 18 through 64 years with a diagnosis of acute bronchitis who were **not prescribed or dispensed** an antibiotic prescription on or within 3 days of the initial date of service	NCQ A	X	X				
0055/ 117		Clinical Process/ Effective ness	**Diabetes Mellitus: Dilated Eye Exam:** Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam	NCQ A	X	X	X		X	MU1/ MU2
0066/ 118		Clinical Process/ Effective ness	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy	AMA - PCPI/ ACC F/AH A		X		X		ACO
0062/ 119		Clinical Process/ Effective ness	**Diabetes: Medical Attention for Nephropathy:** Percentage of patients aged 18 through 75 years with diabetes mellitus who received urine protein screening or medical attention for nephropathy during at least one office visit within 12 months	NCQ A	X	X	X		X	MU1/ MU2
AQA adopt ed/ 121		Clinical Process/ Effective ness	**Adult Kidney: Disease Laboratory Testing (Lipid Profile):** Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period	AMA -PCPI	X	X			X	
AQA adopt ed/ 122		Clinical Process/ Effective ness	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and documented proteinuria with a blood	AMA -PCPI	X	X			X	

			pressure < 130/80 mmHg OR ≥ 130/80 mmHg with a documented plan of care							
AQA adopted/ 123		Clinical Process/ Effectiveness	**Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL:** Percentage of calendar months within a 12-month period during which a Hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 4 or 5, not receiving RRT [Renal Replacement Therapy]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy AND have a Hemoglobin level > 12.0 g/dL	AMA -PCPI	X	X			X	
0417/ 126		Clinical Process/ Effectiveness	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months	APM A	X	X				
0416/ 127		Clinical Process/ Effectiveness	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing	APM A	X	X				
0421/ 128		Population/Public Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with a calculated BMI in the past 6 months or during the current visit documented in the medical record AND if the most recent BMI is **outside of normal parameters**, a follow-up plan is documented within the past 6 months or during the current visit **Normal Parameters:** Age 65 years and older BMI ≥ 23 and < 30; Age 18 – 64 years BMI ≥ 18.5 and < 25	CMS/ QIP	X	X	X	X	X	MU1/ MU2 ACO
0419/ 130		Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-	CMS/ QIP	X	X			X	MU2

			counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration							
0420/ 131		Population/Public Health	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment through discussion with the patient including the use of a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	CMS/ QIP	X	X				
0418/ 134		Population/Public Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of encounter using an age appropriate standardized depression screening tool AND, if positive, a follow-up plan is documented on the date of the positive screen	CMS/ QIP	X	X		X		MU2 ACO
0650/ 137		Clinical Process/ Effectiveness	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment	AMA - PCPI/ NCQA		X				
0561/ 138		Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis	AMA - PCPI/ NCQA		X				
0566/ 140		Clinical Process/ Effectiveness	**Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for	AMA - PCPI/ NCQA	X	X				

			preventing progression of AMD							
0563/ 141		Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre- intervention level, a plan of care was documented within 12 months	AMA - PCPI/ NCQA	X	X				
0051/ 142		Clinical Process/ Effectiveness	**Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with an assessment for use of anti-inflammatory or analgesic OTC medications	AMA -PCPI	X	X				
0384/ 143		Patient and Family Engagement	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	AMA -PCPI		X			X	MU2
0383/ 144		Patient and Family Engagement	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain	AMA -PCPI		X			X	
0510/ 145		Patient Safety	**Radiology: Exposure Time Reported for Procedures Using Fluoroscopy:** Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time	AMA - PCPI/ NCQA	X	X				
0508/ 146		Efficient Use of Healthcare Resources	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening:** Percentage of final reports for screening mammograms that are classified as "probably benign"	AMA - PCPI/ NCQA	X	X				
0511/ 147		Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone**	AMA -PCPI	X	X				

			Scintigraphy: Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed							
0322/148		Efficient Use of Healthcare Resources	**Back Pain: Initial Visit:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain	NCQA					X	
0319/149		Clinical Process/ Effectiveness	**Back Pain: Physical Exam:** Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain	NCQA					X	
0314/150		Clinical Process/ Effectiveness	**Back Pain: Advice for Normal Activities:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain	NCQA					X	
0313/151		Clinical Process/ Effectiveness	**Back Pain: Advice Against Bed Rest:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting 4 days or longer at the initial visit to the clinician for the episode of back pain	NCQA					X	
0101/154		Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months	AMA-PCPI/NCQA	X	X				
0101/155		Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	AMA-PCPI/NCQA	X	X				
0382/156		Patient Safety	**Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of pancreatic or lung cancer receiving 3D conformal radiation therapy with documentation in medical record that	AMA-PCPI	X	X				

			radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues							
0455/ 157		Patient Safety	**Thoracic Surgery: Recording of Clinical Stage Prior to Lung Cancer or Esophageal Cancer Resection:** Percentage of surgical patients aged 18 years and older undergoing resection for lung or esophageal cancer who had clinical staging provided prior to surgery	STS	X	X				
0404/ 159		Clinical Process/ Effective ness	**HIV/AIDS: CD4+ Cell Count or CD4+ Percentage:** Percentage of patients aged 6 months and older with a diagnosis of HIV/AIDS for whom a CD4+ cell count or CD4+ cell percentage was performed at least once every 6 months	AMA - PCPI/ NCQ A		X			X	
0405/ 160		Clinical Process/ Effective ness	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 years and older with a diagnosis of HIV/AIDS and CD4+ cell count < 200 cells/mm^3 who were prescribed PCP prophylaxis within 3 months of low CD4+ cell count	AMA - PCPI/ NCQ A		X			X	MU2
0406/ 161		Clinical Process/ Effective ness	**HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy:** Percentage of patients with a diagnosis of HIV/AIDS aged 13 years and older: who have a history of a nadir CD4+ cell count below 350/mm^3 or who have a history of an AIDS-defining condition, regardless of CD4+ cell count; or who are pregnant, regardless of CD4+ cell count or age, who were prescribed potent antiretroviral therapy	AMA - PCPI/ NCQ A		X			X	
N/A/ 162		Clinical Process/ Effective ness	**HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who are receiving potent antiretroviral therapy, who have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy or patients whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and have documentation of a plan of care	AMA - PCPI/ NCQ A		X			X	MU2
0056/ 163		Clinical Process/	**Diabetes Mellitus: Foot Exam:** The percentage of patients aged 18 through	NCQ A	X	X	X		X	MU1/ MU2

		Effective ness	75 years with diabetes who had a foot examination							
0129/ 164		Clinical Process/ Effective ness	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require intubation > 24 hours	STS		X			X	
0130/ 165		Clinical Process/ Effective ness	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention	STS		X			X	
0131/ 166		Clinical Process/ Effective ness	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a **postoperative** stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours	STS		X			X	
0114/ 167		Clinical Process/ Effective ness	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis	STS		X			X	
0115/ 168		Clinical Process/ Effective ness	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	STS		X			X	
0116/ 169		Clinical Process/ Effective ness	**Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on antiplatelet medication	STS		X			X	
0117/ 170		Clinical Process/	**Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered**	STS		X			X	

		Effectiveness	**at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on beta-blockers							
0118/171		Clinical Process/Effectiveness	**Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on a statin or other lipid-lowering regimen	STS		X			X	
0259/172		Clinical Process/Effectiveness	**Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula:** Percentage of patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 4 or 5) or End Stage Renal Disease (ESRD) requiring hemodialysis vascular access documented by surgeon to have received autogenous AV fistula	SVS	X	X				
AQA adopted/173	◊	Population/Public Health	**Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months	AMA-PCPI	X	X	X		X	
AQA adopted/176		Clinical Process/Effectiveness	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of RA who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD)	AMA-PCPI/NCQA	X	X			X	
AQA adopted/177		Clinical Process/Effectiveness	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease activity within 12 months	AMA-PCPI/NCQA	X	X			X	
AQA adopted/178		Clinical Process/Effectiveness	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months	AMA-PCPI/NCQA	X	X			X	
AQA adopt		Clinical Process/	**Rheumatoid Arthritis (RA): Assessment and Classification of**	AMA-	X	X			X	

ed/ 179		Effective ness	**Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease prognosis at least once within 12 months	PCPI/ NCQ A						
AQA adopt ed/ 180		Care Coordinat ion	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of RA who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	AMA - PCPI/ NCQ A	X	X			X	
AQA adopt ed/ 181		Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen on the date of encounter AND a documented follow-up plan on the date of the positive screen	CMS/ QIP	X	X				
AQA adopt ed/ 182		Care Coordinat ion	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies	CMS/ QIP	X	X				
0399/ 183		Populatio n/Public Health	**Hepatitis C: Hepatitis A Vaccination in Patients with HCV:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A	AMA -PCPI	X	X			X	
0400/ 184		Populatio n/Public Health	**Hepatitis C: Hepatitis B Vaccination in Patients with HCV:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B	AMA -PCPI	X	X			X	
0659/ 185		Care Coordinat ion	**Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and	AMA - PCPI/ NCQ A	X	X				

			older receiving a surveillance colonoscopy, with a history of a prior colonic polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy							
0437/ 187		Clinical Process/ Effective ness	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 2 hours of time last known well and for whom IV t-PA was initiated within 3 hours of time last known well	AHA/ ASA/ TJC		X				
N/A/ 188		Care Coordinat ion	**Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear:** Percentage of patients aged birth and older referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with a congenital or traumatic deformity of the ear (internal or external)	AQC	X	X				
N/A/ 189		Care Coordinat ion	**Referral for Otologic Evaluation for Patients with History of Active Drainage from the Ear Within the Previous 90 Days:** Percentage of patients aged birth and older who have disease of the ear and mastoid processes referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with a history of active drainage from the ear within the previous 90 days	AQC	X	X				
N/A/ 190		Care Coordinat ion	**Referral for Otologic Evaluation for Patients with a History of Sudden or Rapidly Progressive Hearing Loss:** Percentage of patients aged birth and older referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation immediately following an audiologic evaluation that verifies and documents sudden or rapidly progressive hearing loss	AQC	X	X				
0565/ 191		Clinical Process/ Effective	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of	AMA - PCPI/		X			X	MU2

		ness	patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery	NCQA						
0564/192		Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence	AMA-PCPI/NCQA		X			X	MU2
0454/193		Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, undergoing surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer, except patients undergoing cardiopulmonary bypass, for whom *either* active warming was used intraoperatively for the purpose of maintaining normothermia, OR at least one body temperature equal to or greater than 36 degrees Centigrade (or 96.8 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time	AMA-PCPI	X	X				
0386/194		Clinical Process/Effectiveness	**Oncology: Cancer Stage Documented:** Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline AJCC cancer stage or documentation that the cancer is metastatic in the medical record at least once within 12 months	AMA-PCPI/ASCO	X	X			X	
0507/195		Clinical Process/Effectiveness	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck	AMA-PCPI/NCQA	X	X				

			duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement							
0074/ 197		Clinical Process/ Effective ness	**Coronary Artery Disease (CAD): Lipid Control:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C < 100 mg/dL, including at a minimum the prescription of a statin	AMA - PCPI/ ACC F/AH A		X	X	X	X	MU1 ACO
0079/ 198		Clinical Process/ Effective ness	**Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment:** Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative results of a recent or prior [any time in the past] LVEF assessment is documented within a 12 month period	AMA - PCPI/ ACC F/AH A		X			X	
0084/ 200	◊	Clinical Process/ Effective ness	**Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation:** Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy	AMA - PCPI/ ACC F/A HA			X			MU1
0073/ 201		Clinical Process/ Effective ness	**Ischemic Vascular Disease (IVD): Blood Pressure Management:** Percentage of patients aged 18 to 75 years with Ischemic Vascular Disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg)	NCQ A	X	X	X		X	MU1
0068/ 204		Clinical Process/ Effective ness	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) with documented use of aspirin or another antithrombotic	NCQ A	X	X	X	X	X	MU1/ MU2 ACO Million Hearts
0409/ 205		Clinical Process/ Effective ness	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia and gonorrhea screenings were performed at least once since the diagnosis of HIV infection	AMA - PCPI/ NCQ A		X			X	

0410/ 208		Clinical Process/ Effective ness	**HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for syphilis at least once within 12 months	AMA - PCPI/ NCQ A		X			X	
0445/ 209		Clinical Process/ Effective ness	**Functional Communication Measure - Spoken Language Comprehension:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Comprehension Functional Communication Measure	ASH A		X				
0449/ 210		Clinical Process/ Effective ness	**Functional Communication Measure – Attention:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Attention Functional Communication Measure	ASH A		X				
0448/ 211		Clinical Process/ Effective ness	**Functional Communication Measure – Memory:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Memory Functional Communication Measure	ASH A		X				
0447/ 212		Clinical Process/ Effective ness	**Functional Communication Measure - Motor Speech:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Motor Speech Functional Communication Measure	ASH A		X				
0446/ 213		Clinical Process/ Effective ness	**Functional Communication Measure – Reading:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Reading Functional Communication Measure	ASH A		X				
0444/ 214		Clinical Process/ Effective ness	**Functional Communication Measure - Spoken Language Expression:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Expression Functional Communication Measure	ASH A		X				
0442/ 215		Clinical Process/	**Functional Communication Measure – Writing:** Percentage of patients aged 16	ASH A		X				

		Effectiveness	years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Writing Functional Communication Measure							
0443/216		Clinical Process/Effectiveness	**Functional Communication Measure – Swallowing:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Swallowing Functional Communication Measure	ASHA		X				
0422/217		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the knee in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				
0423/218		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the hip in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				
0424/219		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lower leg, foot or ankle in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				
0425/220		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lumbar spine in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				
0426/221		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments:**	FOTO		X				

			Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the shoulder in which the change in their Risk-Adjusted Functional Status is measured							
0427/ 222		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the elbow, wrist or hand in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				
0428/ 223		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the neck, cranium, mandible, thoracic spine, ribs, or other general orthopedic impairment in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				
0562/ 224		Efficient Use of Healthcare Resources	**Melanoma: Overutilization of Imaging Studies in Melanoma:** Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered	AMA-PCPI/NCQA		X				
0509/ 225		Care Coordination	**Radiology: Reminder System for Mammograms:** Percentage of patients aged 40 years and older undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram	AMA-PCPI/NCQA	X	X				
0028/ 226		Population/Public Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a	AMA-PCPI	X	X	X	X	X	MU1/ MU2 ACO Million Hearts

			tobacco user							
N/A/ 228		Clinical Process/ Effective ness	**Heart Failure (HF): Left Ventricular Function (LVF) Testing:** Percentage of patients 18 years and older with Left Ventricular Function (LVF) testing performed within the previous 12 months for patients who are hospitalized with a principal diagnosis of Heart Failure (HF) during the reporting period	CMS/ QIP		X				
N/A/ 231		Clinical Process/ Effective ness	**Asthma: Tobacco Use: Screening - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period	AMA - PCPI/ NCQ A	X	X			X	
N/A/ 232		Clinical Process/ Effective ness	**Asthma: Tobacco Use: Intervention - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were identified as tobacco users (patients who currently use tobacco AND patients who do not currently use tobacco, but are exposed to second hand smoke in their home environment) who received tobacco cessation intervention at least once during the one-year measurement period	AMA - PCPI/ NCQ A	X	X			X	
0457/ 233		Clinical Process/ Effective ness	**Thoracic Surgery: Recording of Performance Status Prior to Lung or Esophageal Cancer Resection:** Percentage of patients aged 18 years and older undergoing resection for lung or esophageal cancer who had performance status documented and reviewed within 2 weeks prior to surgery	STS		X				
0458/ 234		Patient Safety	**Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy, or Formal Segmentectomy):** Percentage of thoracic surgical patients aged 18 years and older undergoing at least one pulmonary function test within 12 months prior to a major lung resection (pneumonectomy, lobectomy, or formal segmentectomy)	STS		X				
0018/ 236		Clinical Process/ Effective	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age	NCQ A	X	X	X	X	X	MU1/ MU2 ACO

		ness	who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)							Million Hearts
0013/ 237	◊	Clinical Process/ Effective ness	**Hypertension (HTN): Blood Pressure Measurement:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of hypertension with blood pressure (BP) recorded	AMA -PCPI			X			MU1
0022/ 238		Patient Safety	**Drugs to be Avoided in the Elderly:** Percentage of patients ages 65 years and older who received at least one drug to be avoided in the elderly and/or two different drugs to be avoided in the elderly in the measurement period	NCQ A			X			MU2
0024/ 239		Populatio n/Public Health	**Weight Assessment and Counseling for Children and Adolescents:** Percentage of children 2 through 17 years of age who had an outpatient visit with a PCP or OB/GYN and who had evidence of BMI percentile documentation, counseling for nutrition and counseling for physical activity during the measurement period	NCQ A			X			MU1/ MU2
0038/ 240		Populatio n/Public Health	**Childhood Immunization Status:** The percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV); one measles, mumps, rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); two hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday	NCQ A			X			MU1/ MU2
0075/ 241		Clinical Process/ Effective ness	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)	NCQ A	X	X	X	X	X	MU1/ MU2 ACO Million Hearts
N/A/ 242		Clinical Process/ Effective ness	**Coronary Artery Disease (CAD): Symptom Management:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period with an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with	AMA - PCPI/ ACC F/AH A		X			X	

			appropriate management of anginal symptoms within a 12 month period							
0643/ 243		Clinical Process/ Effective ness	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program	ACC F-AHA		X				
N/A/ 244		Clinical Process/ Effective ness	**Hypertension: Blood Pressure Management:** Percentage of patients aged 18 years and older with a diagnosis of hypertension seen within a 12 month period with a blood pressure < 140/90 mmHg OR patients with a blood pressure ≥ 140/90 mmHg and prescribed two or more anti-hypertensive medications during the most recent office visit	AMA - PCPI/ ACC F/AH A		X				
AQA adopt ed/ 245		Clinical Process/ Effective ness	**Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers (Overuse Measure):** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer **without** the use of a wound surface culture technique	AMA - PCPI/ NCQ A	X	X				
AQA adopt ed/ 246		Clinical Process/ Effective ness	**Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers (Overuse Measure):** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer **without** a prescription or recommendation to use wet to dry dressings	AMA - PCPI/ NCQ A	X	X				
AQA adopt ed/ 247		Clinical Process/ Effective ness	**Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence:** Percentage of patients aged 18 years and older with a diagnosis of current alcohol dependence	AMA - PCPI/ NCQ A	X	X				

			who were counseled regarding psychosocial AND pharmacologic treatment options for alcohol dependence within the 12-month reporting period							
AQA adopted/ 248		Clinical Process/ Effectiveness	**Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence:** Percentage of patients aged 18 years and older with a diagnosis of current substance abuse or dependence who were screened for depression within the 12-month reporting period	AMA - PCPI/ NCQA	X	X				
N/A/ 249		Clinical Process/ Effectiveness	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia	CAP	X	X				
N/A/ 250		Clinical Process/ Effectiveness	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status	CAP	X	X				
N/A/ 251		Clinical Process/ Effectiveness	**Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients:** This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer	CAP	X	X				
0503/ 252		Clinical Process/ Effectiveness	**Anticoagulation for Acute Pulmonary Embolus Patients:** Anticoagulation ordered for patients who have been discharged from the emergency department (ED) with a diagnosis of acute pulmonary embolus	ACEP	X	X				
0651/ 254		Clinical Process/ Effectiveness	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine	ACEP	X	X				

			pregnancy location							
0652/ 255		Clinical Process/ Effective ness	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED)	ACEP	X	X				
N/A/ 256		Care Coordinat ion	**Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR):** Percentage of patients 18 years of age or older undergoing endovascular abdominal aortic aneurysm repair (EVAR) who have at least one follow-up imaging study after 3 months and within 15 months of EVAR placement that documents aneurysm sac diameter and endoleak status	SVS		X				
N/A/ 257		Clinical Process/ Effective ness	**Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge	SVS		X				
N/A/ 258		Care Coordinat ion	**Rate of Open Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7)	SVS		X				
N/A/ 259		Care Coordinat ion	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2)	SVS		X				
N/A/ 260		Care Coordinat ion	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-**	SVS		X				

			Operative Day #2): Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2							
N/A/ 261		Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness	AQC	X	X				
N/A/ 262		Patient Safety	**Image Confirmation of Successful Excision of Image–Localized Breast Lesion:** Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion, focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy.	ASBS	X	X				
N/A/ 263		Clinical Process/ Effectiveness	**Preoperative Diagnosis of Breast Cancer:** The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method	ASBS	X	X				
N/A/ 264		Clinical Process/ Effectiveness	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients who undergo a sentinel lymph node (SLN) procedure	ASBS		X				
0645/ 265		Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	AAD		X				
N/A/ 266		Clinical Process/ Effectiveness	**Epilepsy: Seizure Type(s) and Current Seizure Frequency(ies):** Percentage of patient visits with a diagnosis of epilepsy who had the	AAN	X	X				

			type(s) of seizure(s) and current seizure frequency(ies) for each seizure type documented in the medical record							
N/A/ 267		Clinical Process/ Effective ness	**Epilepsy: Documentation of Etiology of Epilepsy or Epilepsy Syndrome:** All visits for patients with a diagnosis of epilepsy who had their etiology of epilepsy or with epilepsy syndrome(s) reviewed and documented if known, or documented as unknown or cryptogenic	AAN	X	X				
N/A/ 268		Clinical Process/ Effective ness	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12-44 years old) diagnosed with epilepsy who were counseled about epilepsy and how its treatment may affect contraception and pregnancy at least once a year	AAN	X	X				
N/A/ 269		Clinical Process/ Effective ness	**Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Documented:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have documented the disease type, anatomic location and activity, at least once during the reporting period	AGA					X	
N/A/ 270		Clinical Process/ Effective ness	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year	AGA					X	
N/A/ 271		Clinical Process/ Effective ness	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have received dose of corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days and were assessed for risk of bone loss once per the reporting year	AGA					X	
N/A/ 272		Clinical Process/ Effective	**Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization:** Percentage of patients	AGA					X	

		ness	aged 18 years and older with a diagnosis of inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year							
N/A/ 273		Clinical Process/ Effective ness	**Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received	AGA					X	
N/A/ 274		Clinical Process/ Effective ness	**Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA					X	
N/A/ 275		Clinical Process/ Effective ness	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA					X	
N/A/ 276		Clinical Process/ Effective ness	**Sleep Apnea: Assessment of Sleep Symptoms:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of symptoms, including presence or absence of snoring and daytime sleepiness	AMA - PCPI/ NCQ A					X	
N/A/ 277		Clinical Process/ Effective ness	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis	AMA - PCPI/ NCQ A					X	
N/A/ 278		Clinical Process/	**Sleep Apnea: Positive Airway Pressure Therapy Prescribed:**	AMA -					X	

		Effectiveness	Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy	PCPI/NCQA						
N/A/279		Clinical Process/Effectiveness	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured	AMA-PCPI/NCQA					X	
N/A/280		Care Coordination	**Dementia: Staging of Dementia:** Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period	AMA-PCPI					X	
N/A/281		Clinical Process/Effectiveness	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period	AMA-PCPI					X	MU2
N/A/282		Clinical Process/Effectiveness	**Dementia: Functional Status Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of patient's functional status is performed and the results reviewed at least once within a 12 month period	AMA-PCPI					X	
N/A/283		Clinical Process/Effectiveness	**Dementia: Neuropsychiatric Symptom Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of patient's neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period	AMA-PCPI					X	
N/A/284		Clinical Process/Effectiveness	**Dementia: Management of Neuropsychiatric Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period	AMA-PCPI					X	
N/A/285		Clinical Process/	**Dementia: Screening for Depressive Symptoms:** Percentage of patients,	AMA-PCPI					X	

		Effectiveness	regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period							
N/A/286		Patient Safety	**Dementia: Counseling Regarding Safety Concerns:** Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period	AMA-PCPI					X	
N/A/287		Clinical Process/Effectiveness	**Dementia: Counseling Regarding Risks of Driving:** Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period	AMA-PCPI					X	
N/A/288		Clinical Process/Effectiveness	**Dementia: Caregiver Education and Support:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period	AMA-PCPI					X	
N/A/289		Clinical Process/Effectiveness	**Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review:** All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications than can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually	AAN					X	
N/A/290		Clinical Process/Effectiveness	**Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually	AAN					X	

N/A/ 291		Clinical Process/ Effective ness	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually	AAN					X	
N/A/ 292		Clinical Process/ Effective ness	**Parkinson's Disease: Querying about Sleep Disturbances:** All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually	AAN					X	
N/A/ 293		Clinical Process/ Effective ness	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually	AAN					X	
N/A/ 294		Clinical Process/ Effective ness	**Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually	AAN					X	
N/A/ 295		Clinical Process/ Effective ness	**Hypertension: Appropriate Use of Aspirin or Other Antithrombotic Therapy:** Percentage of patients aged 30 through 90 years old with a diagnosis of hypertension and are eligible for asprin or other antithrombotic therapy who were prescribed aspirin or other antithrombotic therapy	ABI M					X	
N/A/ 296		Clinical Process/ Effective ness	**Hypertension: Complete Lipid Profile:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within **60 months**	ABI M					X	
N/A/ 297		Clinical Process/ Effective ness	**Hypertension: Urine Protein Test:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within **36 months**	ABI M					X	
N/A/ 298		Clinical Process/	**Hypertension: Annual Serum Creatinine Test:** Percentage of patients	ABI M					X	

		Effectiveness	aged 18 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within **12 months**							
N/A/299		Clinical Process/Effectiveness	**Hypertension: Diabetes Mellitus Screening Test:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within **36 months**	ABIM					X	
N/A/300		Clinical Process/Effectiveness	**Hypertension: Blood Pressure Control:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had most recent blood pressure level under control (at goal)	ABIM					X	
N/A/301		Clinical Process/Effectiveness	**Hypertension: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had most recent LDL cholesterol level under control (at goal)	ABIM					X	
N/A/302		Clinical Process/Effectiveness	**Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within **12 months**	ABIM					X	
N/A/303		Clinical Process/Effectiveness	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey	AAO		X			X	
N/A/304		Patient and Family Engagement	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey	AAO		X			X	
0004/305		Clinical Process/Effectiveness	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement:** Percentage of adolescent and adult patients with a new episode of alcohol or other drug (AOD) dependence	NCQA			X			MU1/MU2

			who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis and who initiated treatment **AND** who had two or more additional services with an AOD diagnosis within 30 days of the initial visit							
0012/ 306	◊	Population/Public Health	**Prenatal Care: Screening for Human Immunodeficiency Virus (HIV):** Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal visit	AMA -PCPI			X			MU1
0014/ 307	◊	Patient Safety	**Prenatal Care: Anti-D Immune Globulin:** Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation	AMA -PCPI			X			MU1
0027/ 308	◊	Population/Public Health	**Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies:** Percentage of patients aged 18 years and older who were current smokers or tobacco users, who were seen by a practitioner during the measurement year and who received advice to quit smoking or tobacco use or whose practitioner recommended or discussed smoking or tobacco use cessation medications, methods or strategies	NCQ A			X			MU1
0032/ 309		Clinical Process/ Effectiveness	**Cervical Cancer Screening:** Percentage of women aged 21 through 63 years who received one or more Pap tests to screen for cervical cancer	NCQ A			X			MU1/ MU2
0033/ 310		Population/Public Health	**Chlamydia Screening for Women:** Percentage of women aged 15 through 24 years who were identified as sexually active and who had at least one test for chlamydia during the measurement year	NCQ A			X			MU1/ MU2
0036/ 311		Clinical Process/ Effectiveness	**Use of Appropriate Medications for Asthma:** Percentage of patients aged 5 through 50 years of age who were identified as having persistent asthma and were appropriately prescribed	NCQ A			X			MU1/ MU2

			medication during the measurement year							
0052/ 312		Efficient Use of Healthcare Resources	**Low Back Pain: Use of Imaging Studies:** Percentage of patients with a primary diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of diagnosis	NCQA			X			MU1/ MU2
0575/ 313	◊	Clinical Process/ Effectiveness	**Diabetes Mellitus: Hemoglobin A1c Control (< 8%):** The percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 or type 2) who had HbA1c < 8%	NCQA			X			MU1
N/A/ 316		Clinical Process/ Effectiveness	**Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL:** Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed *There are three criteria for this measure based on the patient's risk category. 1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent 2. Moderate Level of Risk: Multiple (2+) Risk Factors 3. Lowest Level of Risk: 0 or 1 Risk Factor	CMS/ QIP			X			MU2 Million Hearts
N/A/ 317		Population/Public Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated	CMS/ QIP	X	X	X	X	X	MU2 ACO Million Hearts
0101/ 318		Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients aged 65 years and older who were screened for future fall risk at least once within the reporting period	AMA-PCPI/ NCQA				X		MU2 ACO
0729/ TBD	‡	Clinical Process/ Effectiveness	**Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: • A1c < 8.0%, • LDL < 100 mg/dL, • blood pressure < 140/90 mmHg,	MNCM				X		ACO

			• tobacco non-user and • for patients with a diagnosis of ischemic vascular disease daily aspirin use unless contraindicated							
0658/ TBD	‡	Care Coordination	**Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report	AMA -PCPI	X	X				
0493/ TBD	‡	Care Coordination	**Participation by a Hospital, Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality:** Participation in a systematic qualified clinical database registry involves: a. Physician or other clinician submits standardized data elements to registry. b. Data elements are applicable to consensus endorsed quality measures. c. Registry measures shall include at least two (2) representative NQF consensus endorsed measures for registry's clinical topic(s) and report on all patients eligible for the selected measures. d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians. e. Registry must receive data from more than 5 separate practices and may not be located (warehoused) at an individual group's practice. Participation in a national or state-wide registry is encouraged for this measure. f. Registry may provide feedback directly to the provider's local registry if one exists.	OFM Q	X	X				
0005 & 0006/ TBD	‡	Care Coordination	**CG-CAHPS Clinician/Group Survey** • Getting timely care, appointments and information • How well your doctors communicate • Patients rating of doctor • Access to specialists	ASPE				X		ACO

			• Health promotion and education • Shared decision making • Health status/Functional status							
0670/ TBD	‡	Efficient Use of Healthcare Resources	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12-month reporting period	ACC		X				
0671/ TBD	‡	Efficient Use of Healthcare Resources	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status	ACC		X				
0672/ TBD	‡	Efficient Use of Healthcare Resources	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment	ACC		X				
TBD/ TBD	‡	Clinical Process/ Effectiveness	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major	AMA -PCPI		X				

			depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], ESRD or congestive heart failure) being treated by another clinician with communication to the other clinician treating the comorbid condition							
1525/ TBD	‡ ‡	Patient Safety	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Patients aged 18 and older with a diagnosis of nonvalvular AF or atrial flutter whose assessment of specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism	AMA - PCPI/ ACC F/AH A	X	X				
TBD/ TBD	‡ ‡	Clinical Process/ Effective ness	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist	AMA	X	X				
1667/ TBD	‡ ‡	Clinical Process/ Effective ness	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL	AMA -PCPI	X	X				
N/A/ TBD	○	Care Coordinat ion	**Total Knee Replacement: Coordination of Post Discharge Care:** Percentage of patients undergoing total knee replacement who received written instructions for post discharge care including all the following: post discharge physical therapy, home health care, post discharge deep vein thrombosis (DVT) prophylaxis and follow-up physician visits	AAH KS/A MA- PCPI					X	

N/A/ TBD	○	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including history of deep vein thrombosis (DVT), pulmonary embolism (PE), myocardial infarction (MI), arrhythmia and stroke	AAH KS/A MA-PCPI					X	
N/A/ TBD	○	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	AAH KS/A MA-PCPI)					X	
N/A/ TBD	○	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant	AAH KS/A MA-PCPI					X	
TBD/ TBD	○	Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for CT Imaging Description:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature (e.g., RadLex®) and the standardized nomenclature is used in institutions computer systems	AMA -PCPI					X	
TBD/ TBD	○	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation : Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) Scans and Cardiac Nuclear Medicine Scans:** Percentage of CT and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT studies (any type of CT) and cardiac nuclear medicine (myocardial perfusion studies) studies	AMA -PCPI					X	

			that the patient has received in the 12-month period prior to the current study							
TBD/ TBD	○	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements	AMA -PCPI					X	
TBD/ TBD	○	Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: CT Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study	AMA -PCPI					X	
TBD/ TBD	○	Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Imaging Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient imaging studies completed at non-affiliated external entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed	AMA -PCPI					X	
N/A/ TBD	○	Clinical Process/ Effectiveness	**Osteoporosis: Status of Participation in Weight-Bearing Exercise and Weight-bearing Exercise Advice:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose status regarding participation in weight-bearing exercise was documented and for those not	ABIM					X	

			participating regularly who received advice within 12 months to participate in weight-bearing exercise							
N/A/ TBD	○	Clinical Process/ Effective ness	**Osteoporosis: Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose current level of alcohol use was documented and for those engaging in potentially hazardous drinking who received counseling within 12 months	ABI M					X	
N/A/ TBD	○	Patient Safety	**Osteoporosis: Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a screen for falls risk evaluation within the past 12 months and for those reported as having a history of two or more falls, or fall-related injury who had a complete risk assessment for falls and a falls plan of care within the past 12 months	ABI M					X	
N/A/ TBD	○	Care Coordinat ion	**Osteoporosis: Dual-Emission X-ray Absorptiometry (DXA) Scan:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a DXA scan and result documented	ABI M					X	
N/A/ TBD	○	Clinical Process/ Effective ness	**Osteoporosis: Calcium Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had calcium intake assessment and counseling at least once within 12 months	ABI M					X	
N/A/ TBD	○	Clinical Process/ Effective ness	**Osteoporosis: Vitamin D Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70	ABI M					X	

			and older who had vitamin D intake assessment and counseling at least once within 12 months							
N/A/ TBD	○	Clinical Process/ Effective ness	**Osteoporosis: Pharmacologic Therapy:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who were prescribed pharmacologic therapy approved by the Food and Drug Administration	ABI M					X	
N/A/ TBD	○	Clinical Process/ Effective ness	**Preventive Cardiology Composite: Blood Pressure at Goal:** Percentage of patients in the sample whose most recent blood pressure reading was at goal	ABI M					X	
N/A/ TBD	○	Clinical Process/ Effective ness	**Preventive Cardiology Composite: Low Density Lipids (LDL) Cholesterol at Goal:** Percentage of patients in the sample whose LDL cholesterol is considered to be at goal, based upon their coronary heart disease (CHD) risk factors	ABI M					X	
N/A/ TBD	○	Clinical Process/ Effective ness	**Preventive Cardiology Composite: Timing of Lipid Testing Complies with Guidelines:** Percentage of patients in the sample whose timing of lipid testing complies with guidelines (lipid testing performed in the preceding 12-month period (with a 3-month grace period) for patients with known coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus); or in the preceding 24-month period (with a 3-month grace period) for patients with ≥ 2 risk factors for CHD (smoking, hypertension, low high density lipid (HDL), men ≥ 45 years, women ≥ 55 years, family history of premature CHD; HDL ≥ 60 mg/dL acts as a negative risk factor); or in the preceding 60-month period (with a 3-month grace period) for patients with ≤ 1 risk factor for CHD)	ABI M					X	
N/A/ TBD	○	Clinical Process/ Effective ness	**Preventive Cardiology Composite: Diabetes Documentation or Screen Test:** Percentage of patients in the sample who had a screening test for type 2 diabetes or had a diagnosis of diabetes	ABI M					X	

N/A/ TBD	○	Clinical Process/ Effective ness	**Preventive Cardiology Composite: Correct Determination of Ten-Year Risk for Coronary Death or Myocardial Infarction (MI):** Number of patients in the sample whose ten-year risk of coronary death or MI is correctly assessed and documented	ABI M					X	
N/A/ TBD	○	Clinical Process/ Effective ness	**Preventive Cardiology Composite: Counseling for Diet and Physical Activity:** Percentage of patients in the sample who received dietary and physical activity counseling	ABI M					X	
N/A/ TBD	○	Clinical Process/ Effective ness	**Preventive Cardiology Composite: Appropriate Use of Aspirin or Other Antiplatelet/Anticoagulant Therapy:** Percentage of patients in the sample who are: 1) taking aspirin or other anticoagulant/antiplatelet therapy, or 2) under age 30, or 3) age 30 or older and who are documented to be at low risk. Low-risk patients include those who are documented with no prior coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus) and whose ten-year risk of developing CHD is < 10%	ABI M					X	
N/A/ TBD	○	Clinical Process/ Effective ness	**Preventive Cardiology Composite: Smoking Status and Cessation Support:** Percentage of patients in the sample whose current smoking status is documented in the chart, and if they were smokers, were documented to have received smoking cessation counseling during the reporting period	ABI M					X	
0060/ TBD	○	Clinical Process/ Effective ness	**Hemoglobin A1c Test for Pediatric Patients:** Percentage of pediatric patients 5-17 years of age with diabetes with a HbA1c test during the measurement period	NCQ A			X			MU2
0108/ TBD	○	Clinical Process/ Effective ness	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. A. Percentage of children who had one	NCQ A			X			MU2

			follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. B. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.							
0110/ TBD	○	Clinical Process/ Effectiveness	**Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use	Center for Quality Assessment and Improvement in Mental Health			X			MU2
0403/ TBD	○	Efficient Use of Healthcare Resources	**HIV/AIDS: Medical Visit:** Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 60 days between each visit	AMA /NCQA			X			MU2
0608/ TBD	○	Clinical Process/ Effectiveness	**Pregnant women that had HBsAg testing:** This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy	Ingenix			X			MU2
0710/ TBD	○	Clinical Process/ Effectiveness	**Depression Remission at Twelve Months:** Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at 12 months defined as PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment	MNCM			X			MU2
0712/ TBD	○	Clinical Process/ Effectiveness	**Depression Utilization of the PHQ-9 Tool:** Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ-9 tool administered at least once during a 4 month period in which there was a qualifying visit	MNCM			X			MU2
1401/	○	Populati	**Maternal depression screening:** The	NCQ			X			MU2

TBD		on/Public Health	percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life	A						
Not yet endorsed/ TBD	○	Clinical Process/Effectiveness	**Hypertension: Improvement in blood pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period	CMS			X			MU2
Not yet endorsed/ TBD	○	Care Coordination	**Closing the referral loop: receipt of specialist report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred	CMS			X			MU2
Not yet endorsed/ TBD	○	Patient and Family Engagement	**Functional status assessment for knee replacement:** Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments	CMS			X			MU2
Not yet endorsed/ TBD	○	Patient and Family Engagement	**Functional status assessment for hip replacement:** Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments	CMS			X			MU2
Not yet endorsed/ TBD	○	Patient and Family Engagement	**Functional status assessment for complex chronic conditions:** Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments	CMS			X			MU2
TBD/ TBD	○	Clinical Process/ Effectiveness	**Children who have dental decay or cavities:** Percentage of children ages 0-20, who have had tooth decay or cavities during the measurement period	Maternal and Child Health Bureau, Health Resources			X			MU2

				and Services						
TBD/ TBD	○	Clinical Process/ Effectiveness	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period	University of Minnesota			X			MU2
TBD/ TBD	○	Patient Safety	**ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range:** Average percentage of time in which individuals with atrial fibrillation who are on chronic anticoagulation have International Normalized Ratio (INR) test results within the therapeutic range during the measurement period	CMS			X			MU2

* MU1 refers to CQMs included in the EHR Incentive Program – Stage 1 Final Rule for reporting in 2011-2013.
MU2 refers to CQMs included in the EHR Incentive Program – Stage 2 Final Rule for reporting beginning in 2014

(3) PQRS Quality Measures Available for Group Practices Using the GPRO Web Interface

We have previously discussed our measure proposals for group practices using the GPRO web interface in the proposed rule (77 FR 44954). A summary of these proposed measures for group practices using the GPRO web interface can be found in Table 35 of the CY 2013 PFS proposed rule (77 FR 44960). We proposed (77 FR 44959) 18 measures—including 2 composite measures for diabetes (5 component measures) and CAD (2 component measures), for a total of 22 measures—for reporting under the PQRS using the GPRO web interface for 2013 and beyond to align with the quality measures available for reporting under the Medicare Shared Savings Program (76 FR 67890). Because of our desire to align with measures available for reporting under the Medicare Shared Savings Program, we did not propose to retain the 13 measures specified in Table 36 of the CY 2013 PFS proposed rule for purpose of reporting via the GPRO web interface beginning in 2013 (77 FR 44963). We invited public comment on the proposed PQRS quality measures available for reporting under the GPRO web interface for 2013 and beyond. We did not receive public comment on a majority of the measures we proposed for reporting in the GPRO web interface. The following is a summary of the comments we did receive regarding the proposed measures for the GPRO web interface:

Comment: Several commenters supported our overall proposal to align the measures available for reporting in the GPRO web interface with the measures that are available for reporting under the Medicare Shared Savings Program.

Response: We appreciate the commenters' support and are moving forward with our proposals to align the measures available for reporting in the GPRO web interface with the measures that are available for reporting under the Medicare Shared Savings Program. Therefore, mainly due to our desire to align measures available under PQRS and the Medicare Shared Savings Program, as indicated in Table 96 of this final rule, we are finalizing the 18 measures—which includes 2 composites, for a total of 22 measures — we proposed to be available for reporting via the GPRO web interface and not retaining 13 measures that were previously available for reporting under the GPRO web interface in 2012.

We also proposed to have the following measure available for reporting occurring in 2013 and beyond: CG–CAHPS Clinician/Group Survey: Getting timely care, appointments and information; How well your doctors communicate; Patients' rating of doctor; Access to specialists; Health promotion and education; Shared decision making; Courteous and helpful office staff; Care coordination; Between visit communication; Educating patients about medication adherences; and Stewardship of patient resources (77 FR 44964).

Comment: One commenter noted that the proposed CAHPS measures do not apply to hospital-based physicians and encouraged PQRS to incorporate measures that reflect care provided by all types of physicians.

Response: We believe that PQRS measures should be broadly applicable to eligible professionals of varying practices. Therefore, we are not excluding hospital-based physicians from reporting the CAHPS measures, as we believe these CAHPS measures may be relevant to the practice of hospital-based physicians.

Comment: One commenter requested that our proposal to report the CG–CAHPS survey measure under the GPRO web interface be made voluntary as the survey is expensive to administer.

Response: We understand the commenter's concern regarding the expense of administering the CG–CAHPS survey. However, we require group practices using the GPRO web interface to report on all measures available under the GPRO web interface. As this CG–CAHPS survey is part of the GPRO web interface, it will be mandatory for group practices using the GPRO web interface to also be held accountable for the survey results. We are developing a process, however, to standardize the administration of the survey, which should help lower the cost. We note that this survey measure requires a different form of data collection and analysis than the other proposed measures in the PQRS. Therefore, for these measures only, CMS intends to administer the survey on

behalf of the group practices participating in the 2013 and 2014 PQRS GPRO. In other words, CMS initially intends to fund data collection for this measure on group practices' behalf for the CYs 2013 and 2014 reporting periods.

The final measures available for reporting using the GPRO web interface beginning in 2013 and listed in Table 96:

Table 96: PQRS Quality Measures Available for Reporting for Group Practices Using the GPRO Web Interface for 2013 and Beyond

NQF/ PQRS	GPRO Disease Module	National Quality Strategy Domain	Measure and Title Description¥	Measure Steward	Other Quality Reporting Programs
0059/ 1	Diabetes Mellitus	Clinical Process/ Effectiveness	**Diabetes: Hemoglobin A1c Poor Control:** Percentage of patients aged 18 through75 years of age with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%	NCQA	HITECH ACO
0083/ 8	Heart Failure	Clinical Process/ Effectiveness	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at **each** hospital discharge	AMA-PCPI/ ACCF /AHA	HITECH ACO
0097/ 46	Care Coordination/ Patient Safety	Patient Safety	**Medication Reconciliation:** Percentage of patients aged 65 years and older **discharged from any inpatient facility** (e.g. hospital, skilled nursing facility, or rehabilitation facility) and **seen within 60 days following discharge** in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented	AMA-PCPI/ NCQA	ACO
0041/ 110	Preventive Care	Population /Public Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI	HITECH ACO
0043/ 111	Preventive Care	Clinical Process/ Effectiveness	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQA	HITECH ACO
0031/ 112	Preventive Care	Clinical Process/ Effectiven	**Preventive Care and Screening: Breast Cancer Screening:** Percentage of women aged 40 through69 years who had a mammogram to	NCQA	HITECH ACO

		ess	screen for breast cancer within 24 months		
0034/ 113	Preventi ve Care	Clinical Process/ Effectiven ess	**Colorectal Cancer Screening:** Percentage of patients aged 50 through75 years who received the appropriate colorectal cancer screening	NCQA	HITECH ACO
0066/ 118	Coronar y Artery Disease	Clinical Process/ Effectiven ess	**Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy	AMA-PCPI/ ACCF /AHA	ACO
0421/ 128	Preventi ve Care	Population /Public Health	**Adult Weight Screening and Follow-Up:** Percentage of patients aged 18 years and older with a calculated body mass index (BMI) in the past 6 months or during the current visit documented in the medical record AND if the most recent BMI is **outside of normal parameters**, a follow-up plan is documented within the past 6 months or during the current visit **Normal Parameters**: Age 65 years and older BMI ≥ 23 and < 30; Age 18-64 years BMI ≥ 18.5 and < 25	CMS/ QIP	HITECH ACO
0418/ 134	Preventi ve Care	Population /Public Health	**Preventive Care and Screening: Screening for Clinical Depression:** Percentage of patients aged 12 years and older screened for clinical depression on the date of encounter using an age appropriate standardized depression screening tool AND, if positive, a follow-up plan documented on the date of the positive screen	CMS/ QIP	HITECH ACO
0074/ 197	Coronar y Artery Disease	Clinical Process/ Effectiven ess	**Coronary Artery Disease (CAD): Lipid Control:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C < 100mg/dL, including at a minimum the prescription of a statin	AMA-PCPI/ ACCF /AHA	ACO
0068/ 204	Ischemi c	Clinical Process/	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:**	NCQA	HITECH ACO

	Vascular Disease	Effectiveness	Percentage of patients 18 years of age and older with Ischemic Vascular Disease (IVD) with documented use of aspirin or another antithrombotic		Million Hearts
0028/ 226	Preventive Care	Population /Public Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI	HITECH ACO Million Hearts
0018/ 236	Hypertension	Clinical Process/ Effectiveness	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged18 through85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure was adequately controlled (< 140/90 mmHg)	NCQA	HITECH ACO Million Hearts
0075/ 241	Ischemic Vascular Disease	Clinical Process/ Effectiveness	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)	NCQA	HITECH ACO Million Hearts
N/A/ 317	Preventive Care	Population /Public Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the measurement period who were screened for high blood pressure (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated	CMS/ QIP	HITECH ACO Million Hearts
0101/ 318	Care Coordination/ Patient Safety	Patient Safety	**Falls: Screening for Fall Risk:** Percentage of patients aged 65 years and older who were screened for future fall risk at least once within the reporting period	AMA-PCPI/ NCQA	HITECH ACO
0729/ TBD	Diabetes Mellitus	Clinical Process/ Effectiveness	**Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: • A1c < 8.0% • LDL < 100 mg/dL • blood pressure < 140/90 mmHg • tobacco non-user • (for patients with a diagnosis of ischemic vascular disease) daily aspirin use unless contraindicated	MN Community Measurement	ACO

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(4) PQRS Measures Groups Available for Reporting for 2013 and Beyond

We proposed the following 20 measures groups for reporting in the PQRS beginning with reporting periods occurring in 2013: Diabetes Mellitus; Chronic Kidney Disease (CKD); Preventive Care; Coronary Artery Bypass Graft (CABG); Rheumatoid Arthritis (RA); Perioperative Care; Back Pain; Hepatitis C; Heart Failure (HF); Coronary Artery Disease (CAD); Ischemic Vascular Disease (IVD); HIV/AIDS; Asthma; Chronic Obstructive Pulmonary Disease (COPD); Inflammatory Bowel Disease (IBD); Sleep Apnea; Dementia; Parkinson's Disease; Hypertension; Cardiovascular Prevention; and Cataracts (77 FR 44964). These 20 proposed measures groups are also available for reporting under the PQRS in 2012.

Beginning in 2013, we proposed the oncology measures group for reporting under the PQRS that provides measures available for reporting related to breast cancer and colon cancer. We believe it is important to measure cancer care (77 FR 44964).

We proposed the following 4 measures groups for inclusion in the PQRS beginning with reporting periods occurring in 2014: Osteoporosis; Total Knee Replacement; Radiation Dose; and Preventive Cardiology. These measures groups address conditions that the measures groups established in 2012 do not address.

Therefore, we proposed to finalize a total of 26 measures groups for inclusion in PQRS.

We invited public comment on these proposed PQRS measures groups. The following is a summary of the comments we received regarding these proposed measures groups:

Comment: One commenter supported inclusion of the Cataracts measures group for 2013 and beyond, as the measures included in the measures group are relevant to an ophthalmologist's practice.

Response: Based on the comment we received and for the reasons stated previously, we are finalizing the Cataracts measures group for 2013 and beyond.

Comment: One commenter generally supported the proposed osteoporosis measures group. However, the commenter suggests a change in the composition of the measures group. Specifically, the commenter suggested that CMS remove the proposed ABIM-sourced osteoporosis measures from the proposed osteoporosis measures group and, instead, include all six individual osteoporosis measures (PQRS measure numbers 24, 39, 40, 41, 154, and 155) currently available for reporting under PQRS. The commenter believes these six measures more closely reflect the desired outcomes to improve osteoporosis disease prevention and management.

Response: We appreciate the commenters' feedback. However, we note that the measures within the osteoporosis measures group have been examined to determine the ability to report and analyze the measures contained within the measures group as a whole, whereas the suggested PQRS measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing the osteoporosis measures group as proposed.

Comment: One commenter supported the addition of a new Oncology measures group for 2013 and beyond.

Response: Based on the comments received, we are finalizing the Oncology measures group for 2013 and beyond as proposed.

Comment: One commenter opposed the measures contained within the proposed Diabetes Mellitus measures group because the measures are not reflective of the highly-skilled, labor intensive cognitive care provided by an endocrinologist over a long period of time to treat patients with uncontrolled diabetes. The commenter also believed that use of the measures contained in the Diabetes Mellitus measures group provides an incentive for primary care physicians to cherry pick diabetes patients who have well-controlled diabetes and to request endocrinologic care for difficult and complicated patients.

Response: We appreciate the commenter's feedback regarding the measures contained within the Diabetes Mellitus measures group. While we understand that the measures contained within the Diabetes Mellitus measures group do not address every aspect of care to those patients with diabetes, we believe that the measures collect appropriate data and address an important issue. Therefore, we are finalizing the Diabetes Mellitus measures group with all of the proposed component measures for 2013 and beyond. However, we welcome other suggested measures addressing care of diabetes patients in the future.

In addition, in 2012, the PQRS included a community-acquired pneumonia (CAP) measures group among others. We did not propose to include this measures group again in the PQRS measure set for the 2013 PQRS or subsequent years because measures contained within this measures group were not recommended for retention by the Measure Applications Partnership. We received no comments regarding our decision not to continue inclusion this measures group for reporting in PQRS beginning in 2013.

We also proposed, as identified in Table 47 of the CY 2013 PFS proposed rule, to change the composition of the Coronary Artery Disease (CAD) measures group from what was finalized for 2012 (77 FR 44970). Specifically, we proposed to remove PQRS measure #196: Coronary Artery Disease (CAD): Symptom and Activity Assessment and replace this measure with PQRS measure #242: Coronary Artery Disease (CAD): Symptom Management in the CAD measures group, because the measure #196 was not recommended for retention by the Measure Applications Partnership (77 FR 44964). On the other hand, measure #242 was recommended for retention by the Measure Applications Partnership. We received no comments regarding our proposal to change the composition of the CAD measures group. Therefore, we are finalizing the CAD measures group, as proposed.

Based on the comments received and for the reasons previously stated, we are finalizing the following 26 measures groups indicated in Tables 97 through 122. Descriptions of the measures within each measures group are provided in Tables 97 through 122. Please note that some of the proposed measures included within a final PQRS quality measures group may also be available for reporting as an individual measure. In addition, please note that the Osteoporosis and Preventive Cardiology measures groups contain composite measures. Since composite measures must be reported as a group, similar to reporting measures within a measures group, we felt it was appropriate to classify these two composite measures as measures groups.

TABLE 97—DIABETES MELLITUS MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0059/1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0 percent.	NCQA.
0064/2	Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL–C level in control (less than 100 mg/dL).	NCQA.
0061/3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg).	NCQA.
0055/117	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient: Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam.	NCQA.
0062/119	Diabetes Mellitus: Urine Screening: Percentage of patients aged 18 through 75 years with diabetes (type 1 or type 2) who had a nephropathy screening test or evidence of nephropathy.	NCQA.
0056/163	Diabetes Mellitus: Foot Exam: The percentage of patients aged 18 through 75 years with diabetes who had a foot examination.	NCQA.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 98—CHRONIC KIDNEY DISEASE (CKD) MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31).	AMA–PCPI.
AQA adopted/121	Adult Kidney Disease: Laboratory Testing (Lipid Profile): Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period.	AMA–PCPI.
AQA adopted/122	Adult Kidney Disease: Blood Pressure Management: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and documented proteinuria with a blood pressure < 130/80 mmHg OR ≥ 130/80 mmHg with a documented plan of care.	AMA–PCPI.
AQA adopted/123	Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA)—Hemoglobin Level > 12.0 g/dL: Percentage of calendar months within a 12-month period during which a Hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy AND have a Hemoglobin level > 12.0 g/dL.	AMA–PCPI.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 99—PREVENTIVE CARE MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0046/39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.	AMA–PCPI/NCQA.
0098/48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	AMA–PCPI/NCQA.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31).	AMA–PCPI.
0043/111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older: Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine.	NCQA.
0031/112	Preventive Care and Screening: Screening Mammography: Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer.	NCQA.
0034/113	Preventive Care and Screening: Colorectal Cancer Screening: Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening.	NCQA.
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up: Percentage of patients aged 18 years and older with a calculated BMI in the past 6 months or during the current visit documented in the medical record AND if the most recent BMI is *outside of normal* parameters, a follow-up plan is documented. *Normal Parameters:* Age 65 years and older BMI ≥ 23and < 30; Age 18–64 years BMI > 18.5 and < 25.	CMS/QIP.
AQA adopted/173	Preventive Care and Screening: Unhealthy Alcohol Use—Screening: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months.	AMA–PCPI.

TABLE 99—PREVENTIVE CARE MEASURES GROUP *—Continued

NQF/PQRS	Measure title and description	Measure developer
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 100—CORONARY ARTERY BYPASS GRAFT (CABG) MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0134/43	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG: Surgery Percentage of patients aged 18 years and older undergoing isolated CABG surgery using an IMA graft.	STS.
0236/44	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received a beta-blocker within 24 hours prior to surgical incision.	CMS/QIP.
0129/164	Coronary Artery Bypass Graft (CABG): Prolonged Intubation: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require intubation >24 hours.	STS.
0130/165	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days post-operatively, develop deep sternal wound infection (involving muscle, bone, and/or mediastinum requiring operative intervention).	STS.
0131/166	Coronary Artery Bypass Graft (CABG): Stroke: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a *postoperative* stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	STS.
0114/167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	STS.
0115/168	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	STS.
0116/169	Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on antiplatelet medication.	STS.
0117/170	Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on beta-blockers.	STS.
0118/171	Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on a statin or other lipid-lowering regimen.	STS.

* This measures group is reportable through registry-based reporting only.
This measures group is available for reporting beginning in 2013.

TABLE 101—RHEUMATOID ARTHRITIS (RA) MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0054/108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy: Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a DMARD.	NCQA.
AQA adopted/176	Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a diagnosis of RA who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	AMA–PCPI/NCQA.
AQA adopted/177	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease activity within 12 months.	AMA–PCPI/NCQA.
AQA adopted/178	Rheumatoid Arthritis (RA): Functional Status Assessment: Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months.	AMA–PCPI/NCQA.
AQA adopted/179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease prognosis at least once within 12 months.	AMA–PCPI/NCQA.

TABLE 101—RHEUMATOID ARTHRITIS (RA) MEASURES GROUP *—Continued

NQF/PQRS	Measure title and description	Measure developer
AQA adopted/180	Rheumatoid Arthritis (RA): Glucocorticoid Management: Percentage of patients aged 18 years and older with a diagnosis of RA who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	AMA–PCPI/NCQA.

* This measures group is reportable through both claims and registry-based reporting.

TABLE 102—PERIOPERATIVE CARE MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0270/20	Perioperative Care: Timing of Antibiotic Prophylaxis—Ordering Physician: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or vancomycin, 2 hours), prior to the surgical incision (or start of procedure when no incision is required).	AMA–PCPI/NCQA.
0268/21	Perioperative Care: Selection of Prophylactic Antibiotic—First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin OR cefuroxime for antimicrobial prophylaxis.	AMA–PCPI/NCQA.
0271/22	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures): Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time.	AMA–PCPI/NCQA.
0239/23	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	AMA–PCPI/NCQA.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 103—BACK PAIN MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0322/148	Back Pain: Initial Visit: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain.	NCQA.
0319/149/	Back Pain: Physical Exam: Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain.	NCQA.
0314/150	Back Pain: Advice for Normal Activities: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain.	NCQA.
0313/151	Back Pain: Advice Against Bed Rest: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting 4 days or longer at the initial visit to the clinician for the episode of back pain.	NCQA.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 104—HEPATITIS C MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0395/84	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment.	AMA–PCPI.
0396/85	Hepatitis C: HCV Genotype Testing Prior to Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment.	AMA–PCPI.
0397/86	Hepatitis C: Antiviral Treatment Prescribed: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12month reporting period.	AMA–PCPI.

TABLE 104—HEPATITIS C MEASURES GROUP *—Continued

NQF/PQRS	Measure title and description	Measure developer
0398/87	Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment.	AMA–PCPI.
0401/89	Hepatitis C: Counseling Regarding Risk of Alcohol Consumption: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12-months.	AMA–PCPI.
0394/90	Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy: Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment.	AMA–PCPI.
0399/183	Hepatitis C: Hepatitis A Vaccination in Patients with HCV: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A.	AMA–PCPI.
0400/184	Hepatitis C: Hepatitis B Vaccination in Patients with HCV: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B.	AMA–PCPI.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 105—HEART FAILURE (HF) MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0081/5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure and LVSD (LVEF <40%) who were prescribed ACE inhibitor or ARB therapy.	AMA–PCPI/ACCF/AHA.
0083/8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD (LVEF <40%) and who were prescribed beta-blocker therapy.	AMA–PCPI/ACCF/AHA.
0079/198	Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment: Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative result (of a recent or prior [any time in the past] LVEF assessment) is documented within a 12 month period.	AMA–PCPI/ACCF/AHA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.

* This measures group is reportable through registry-based reporting only.
This measures group is available for reporting beginning in 2013.

TABLE 106—CORONARY ARTERY DISEASE (CAD) MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0067/6	Coronary Artery Disease (CAD): Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel.	AMA–PCPI/ACCF/AHA.
0074/197	Coronary Artery Disease (CAD): Lipid Control: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL–C result <100 mg/dL OR patients who have a LDL–C result ≥100 mg/dL and have a documented plan of care to achieve LDL–C <100 mg/dL, including at a minimum the prescription of a statin.	AMA–PCPI/ACCF/AHA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.
N/A/242	Coronary Artery Disease (CAD): Symptom Management: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period and with results of an evaluation of level of activity AND an assessment for the presence *or* absence of anginal symptoms, with a plan of care to manage anginal symptoms, if present.	AMA–PCPI/ACCF/AHA.

* This measures group is reportable through registry-based reporting only.
This measures group is available for reporting beginning in 2013.

TABLE 107—ISCHEMIC VASCULAR DISEASE (IVD) MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0073/201	Ischemic Vascular Disease (IVD): Blood Pressure Management Control: Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg).	NCQA.
0068/204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic: Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or other antithrombotic.	NCQA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.
0075/241	Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL–C) Control: Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL–C level was in control (less than 100 mg/dL).	NCQA.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 108—HIV/AIDS MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0404/159	HIV/AIDS: CD4+ Cell Count or CD4+ Percentage: Percentage of patients aged 6 months and older with a diagnosis of HIV/AIDS for whom a CD4+ cell count or CD4+ cell percentage was performed at least once every 6 months.	AMA–PCPI/NCQA.
0405/160	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis: Percentage of patients aged 6 years and older with a diagnosis of HIV/AIDS and CD4+ cell count < 200 cells/mm3 who were prescribed PCP prophylaxis within 3 months of low CD4+ cell count.	AMA–PCPI/NCQA.
0406/161	HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy: Percentage of patients with a diagnosis of HIV/AIDS aged 13 years and older: who have a history of a nadir CD4+ cell count below 350/mm3 or who have a history of an AIDS-defining condition, regardless of CD4+ cell count; or who are pregnant, regardless of CD4+ cell count or age, who were prescribed potent antiretroviral therapy.	AMA–PCPI/NCQA.
0407/162	HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who are receiving potent antiretroviral therapy, who have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy or patients whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and have documentation of a plan of care.	AMA–PCPI/NCQA.
0409/205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia and gonorrhea screenings were performed at least once since the diagnosis of HIV infection.	AMA–PCPI/NCQA.
0413/206	HIV/AIDS: Screening for High Risk Sexual Behaviors: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for high risk sexual behaviors at least once within 12 months.	AMA–PCPI/NCQA.
0415/207	HIV/AIDS: Screening for Injection Drug Use: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for injection drug use at least once within 12 months.	AMA–PCPI/NCQA.
0410/208	HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for syphilis at least once within 12 months.	AMA–PCPI/NCQA.

* This measures group is reportable through registry-based reporting only.
This measures group is available for reporting beginning in 2013.

TABLE 109—ASTHMA MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0047/53	Asthma: Pharmacologic Therapy for Persistent Asthma: Percentage of patients aged 5 through 50 years with a diagnosis of mild, moderate, or severe persistent asthma who were prescribed either the preferred long-term control medication (inhaled corticosteroid) or an acceptable alternative treatment.	AMA–PCPI/NCQA.
0001/64	Asthma: Assessment of Asthma Control: Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated during at least one office visit within 12 months for the frequency (numeric) of daytime and nocturnal asthma symptoms.	AMA–PCPI/NCQA.
N/A/231	Asthma: Tobacco Use: Screening—Ambulatory Care Setting: Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period.	AMA–PCPI/NCQA.

TABLE 109—ASTHMA MEASURES GROUP *—Continued

NQF/PQRS	Measure title and description	Measure developer
N/A/232	Asthma: Tobacco Use: Intervention—Ambulatory Care Setting: Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were identified as tobacco users (patients who currently use tobacco AND patients who do not currently use tobacco, but are exposed to second hand smoke in their home environment) who received tobacco cessation intervention at least once during the one-year measurement period.	AMA–PCPI/NCQA.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 110—CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0091/51	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation: Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented.	AMA–PCPI.
0102/52	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy: Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70 percent and have symptoms who were prescribed an inhaled bronchodilator.	AMA–PCPI.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31).	AMA–PCPI.
0043/111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older: Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine.	NCQA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 111—INFLAMMATORY BOWEL DISEASE (IBD) MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.
N/A/269	Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Documented: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have documented the disease type, anatomic location and activity, at least once during the reporting period.	AGA.
N/A/270	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year.	AGA.
N/A/271	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury—Bone Loss Assessment: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have received dose of corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days and were assessed for risk of bone loss once per the reporting year.	AGA.
N/A/272	Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year.	AGA.
N/A/273	Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received.	AGA.
N/A/274	Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.	AGA.
N/A/275	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.	AGA.

* This measures group is reportable through registry-based reporting only.

This measures group is available for reporting beginning in 2013.

TABLE 112—SLEEP APNEA MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
N/A/276	Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of symptoms, including presence or absence of snoring and daytime sleepiness.	AMA–PCPI/NCQA.
N/A/277	Sleep Apnea: Severity Assessment at Initial Diagnosis: Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	AMA–PCPI/NCQA.
N/A/278	Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy.	AMA–PCPI/NCQA.
N/A/279	Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	AMA–PCPI/NCQA.

* This measures group is reportable through registry-based reporting only.
This measures group is available for reporting beginning in 2013.

TABLE 113—DEMENTIA MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
N/A/280	Dementia: Staging of Dementia: Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period.	AMA–PCPI.
N/A/281	Dementia: Cognitive Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period.	AMA–PCPI.
N/A/282	Dementia: Functional Status Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of patient's functional status is performed and the results reviewed at least once within a 12 month period.	AMA–PCPI.
N/A/283	Dementia: Neuropsychiatric Symptom Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of patient's neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period.	AMA–PCPI.
N/A/284	Dementia: Management of Neuropsychiatric Symptoms: Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period.	AMA–PCPI.
N/A/285	Dementia: Screening for Depressive Symptoms: Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period.	AMA–PCPI.
N/A/286	Dementia: Counseling Regarding Safety Concerns: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period.	AMA–PCPI.
N/A/287	Dementia: Counseling Regarding Risks of Driving: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and driving alternatives within a 12 month period.	AMA–PCPI.
N/A/288	Dementia: Caregiver Education and Support: Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period.	AMA–PCPI.

* This measures group is reportable through claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 114—PARKINSON'S DISEASE MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
N/A/289	Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review: All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications than can produce Parkinson- like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually.	AAN.
N/A/290	Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually.	AAN.
N/A/291	Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually.	AAN.

TABLE 114—PARKINSON'S DISEASE MEASURES GROUP *—Continued

NQF/PQRS	Measure title and description	Measure developer
N/A/292	Parkinson's Disease: Querying about Sleep Disturbances: All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually.	AAN.
N/A/293	Parkinson's Disease: Rehabilitative Therapy Options: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually.	AAN.
N/A/294	Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually.	AAN.

* This measures group is reportable through registry-based reporting only
This measures group is available for reporting beginning in 2013.

TABLE 115—HYPERTENSION MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
N/A/295	Hypertension: Appropriate Use of Aspirin or Other Antiplatelet or Anticoagulant Therapy: Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who were prescribed aspirin or other anticoagulant/antiplatelet therapy.	ABIM.
N/A/296	Hypertension: Complete Lipid Profile: Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within 24 months.	ABIM.
N/A/297	Hypertension: Urine Protein Test: Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within 36 months.	ABIM.
N/A/298	Hypertension: Annual Serum Creatinine Test: Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within 12 months.	ABIM.
N/A/299	Hypertension: Diabetes Mellitus Screening Test: Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within 36 months.	ABIM.
N/A/300	Hypertension: Blood Pressure Control: Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had most recent blood pressure level under control (at goal).	ABIM.
N/A/301	Hypertension: Low Density Lipoprotein (LDL–C) Control: Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had most recent LDL cholesterol level under control (at goal).	ABIM.
N/A/302	Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed: Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within 12 months.	ABIM.

* This measures group is reportable through registry-based reporting only.
This measures group is available for reporting beginning in 2013.

TABLE 116—CARDIOVASCULAR PREVENTION MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0064/2	Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL–C level in control (less than 100 mg/dL).	NCQA.
0068/204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic: Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or other antithrombotic.	NCQA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.
0018/236	Hypertension (HTN): Controlling High Blood Pressure: Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg).	NCQA.
0075/241	Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL–C) Control: Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL–C level was in control (less than 100 mg/dL).	NCQA.
N/A/317	Preventive Care and Screening: Screening for High Blood Pressure: Percentage of patients aged 18 and older who are screened for high blood pressure.	CMS/QIP.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2013.

TABLE 117—CATARACTS MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0565/191	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	AMA–PCPI/NCQA.
0564/192	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: Retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	AMA–PCPI/NCQA.
N/A/303	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	AAO.
N/A/304	Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	AAO.

* This measures group is reportable through registry-based reporting only.
This measures group is available for reporting beginning in 2013.

TABLE 118—ONCOLOGY MEASURES GROUP *

NQF/PQRS	Measure title and description	Measure developer
0387/71	Breast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer: Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.	AMA–PCPI/ASCO/NCCN.
0385/72	Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients: Percentage of patients aged 18 years and older with Stage IIIA through IIIC colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period.	AMA–PCPI/ASCO/NCCN.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31).	AMA–PCPI.
0419/130	Documentation of Current Medications in the Medical Record: Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list *must* include ALL prescriptions, over-the-counters, herbals, vitamin/mineral/dietary (nutritional) supplements AND *must* contain the medications' name, dosage, frequency and route.	CMS/QIP.
0384/143	Oncology: Medical and Radiation—Pain Intensity Quantified: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	AMA–PCPI.
0383/144	Oncology: Medical and Radiation—Plan of Care for Pain: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	AMA–PCPI.
0386/194	Oncology: Cancer Stage Documented: Percentage of patients, regardless of age, with a diagnosis of breast, colon, or rectal cancer who are seen in the ambulatory setting who have a baseline AJCC cancer stage or documentation that the cancer is metastatic in the medical record at least once within 12 months.	AMA–PCPI/ASCO.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.

* This measures group is reportable through registry-based reporting only
This measures group is available for reporting beginning in 2013.

TABLE 119—OSTEOPOROSIS MEASURES GROUP *

NQF/PQRS	Measure title	Measure developer
0046/39	Osteoporosis: Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.	AMA.
0049/41	Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months.	AMA.

TABLE 119—OSTEOPOROSIS MEASURES GROUP *—Continued

NQF/PQRS	Measure title	Measure developer
AQA Selected/154	Falls: Risk Assessment for Falls: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	NCQA.
AQA Selected/155	Falls: Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	NCQA.
N/A/TBD	Osteoporosis: Status of Participation in Weight-Bearing Exercise and Weight-bearing Exercise Advice: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose status regarding participation in weight-bearing exercise was documented and for those not participating regularly who received advice within 12 months to participate in weight-bearing exercise.	ABIM.
N/A/TBD	Osteoporosis: Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose current level of alcohol use was documented and for those engaging in potentially hazardous drinking who received counseling within 12 months.	ABIM.
N/A/TBD	Osteoporosis: Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a screen for falls risk evaluation within the past 12 months and for those reported as having a history of two or more falls, or fall-related injury who had a complete risk assessment for falls and a falls plan of care within the past 12 months.	ABIM.
N/A/TBD	Osteoporosis: Dual-Emission X-ray Absorptiometry (DXA) Scan: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a DXA scan and result documented.	ABIM.
N/A/TBD	Osteoporosis: Calcium Intake Assessment and Counseling: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had calcium intake assessment and counseling at least once within 12 months.	ABIM.
N/A/TBD	Osteoporosis: Vitamin D Intake Assessment and Counseling: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had vitamin D intake assessment and counseling at least once within 12 months.	ABIM.
N/A/TBD	Osteoporosis: Pharmacologic Therapy: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who were prescribed pharmacologic therapy approved by the Food and Drug Administration.	ABIM.

* This measures group is reportable through claims and registry-based reporting.
This measures group is available for reporting beginning in 2014.

TABLE 120—TOTAL KNEE REPLACEMENT MEASURES GROUP *

NQF/PQRS	Measure title	Measure developer
N/A/TBD	Total Knee Replacement: Coordination of Post Discharge Care: Percentage of patients undergoing total knee replacement who received written instructions for post discharge care including all the following: Post discharge physical therapy, home health care, post discharge deep vein thrombosis (DVT) prophylaxis and follow-up physician visits.	AAHKS/AMA–PCPI.
N/A/TBD	Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation: Percentage of patients undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including history of deep vein thrombosis (DVT), pulmonary embolism (PE), myocardial infarction (MI), arrhythmia and stroke.	AAHKS/AMA–PCPI.
N/A/TBD	Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet: Percentage of patients undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.	AAHKS/AMA–PCPI.
N/A/TBD	Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report: Percentage of patients undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant.	AAHKS/AMA–PCPI.

* This measures group is reportable through and registry-based only.
This measures group is available for reporting beginning in 2014.

TABLE 121—RADIATION DOSE OPTIMIZATION MEASURES GROUP *

NQF/PQRS	Measure title	Measure developer
TBD/TBD	Radiation Dose Optimization: Utilization of a Standardized Nomenclature for CT Imaging Description: Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature (e.g., RadLex®) and the standardized nomenclature is used in institutions computer systems.	AMA–PCPI.

TABLE 121—RADIATION DOSE OPTIMIZATION MEASURES GROUP *—Continued

NQF/PQRS	Measure title	Measure developer
TBD/TBD	Radiation Dose Optimization: Cumulative Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) Scans and Cardiac Nuclear Medicine Scans: Percentage of CT and cardiac nuclear medicine (myocardial perfusion) imaging reports for all patients, regardless of age, that document a count of known previous CT studies (any type of CT) and cardiac nuclear medicine (myocardial perfusion studies) studies that the patient has received in the 12-month period prior to the current study.	AMA–PCPI.
TBD/TBD	Radiation Dose Optimization: Reporting to a Radiation Dose Index Registry: Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements.	AMA–PCPI.
TBD/TBD	Radiation Dose Optimization: Images Available for Patient Follow-up and Comparison Purposes: Percentage of final reports for imaging studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available reciprocally to non-affiliated external entities on a secure, media-free, searchable basis with patient authorization for at least a 12-month period after the study.	AMA–PCPI.
TBD/TBD	Radiation Dose Optimization: Search for Prior Imaging Studies Through a Secure, Authorized, Media-Free, Shared Archive: Percentage of final reports of imaging studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient imaging studies completed at non-affiliated external entities within the past 12 months and are available through a secure, authorized, media-free, shared archive prior to an imaging study being performed.	AMA–PCPI.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2014.

TABLE 122—PREVENTIVE CARDIOLOGY MEASURES GROUP *

NQF/PQRS	Measure title	Measure developer
N/A/TBD	Preventive Cardiology Composite: Blood Pressure at Goal: Percentage of patients in the sample whose most recent blood pressure reading was at goal.	ABIM.
N/A/TBD	Preventive Cardiology Composite: Low Density Lipids (LDL) Cholesterol at Goal: Percentage of patients in the sample whose LDL cholesterol is considered to be at goal, based upon their coronary heart disease (CHD) risk factors.	ABIM.
N/A/TBD	Preventive Cardiology Composite: Timing of Lipid Testing Complies with Guidelines: Percentage of patients in the sample whose timing of lipid testing complies with guidelines (lipid testing performed in the preceding 12-month period (with a 3-month grace period) for patients with known coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus); or in the preceding 24-month period (with a 3-month grace period) for patients with ≥ 2 risk factors for CHD (smoking, hypertension, low high density lipid (HDL), men ≥ 45 years, women ≥ 55 years, family history of premature CHD; HDL ≥ 60 mg/dL acts as a negative risk factor); or in the preceding 60-month period (with a 3-month grace period) for patients with ≤ 1 risk factor for CHD).	ABIM.
N/A/TBD	Preventive Cardiology Composite: Diabetes Documentation or Screen Test: Percentage of patients in the sample who had a screening test for type 2 diabetes or had a diagnosis of diabetes.	ABIM.
N/A/TBD	Preventive Cardiology Composite: Correct Determination of Ten-Year Risk for Coronary Death or Myocardial Infarction (MI): Number of patients in the sample whose ten-year risk of coronary death or MI is correctly assessed and documented.	ABIM.
N/A/TBD	Preventive Cardiology Composite: Counseling for Diet and Physical Activity: Percentage of patients in the sample who received dietary and physical activity counseling.	ABIM.
N/A/TBD	Preventive Cardiology Composite: Appropriate Use of Aspirin or Other Antiplatelet/Anticoagulant Therapy: Percentage of patients in the sample who are: 1) taking aspirin or other anticoagulant/antiplatelet therapy, or 2) under age 30, or 3) age 30 or older and who are documented to be at low risk. Low-risk patients include those who are documented with no prior coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus) and whose ten-year risk of developing CHD is < 10%.	ABIM.
N/A/TBD	Preventive Cardiology Composite: Smoking Status and Cessation Support: Percentage of patients in the sample whose current smoking status is documented in the chart, and if they were smokers, were documented to have received smoking cessation counseling during the reporting period.	ABIM.

* This measures group is reportable through both claims and registry-based reporting.
This measures group is available for reporting beginning in 2014.

(5) Physician Quality Reporting System Measures for Eligible Professionals and Group Practices That Report Using Administrative Claims for the 2015 Payment Adjustment

We proposed 19 measures—including 15 process and 4 outcome measures derived from administrative claims—for eligible professionals and group practices that report using administrative claims for the 2015 and 2016 payment adjustments (see Table 63 of the CY 2013 PFS proposed rule, 77 FR 44981). Our proposals on how to attribute beneficiaries to groups of physicians that elect the administrative claims option were discussed in the value-based payment modifier in section III.K. of the proposed rule. We considered all of the 28 process measures included in the program year 2010 individual Physician Feedback reports that can be calculated using administrative claims but proposed only a subset of the measures that were included in the program year 2010 individual Physician Feedback reports. We proposed this subset of measures for both the PQRS payment adjustment and the value-based modifier because we believe these measures are clinically meaningful, focus on highly prevalent conditions among beneficiaries, have the potential to differentiate physicians, and be statistically reliable (77 FR 44980). We also sought comment on whether to include any of the remaining 13 measures included in the program year 2010 individual Physician Feedback Reports (77 FR 44998) (see Table 65 of the CY 2013 PFS proposed rule, 77 FR 45000). The utilization of the administrative claims measures will allow PQRS to implement different reporting options which capture a wider venue of participants without using the traditional methods of reporting.

We invited public comment on these proposed measures. The following is a summary of the comments we received regarding the proposed measures for eligible professionals and group practices that report using the administrative claims-based reporting mechanism for the 2015 and/or 2016 PQRS payment adjustments. Please note that, since we are not finalizing an administrative claims-based reporting option for the 2016 PQRS payment adjustment, they will only be available for the purpose of reporting for the 2015 PQRS payment adjustment.

Comment: Most commenters agreed with assessing performance rates for the measures in the PQRS administrative claims-based reporting option at the TIN level.

Response: We thank commenters for their support for this proposal and we are finalizing our proposal to calculate the Administrative Claims based measures at the single TIN level and applying the TIN's performance to the TIN or to an individual NPI that elects the Administrative Claims option at the individual level.

Comment: One commenter opposed assessing ophthalmologists against the proposed administrative claims-based measures. The commenter notes that only 1 proposed administrative claims-based measure is applicable to ophthalmology. Although an ophthalmologist would be able to elect the administrative claims option and meet the measure targets based on the care their patients received from other physicians, the commenter does not believe it is appropriate for CMS to attribute care of non-eye conditions by other physicians to the ophthalmologist.

Response: We appreciate the commenter's feedback and realize that the proposed administrative claims-based measures may not adequately assess the specific scope of care furnished by ophthalmologists or other specialists to their patients. However, we believe this reporting option promotes shared accountability and care coordination for the quality of care furnished to beneficiaries and therefore provides important and actionable information for physicians about their beneficiaries. We also expect physicians and groups of physicians to report data on quality measures that reflect the care they furnish. We are therefore allowing ophthalmologists and other specialists to elect to be assessed against the administrative claims-based measures for purposes of the 2015 PQRS payment adjustment, both to provide ophthalmologists and other specialists with multiple options to meet the criteria for satisfactory reporting for the 2015 PQRS payment adjustment and to provide them with actionable information about shared accountability and care coordination important to their beneficiaries. We note that establishing the administrative claims-based reporting option for eligible professionals does not preclude ophthalmologists and other specialists to participate in PQRS using other reporting mechanisms and reporting other PQRS measures.

Process Quality Measures. Of the 19 measures we proposed for reporting under the administrative claims-based reporting mechanism, 15 of these proposed measures were process measures. The following is a summary of the comments we received on these proposed process measures.

Comment: Most commenters supported the Administrative Claims option and proposed process measures and saw it as a ''low burden method to avoid the PQRS and value-based payment modifier adjustment,'' although many expressed their dissatisfaction with administrative-claims-based measures in general, since these measures are derived from billing data and, as a result, lack the nuances of clinical data. Other commenters noted that the proposed measures were most applicable to the care of chronic conditions and preventive care and would not apply to the practice of many specialists and subspecialists. Commenters recommended that CMS include only measures that are NQF endorsed and that they be endorsed at the physician and/or group practice level.

Response: We thank the commenters for their suggestions. As commenters stated, while administrative claims-based measures have shortcomings for clinical process measurement due to their lack of clinical data, we have chosen to preferentially use claims-based process measures that have NQF endorsement and were found to have high reliability in the program year 2010 physician feedback reports. As we have stated above, by providing physicians with information about their beneficiaries outside of their specialty, we are promoting shared accountability and care coordination for beneficiaries, which we believe are important domains promoted by the National Quality Strategy. We are finalizing 13 of the proposed 15 process measures and are adding NQF 0022, ''Use of High Risk Medicines in the Elderly,'' which we had used in the 2010 physician feedback reports. We agree with the comments that we should, where possible, use NQF-endorsed measures for this reporting option, but we do not believe that CMS should change or update measures that have been endorsed. We believe updating measure specifications is the responsibility of the measure steward. With that being said, we do plan to monitor NQF endorsement activity and will adjust the measures in the Administrative Claims option in future years accordingly.

We are not finalizing NQF 0021 measure titled ''Annual Monitoring for Beneficiaries on Persistent Medications,'' for the Administrative Claims option. The measure steward, NCQA, has withdrawn this measure from consideration during NQF Steering Committee review and will update and resubmit the measure at a later date. Instead, we will substitute NQF 0022 ''Use of High Risk Medicines in the

Elderly,'' which was included in Table 65 of the CY 2013 PFS proposed rule (77 FR 45000) and on which we had sought comment for including in the administrative claims option. Like NQF 0021, this process measure is a patient safety measure for medication management in the elderly. Additionally, the measure was suggested for inclusion by several commenters due to its importance in beneficiary care and broad applicability to physicians. Additionally, based on our 2010 analysis of its use in the physician feedback program, it has a high level of reliability. Unlike NQF 0021, NQF 0022 remains endorsed by NQF.

Comment: Some commenters identified attribution of patients to physicians and risk adjustment as challenges with administrative claims-based measures in general. Others noted that the current administrative claims-based measure set is primary care oriented and lacks measures appropriate for specialists.

Response: We appreciate these comments and have acknowledged above the challenges commenters associated with administrated claims-based measures that make them an imperfect data source for measuring certain aspects of quality. Administrative claims-based measures will likely continue to comprise part of the measure set for the value-based modifier, such as the cost measures and measures that extend across the continuum of care. CMS developed the administrative claims option to create an opportunity for physician practices that have not yet invested in the infrastructure and capabilities otherwise required to participate in PQRS to engage meaningfully in quality measurement and quality improvement. Ultimately, we believe that physician practices should actively gather and report quality data, such as through EHRs or registries. Thus, we do not anticipate that an option to participate in PQRS and the value-based payment modifier exclusively using administrative claims will continue beyond the first few years of the program.

Comment: Commenters also suggested removing NQF 0549 measure titled ''Pharmacotherapy Management of COPD Exacerbation,'' because not all COPD patients should receive a corticosteroid and the measure does not take into account if a patient has possession of the medication at home.

Response: We are not finalizing NQF 0549 ''Pharmacotherapy Management of COPD Exacerbation.'' This measure was submitted and reviewed by NQF this year and was not recommended for continued endorsement due to questions raised about the measure's validity.

Comment: Commenters suggested removing the proposed NQF 0576 measure titled ''Follow-up After Hospitalization for Mental Illness'' from the administrative claims-based measure set, because the measure would have minimal potential to distinguish physicians who are not mental health specialists from those who are thus making attribution a concern.

Response: We appreciate this comment and concur that psychiatrists treating patients who have been hospitalized for mental illness should be held accountable for ensuring appropriate follow up after discharge. However, we believe that our objective of effective care coordination and safe care transitions for patients with mental illness are best served when all physicians and providers involved in the care of a patient with mental illness who has been discharged from an inpatient care setting share accountability for effective care coordination. We are therefore finalizing this measure in the claims-based option as supported by many other commenters.

Comment: Commenters suggested removing the proposed NQF 0543 measure titled ''Statin Therapy for Beneficiaries with Coronary Artery Disease'' from the administrative claims-based measure set, because there are multiple influences on why patients may not obtain the medication.

Response: We recognize that physicians play a critical role in influencing patient medical adherence, and the point made would obviate the use of all medication measures. We are therefore finalizing this measure in the claims-based option as supported by many other commenters.

Outcome Measures. Of the 19 measures we proposed for reporting using the administrative claims-based reporting mechanism, 4 of these proposed measures were outcome measures—All Cause Readmission, 30 day Post Discharge Visit, and the Acute and Chronic Preventive Quality Indicator (PQI) Composites. The following is a summary of the comments received on the proposed outcome measures available for the administrative claims-based reporting mechanism.

Comment: Many commenters were opposed to the four outcome measures due to lack of NQF endorsement at the group or physician level, inadequate risk adjustment, lack of ability for verification by the physician group using their own data, or the lack of actionability by the physician groups. The PQIs were cited as population level measures, unlikely to be valid at the provider or smaller group level. Other commenters stated that planned hospital readmissions may constitute appropriate care. And for the 30-day post-discharge follow-up visit measures, commenters pointed out that surgeons are subject to the 90-day global payment period and cannot generate a claim for a 30-day post-discharge follow-up visit, thus questioning the accuracy of the measure. Commenters also indicated that there may be other ways to ensure sufficient care coordination after a hospitalization that does not involve a visit within 30 days of discharge. Many commenters suggested four recently NQF endorsed care coordination measures to replace these four care coordination outcome measures.

A substantial number of commenters from the consumer advocacy and physician value community supported all four of the outcome measures as moving quality measurement in the forward direction and in particular singled out the use of composite scores as a method to increase reliability.

Response: We appreciate the commenters' suggestions. We are finalizing the all cause readmission measure and the Acute and Chronic Preventive Quality Indicator composites for use in the PQRS Administrative Claims option and for all groups of physicians subject to the value-based payment modifier (see discussion below in Section III.K.2). The all cause readmission measure is NQF endorsed at the hospital level, has been respecified for groups of physicians, and we are using the all-cause readmission measure in the Medicare Shared Savings Program. Likewise, the individual PQI measures, while currently endorsed at the population level, have been respecified for medical groups and used in the physician feedback reports. Furthermore, we are collaborating with AHRQ, the measure steward for the PQIs, about our use of PQI composite measures. We will be seeking NQF endorsement of the respecified all cause readmission measure and PQI composite measures. Both the all-cause readmission measure and the PQI measures have been respecified using rigorous risk adjustment methods. We are redesigning our physician feedback reports to allow groups of physicians to verify who the patients included in these measures are, so that they can take appropriate actions. We are persuaded by the comments about the 30-day post-discharge visit measure and we will not finalize that measure.

We believe an effective Administrative Claims option and a meaningful value-based payment modifier in the long-run will place greater emphasis on outcome measures and we believe it is important to include outcome measures that highlight key areas for achieving better care for beneficiaries.

With regard to the suggestions to replace these outcome measures for four recently endorsed AMA–PCPI care coordination measures that were recently NQF endorsed, we note that these suggested care coordination measures are all process measures, and they will be considered for the claims option of the PQRS program in 2014 in future rulemaking.

Therefore, based on the comments received, as specified in Tables 123 and 124, we are finalizing 17 measures, comprised of 14 process and 3 outcome measures (2 of which are PQI composite measures), for inclusion in the PQRS administrative claims-based measure set for reporting for the 2015 PQRS payment adjustment only.

TABLE 123—PROCESS MEASURES FOR ELIGIBLE PROFESSIONALS AND GROUP PRACTICES WHO REPORT USING ADMINISTRATIVE CLAIMS FOR THE 2015 PQRS PAYMENT ADJUSTMENT

[Measures for the Administrative Claims Options for 2015]

NQF No.	Measure title	Measure steward	Domain of care
0576	Follow-Up After Hospitalization for Mental Illness Percentage of discharges for patients who were hospitalized for treatment of selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner.	NCQA	Care Coordination.
0022	Use of High-Risk Medications in the Elderly: (a) Patients Who Receive At Least One Drug To Be Avoided. Percentage of patients ages 65 years and older who received at least one high-risk medication in the measurement year. (b) Patients Who Receive At Least Two Different Drugs To Be Avoided. Percentage of patients 65 years of age and older who received at least two different high-risk medications in the measurement year.	NCQA	Patient Safety.
0555	Lack of Monthly INR Monitoring for Beneficiaries on Warfarin Average percentage of 40-day intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period.	CMS	Patient Safety.
0577	Use of Spirometry Testing to Diagnose COPD Percentage of patients at least 40 years old who have a new diagnosis or newly active chronic obstructive pulmonary disease (COPD) who received appropriate spirometry testing to confirm the diagnosis.	NCQA	Clinical Care.
0543	Statin Therapy for Beneficiaries with Coronary Artery Disease Medication Possession Ratio (MPR) for statin therapy for individuals over 18 years of age with coronary artery disease.	CMS	Clinical Care.
0583	Lipid Profile for Beneficiaries Who Started Lipid-Lowering Medications Percentage of patients age 18 or older starting lipid-lowering medication during the measurement year who had a lipid panel checked within 3 months after starting drug therapy.	Resolution Health	Clinical Care.
0053	Osteoporosis Management in Women ≥ 67 Who Had a Fracture Percentage of women 67 years and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the 6 months after the date of fracture.	NCQA	Clinical Care.
0055	Dilated Eye Exam for Beneficiaries ≤ 75 with Diabetes Percentage of adult patients with diabetes aged 18–75 years who received a dilated eye exam by an ophthalmologist or optometrist during the measurement year, or had a negative retinal exam (no evidence of retinopathy) by an eye care professional in the year prior to the measurement year.	NCQA	Clinical Care.
0057	HbA1c Testing for Beneficiaries ≤ 75 with Diabetes Percentage of adult patients with diabetes aged 18–75 years receiving one or more A1c test(s) per year.	NCQA	Clinical Care.
0062	Urine Protein Screening for Beneficiaries ≤ 75 with Diabetes Percentage of adult diabetes patients aged 18–75 years with at least one test nephropathy screening test during the measurement year or who had evidence existing nephropathy (diagnosis of nephropathy or documentation of microalbuminuria or albuminuria).	NCQA	Clinical Care.
0063	Lipid Profile for Beneficiaries ≤ 75 with Diabetes Percentage of adult patients with diabetes aged 18–75 who had an LDL–C test performed during the measurement year.	NCQA	Clinical Care.
0075	Lipid Profile for Beneficiaries with Ischemic Vascular Disease Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) from January 1–November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to measurement year, who had a complete lipid profile during the measurement year.	NCQA	Clinical Care.
0105	Antidepressant Treatment for Depression Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication and who remained on an antidepressant medication treatment for: (a) At least 84 days (12 weeks) and (b) 180 days (6 months).	NCQA	Clinical Care.

TABLE 123—PROCESS MEASURES FOR ELIGIBLE PROFESSIONALS AND GROUP PRACTICES WHO REPORT USING ADMINISTRATIVE CLAIMS FOR THE 2015 PQRS PAYMENT ADJUSTMENT—Continued

[Measures for the Administrative Claims Options for 2015]

NQF No.	Measure title	Measure steward	Domain of care
0031	Breast Cancer Screening for Women ≤ 69 Percentage of eligible women 40–69 who receive a mammogram in during the measurement year or in the year prior to the measurement year.	NCQA	Clinical Care.

TABLE 124—OUTCOME MEASURES FOR ELIGIBLE PROFESSIONALS AND GROUP PRACTICES WHO REPORT USING ADMINISTRATIVE CLAIMS FOR THE 2015 PQRS PAYMENT ADJUSTMENT

NQF No.	Measure title	Measure steward	Domain of care
N/A	1. Composite of Acute Prevention Quality Indicators (PQIs)	N/A	Care Coordination.
0279	Bacterial Pneumonia The number of admissions for bacterial pneumonia per 100,000 population.	AHRQ	
0281	UTI The number of discharges for urinary tract infection per 100,000 population Age 18 Years and Older in a one year time period.	AHRQ	
0280	Dehydration The number of admissions for dehydration per 100,000 population.	AHRQ	
N/A	2. Composite of Chronic Prevention Quality Indicators (PQIs) Diabetes Composite	N/A	Care Coordination.
0638	Uncontrolled diabetes The number of discharges for uncontrolled diabetes per 100,000 population Age 18 Years and Older in a one year time period.	AHRQ	
0272	Short Term Diabetes complications The number of discharges for diabetes short-term complications per 100,000 Age 18 Years and Older population in a one year period.	AHRQ	
0274	Long term diabetes complications. The number of discharges for long-term diabetes complications per 100,000 population Age 18 Years and in a one year time period.	AHRQ	
0285	Lower extremity amputation for diabetes The number of discharges for lower-extremity amputation among patients with diabetes per 100,000 population Age 18 Years in a one year time period.	AHRQ	
0275	COPD The number of admissions for chronic obstructive pulmonary disease (COPD) per 100,000 population.	AHRQ	
0277	Heart Failure Percent of the population with admissions for CHF.	AHRQ	
N/A	3. All Cause Readmission The rate of provider visits within 30 days of discharge from an acute care hospital per 1,000 discharges among eligible beneficiaries assigned.	CMS	Care Coordination.

7. Maintenance of Certification Program Incentive: Self-Nomination and Qualification Process for Entities Wishing To Be Qualified for the 2013 and 2014 Maintenance of Certification Program Incentives

We proposed that new and previously qualified entities wishing to become qualified to provide their members with an opportunity to earn the 2013 and/or 2014 Maintenance of Certification Program incentives undergo a self-nomination and qualification process (77 FR 44982). Once qualified, we proposed that the entity would be able to submit data on behalf of its eligible professionals.

Maintenance of Certification Program Incentive: Self-Nomination Process. For the self-nomination process, we proposed that an entity wishing to be qualified for the 2013 and/or 2014 Maintenance of Certification Program incentive would be required to submit a self-nomination statement containing all of the following information via the web:

- Provide detailed information regarding the Maintenance of Certification Program with reference to the statutory requirements for such program.
- Indicate the organization sponsoring the Maintenance of Certification Program, and whether the Maintenance of Certification Program is sponsored by an American Board of Medical Specialties (ABMS) board. If not an ABMS board, indicate whether and how the program is substantially equivalent to the ABMS Maintenance of Certification Program process.
- Indicate that the program is in existence as of January 1 the year prior to the year in which the entity seeks to be qualified for the Maintenance of Certification Program incentive. For example, to be qualified for the 2013 Maintenance of Certification Program incentive, the entity would be required to be in existence by January 1, 2012.
- Indicate that the program has at least one (1) active participant.
- The frequency of a cycle of Maintenance of Certification for the specific Maintenance of Certification Program of the sponsoring organization, including what constitutes ''more frequently'' for both the Maintenance of Certification Program itself and the practice assessment for the specific Maintenance of Certification Program of the sponsoring organization.
- Confirmation from the board that the practice assessment will occur and be completed in the year the physician is participating in the Maintenance of Certification Program Incentive.

• What was, is, or will be the first year of availability of the Maintenance of Certification Program practice assessment for completion by an eligible professional.

• What data is collected under the patient experience of care survey and how this information would be provided to CMS.

• Describe how the Maintenance of Certification program monitors that an eligible professional has implemented a quality improvement process for their practice.

• Describe the methods, and data used under the Maintenance of Certification Program, and provide a list of all measures used in the Maintenance of Certification Program for the year prior to which the entity seeks to be qualified for the Maintenance of Certification Program incentive (for example, measures used in 2012 for the 2013 Maintenance of Certification Program incentive), including the title and descriptions of each measure, the owner of the measure, whether the measure is NQF endorsed, and a link to a Web site containing the detailed specifications of the measures, or an electronic file containing the detailed specifications of the measures.

We invited but received no public comment on our proposed self-nomination process for entities who wish to be qualified for the 2013 and 2014 Maintenance of Certification Program incentive. Therefore, we are finalizing the self-nomination process for boards wishing to participate in the Maintenance of Certification Program incentive, as proposed.

Maintenance of Certification Program Incentive: Qualification Process. For the qualification process, we proposed that an entity must meet all of the following requirements to be considered for qualification for purposes of the 2013 and 2014 Maintenance of Certification Program incentives (77 FR 44983):

• The name, NPI and applicable TINs of eligible professionals who would like to participate for the 2013 and/or 2014 Maintenance of Certification Program incentives.

• Attestation from the board that the information provided to CMS is accurate and complete.

• The board has signed documentation from eligible professional(s) that the eligible professional wishes to have the information released to us.

• Information from the patient experience of care survey.

• Information certifying the eligible professional has participated in a Maintenance of Certification Program for a year, ''more frequently'' than is required to qualify for or maintain board certification status, including the year the physician met the board certification requirements for the Maintenance of Certification Program, and the year the eligible professional participated in the Maintenance of Certification Program ''more frequently'' than is required to maintain or qualify for board certification.

• Information certifying the eligible professional has completed the Maintenance of Certification Program practice assessment at least one time each year the eligible professional participates in the Maintenance of Certification Program Incentive.

We proposed this self-nomination and qualification process because the process is identical to the self-nomination and qualification process finalized for the 2011 and 2012 Maintenance of Certification Program incentives and we felt such requirements remain appropriate. Because the incentives only run through 2014, we felt it was important to keep the requirements consistent with what has been required for the 2011 and 2012 Maintenance of Certification Program incentives.

We invited public comment on the proposed qualification process for entitles entities who wish to be qualified for the 2013 and 2014 Maintenance of Certification Program incentive. The following is summary of the comments we received regarding these proposals.

Comment: One commenter suggested that those entities that have previously undergone the qualification process and were previously qualified to participate in this Maintenance of Certification Program incentive be automatically qualified for the following year.

Response: We agree with the commenter's suggestion to allow boards that were fully qualified in a prior program year and successfully submitted data to be fully qualified after CMS review of their application. Since the qualification process is the same from year to year, CMS believes that requiring boards to undergo this process every year is redundant. CMS agrees that this will allow more time for returning boards to encourage participation with their diplomats.

Comment: One commenter suggested that newly participating boards be allowed to bypass the qualification process if they administer a qualified registry.

Response: We agree with the commenter's suggestion. The data submission process for Maintenance of Certification entities is similar to the registry data submission process. Therefore, it would seem redundant for a specialty board that already possesses a qualified registry to have to undergo another separate qualification process to participate in the Maintenance of Certification Program incentive, as the entity's products and characteristics have already been vetted when it submitted its registry for qualification under PQRS. Therefore, we do not believe it is necessary for specialty boards that administer PQRS qualified registries to undergo a separate qualification process for purposes of the Maintenance of Certification Program incentive. Therefore, we are not requiring boards who wish to participate in the Maintenance of Certification Program incentive for the first time to undergo the Maintenance of Certification Program incentive qualification process if they also maintain a PQRS qualified registry. However, we note that these specialty boards must still self-nominate for each year the specialty board wishes to participate in Maintenance of Certification Program incentive.

Comment: One commenter believed that the requirements for receiving a Maintenance of Certification incentive payment are too onerous for both physicians and participating boards.

Response: We appreciate the commenter's feedback. We understand that physicians already participating in Maintenance of Certification programs are already taking proactive steps to maintain their clinical skills and education. In fact, we defer to the boards for what is necessary to demonstrate a physician's ability to maintain certification. However, given the requirement that a physician participate in a Maintenance of Certification program ''more frequently'' than is required to maintain board certification, we believe that earning an additional Maintenance of Certification incentive under PQRS involves extra effort by the physician. Please note that we work with the participating boards to determine what extra steps are necessary to earn this incentive.

Comment: One commenter seeks clarification on how physicians are to participate in a Maintenance of Certification Program ''more frequently'' than is required to maintain or qualify for board certification.

Response: Please note that more information and guidance about how to participate in a Maintenance of Certification Program incentive ''more frequently'' for purposes of the Maintenance of Certification Program incentive is available on the PQRS Web site at *http://www.cms.gov/Medicare/*

Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

Comment: One commenter requested that CMS explore opportunities to leverage the Maintenance of Certification structure that exists within the specialty boards to reduce redundant reporting requirements and enhance the value of PQRS for physicians and their patients.

Response: We appreciate the commenter's feedback. CMS has worked closely with the specialty boards to establish requirements for earning the additional Maintenance of Certification Program incentive under PQRS. In fact, the boards provide the guidelines for determining what is necessary to demonstrate a physician's ability to maintain certification.

Based on the comments received and for the reasons discussed above, we are finalizing the qualification process for boards wishing to become qualified to participate in the Maintenance of Certification Program incentive. However, boards that were previously qualified as a Maintenance of Certification Program entity or newly participating boards that utilize a previously qualified registry for their Maintenance of Certification Program data will not need to undergo the qualification process annually. Rather, these entities will be qualified after these entities complete their self-nomination statements. However, please note that previously qualified boards or boards that use a previously qualified registry must still self-nominate to participate in the Maintenance of Certification Program incentive for each year the boards wish to participate. For boards wishing to newly become qualified, we note that, due to a delay in the availability of the testing tool to qualify the boards, this qualification process will occur later in time for 2013. Please note that we are also making technical changes in § 414.90(d) due to changes in the composition of § 414.90(c) to specify the incentive amounts for the 2013 and 2014 PQRS incentives. We are also making a technical change at § 414.90(d)(1)(iii)(B)(2)(i), as this section incorrectly references (d)(2)(11); the correct reference is (d)(1)(iii).

8. Informal Review

We established an informal review process for 2012 and beyond in the CY 2012 Medicare PFS final rule (76 FR 73390). In this final rule with comment period, we addressed the additional parameters we proposed for eligible professionals and group practices subject to a PQRS payment adjustment requesting an informal review. For eligible professionals and group practices that are subject to the payment adjustments that wish to request an informal review, in addition to the requirements we previously established, we proposed the following:

- An eligible professional electing to utilize the informal review process must request an informal review by February 28 of the year in which the payment adjustment is being applied. For example, if an eligible professional requests an informal review related to the 2015 payment adjustment, the eligible professional would be required to submit his/her request for an informal review by February 28, 2015. We felt this deadline provided ample time for eligible professionals and group practices after their respective claims begin to be adjusted due to the payment adjustment.
- Where we find that the eligible professional or group practice did satisfactorily report for the payment adjustment, we would to cease application of the payment adjustment and reprocess all claims that have been erroneously adjusted to date (77 FR 44983).

We invited public comment on our proposals for the PQRS informal review process. The following is a summary of the comments we received regarding the proposed additional parameters for the PQRS informal review process.

Comment: Several commenters supported our proposal to establish an informal review process for the PQRS payment adjustment.

Response: We appreciate the commenters' feedback and are finalizing an informal review process for the PQRS payment adjustments that is similar to the informal review process established for the PQRS incentives.

Comment: One commenter supported our proposed deadline of February 28 of the payment adjustment year for eligible professionals and group practices to request an informal review of the PQRS payment adjustment.

Response: Based on the comments received, we are finalizing a deadline of February 28 of the payment adjustment year for eligible professionals and group practices to request an informal review of the PQRS payment adjustment.

Comment: One commenter supported CMS' proposal to provide written responses to those eligible professionals and group practices seeking an informal review request.

Response: We appreciate the commenter's feedback and we are finalizing our proposal to provide a timely, written response to eligible professionals and group practices seeking an informal review of the applicability of the PQRS payment adjustment.

Comment: One commenter supported our proposal to make eligible professionals and group practices whole should CMS find error.

Response: We believe it is important to rectify error should CMS find that an error has occurred in application of the PQRS payment adjustment during the informal review process. Therefore, where we find that the eligible professional or group practice did satisfactorily report for the payment adjustment, we will cease application of the payment adjustment and reprocess all claims that have been erroneously adjusted to date.

Based on the comments received and for the reasons stated previously, we are finalizing these additional parameters for the PQRS informal review process as it relates to the PQRS payment adjustments. We are finalizing changes to § 414.90 to reflect the PQRS informal review process for the PQRS incentives and payment adjustments.

H1. The Electronic Prescribing (eRx) Incentive Program

We established the requirements for the 2013 and 2014 eRx Incentive Program in the CY 2012 Medicare PFS final rule (76 FR 73393). This section addresses additional final requirements for the 2013 and 2014 eRx Incentive Program.

Please note that, during the comment period following the proposed rule, we received comments that were not related to our specific proposals for the eRx Incentive Program in the CY 2013 Medicare PFS proposed rule. While we appreciate the commenters' feedback and intend to use these comments to better develop the eRx Incentive Program, these comments will not be specifically addressed in this CY 2013 Medicare PFS final rule.

1. Definition of Group Practice

Under § 414.92(b) a group practice is one that, defined at § 414.90(b), that is participating in the Physician Quality Reporting System; or in a Medicare-approved demonstration project or other Medicare program, under which Physician Quality Reporting System requirements and incentives have been incorporated; and has indicated its desire to participate in the electronic prescribing group practice option. Please note that the definition of group practice for the eRx Incentive Program is therefore tied to the definition of group practice under PQRS. Since we are changing the definition of group practice in PQRS to allow groups of 2–24 eligible professionals to participate

in PQRS as a group practice, accordingly, group practices of 2–24 eligible professionals will be able to participate in the eRx Incentive Program as a group practice in 2013 (that is, for the 2013 incentive and 2014 payment adjustment).

In addition, we would like to clarify the requirement under § 414.92(b) that a group practice under the eRx Incentive Program must be ''participating in the Physician Quality Reporting System''. We developed this definition in light of our goals for group practices to report under both programs, as well as operational considerations for administering the group practice reporting option under the PQRS and ERx Incentive Program. In particular, we expect that group practices participating in the eRx Incentive Program as a group practice will also be participating in PQRS as a group practice. With regard to ''participation,'' we note that we have never required nor indicated that group practices under the eRx GPRO must report PQRS quality measures to demonstrate participation in the PQRS for purposes of this definition. In the past, we have required that group practices wishing to participate in the eRx Incentive Program under the group practice reporting option (eRx GPRO) must complete a self-nomination statement stating the group practice's intent to participate in PQRS as a group practice. We have viewed that as an example of ''participation.'' However, because we believe submission of a self-nomination statement for PQRS as an extra administrative step we have required in order for group practices to participate in the eRx GPRO, in 2013, we no longer view completion of a self-nomination statement to participate in PQRS under the PQRS group practice reporting option (PQRS GPRO) as necessary to demonstration ''participation'' by group practices under the eRx Incentive Program. Therefore, the statement to be ''participating in the Physician Quality Reporting System'' is merely an indication but not a requirement that we expect that group practices participating in the eRx Incentive Program as a group practice will also be participating in PQRS as a group practice.

2. Alternative Self-Nomination Process for Certain Group Practices Under the eRx GPRO

In the CY 2012 Medicare PFS final rule (76 FR 73394), we established that a group practice wishing to participate in the eRx Incentive Program under the eRx GPRO must self-nominate via the web. However, we proposed an alternative submission mechanism for self-nomination by groups participating in the Medicare Shared Savings Program, Pioneer ACO, PGP Demonstration, or other Medicare-approved demonstration project or other Medicare program (77 FR 44983). Specifically, we proposed that the participating TINs within these groups that wish to participate in the eRx Incentive Program using the eRx GPRO would be required to submit a self-nomination statement by sending a letter indicating its intent to participate in the eRx Incentive Program under the eRx GPRO. We also proposed that the group practice would be required to submit an XML file describing the eligible professionals included in the group practice. We proposed this alternative submission mechanism for group practices that are participating as groups in the Medicare Shared Savings Program, Pioneer ACO, or PGP Demonstration because it is not technically feasible for CMS to receive this information from these group practices via the web. We invited public comment on this proposed alternative mechanism for submitting self-nomination statements for groups participating in the Medicare Shared Savings Program, Pioneer ACO, and PGP demonstration and the proposed requirement to provide an XML file to CMS for the types of group practices identified above that want to participate in the eRx Incentive Program using the eRx GPRO. We received no comments regarding these proposed alternative methods related to the self-nomination process for group practices participating in the Medicare Shared Savings Program, Pioneer ACO, and PGP demonstration that wish to participate in the eRx Incentive Program using the eRx GPRO. Therefore, we are finalizing an alternative self-nomination process for these aforementioned groups. However, as we believe that it would be more efficient to accept self-nomination statements electronically, we will not accept these self-nomination statements via U.S. mail. Rather, we will accept these self-nomination statements via email. We are also not finalizing the requirement that these group practices provide an XML file to CMS. The XML file typically provides CMS with a list of the eligible professionals (defined by their individual rendering National Provider Identification numbers or NPIs) within the group practice. Since we do not need NPI-level information to analyze group practice reporting, we no longer need this XML file.

In addition, in the CY 2012 PFS final rule with comment period, we stated we would accept self-nomination statements for group practices that want to participate in the GPROs for PQRS and the eRx Incentive Program via the web (76 FR 73315 and 76 FR 73394). We note that this Web page is only available for those group practices who wish to submit a self-nomination statement to participate in both the PQRS and eRx Incentive Program under the respective GPROs. Therefore, it will not be technically feasible to accept self-nomination statements via this Web page from group practices who wish to submit a self-nomination statement to participate in the eRx GPRO only. Group practices wishing to submit a separate GPRO self-nomination statement to participate in the eRx Incentive Program only must follow the alternative self-nomination process that group practices participating in the Medicare Shared Savings Program using the eRx GPRO follow (76 FR 73395).

We also note that, in the CY 2012 Medicare PFS final rule, we established a deadline of January 31 of the applicable program year (for example, January 31, 2013 for the 2013 program year) for group practices to submit a self-nomination statement to participate in the eRx GPRO (76 FR 73316). Although, as discussed in section III.G, we have extended the deadline for group practices wishing to participate in the GPRO in PQRS to the Fall of the applicable program year (for example, Fall 2013 for the 2013 program year), for operational reasons, group practices wishing to participate in the eRx Incentive Program under the eRx GPRO for 2013 must submit its self-nomination statement by January 31, 2013 as finalized in the CY 2012 Medicare PFS final rule. We understand that having two separate deadlines for submitting GPRO self-nomination statements for PQRS and the eRx Incentive Program may cause confusion for group practices who have submitted self-nomination statements for PQRS and eRx simultaneously in previous years. However, because the 2014 6-month payment adjustment reporting period (that is, January 1, 2013–June 30, 2013) occurs prior to Fall 2013, we must maintain a deadline of January 31, 2013 for those group practices wishing to participate in the eRx Incentive Program as a group practice using the eRx GPRO for reporting periods occurring 2013.

We realize that having two separate self-nomination dates of January 31, 2013 and Fall 2013 for self-nominating to participate in the GPRO for the eRx Incentive Program and PQRS respectively may cause additional administrative concerns, such as situations where a group practice may change its TIN between June 30, 2013

(after the 6-month 2014 payment adjustment reporting period) and Fall 2013. We will try to work with group practices so that they are aware of the applicable deadlines and procedure.

2. The 2013 Incentive: Criterion for Being a Successful Electronic Prescriber for Groups Comprised of 2–24 Eligible Professionals Selected To Participate Under the eRx GPRO

We proposed to add another criterion for becoming a successful electronic prescriber under the program for the 2013 Incentive for groups of 2–24 eligible professionals that may now participate in the eRx Incentive Program using the eRx GPRO in 2013 (77 FR 44983–44984). (For the other criteria we previously adopted for the eRx GPRO, please see 76 FR 73407). Specifically, we proposed the following criterion for being a successful electronic prescriber for group practices participating in the eRx GPRO comprised of 2–24 eligible professionals for purposes of the 2013 eRx incentive: Report the electronic prescribing measure's numerator code during a denominator-eligible encounter for at least 225 times during the 12-month 2013 incentive reporting period (January 1, 2013–December 31, 2013). We proposed a lower criterion for group practices participating under the eRx GPRO with 2–24 eligible professionals because we understand that their smaller sizes necessitate a lower reporting threshold. We proposed this reporting threshold because this reporting threshold is familiar to group practices, as this was the threshold established for group practices comprised of 11–25 eligible professionals that participated in the GPRO II in 2011 (75 FR 73509).

We invited public comment on our proposed criterion for being a successful electronic prescriber for the 2013 incentive for groups comprised of 2–24 eligible professionals. The following is a summary of the comments we received on this proposal.

Comment: Several commenters generally supported our proposal to establish criteria for being a successful electronic prescriber for group practices comprised of 2–24 eligible professionals. However, some commenters stated that our proposed reporting threshold for a group practice of 2–24 eligible professionals to become a successful electronic prescriber is too high, particularly for a group comprised of 2 eligible professionals. One commenter suggested applying a percentage threshold, similar to the electronic prescribing criteria established under the EHR Incentive Program. Other commenters suggested a tiered approach similar to the criteria for becoming a successful electronic prescriber previously established under eRx GPRO II (75 FR 73509). One of these commenters also suggested that, in the alternative, the proposed threshold be lowered. Commenters stated that group practices of 2–24 eligible professionals should be required report the electronic prescribing measure at least 75 times to become a successful electronic prescriber for the 2013 incentive.

Response: We believe it is important to establish an electronic prescribing threshold that group practices of 2–24 eligible professionals can reasonably attain to become successful electronic prescribers. As we explain in greater detail further below, we agree with the commenters' suggestion and therefore, we are finalizing a reporting threshold of 75 times.

For the suggestion to adopt a percentage threshold, we prefer to establish a reporting count as the established criteria for becoming a successful electronic prescriber for larger groups utilize a reporting count rather than a percentage. Therefore, we would like to remain consistent in the reporting criteria that were previously established for larger group practices participating in the eRx GPRO.

For the tiered approach, we believe that adding several tiers for reporting for smaller group practices would add to the complexity of the eRx Incentive Program. To streamline the requirements for becoming a successful electronic prescriber for the eRx Incentive Program, we prefer one criterion for all group practices of 2–24 eligible professionals using the eRx GPRO. We believe that the proposed threshold of 75 offered by commenters is reasonable, particularly because the eRx Incentive Program previously required group practices of 2–10 eligible professionals participating in the eRx GPRO II to report the electronic prescribing measure at least 75 times (75 FR 73509). We note that our proposed threshold of reporting the electronic prescribing measure was also consistent with criteria we established under GPRO II in 2011, but we understand the desire to lower the threshold to 75. We believe that the reporting threshold of 75 also achieves the program goal of ensuring that eligible professionals are generating prescriptions electronically. Therefore, based on the comments received, we are finalizing a lower threshold for reporting the electronic prescribing measure of 75 rather than 225. To be a successful electronic prescriber for the 2013 incentive, group practices comprised of 2–24 eligible professionals that are participating in the eRx GPRO must report the electronic prescribing measure at least 75 times during the applicable 12-month reporting period (that is, January 1, 2013–December 31, 2013) for the 2013 incentives.

3. The 2014 Payment Adjustment: Criterion for Being a Successful Electronic Prescriber for Group Practices Comprised of 2–24 Eligible Professionals Selected To Participate Under the eRx GPRO

We proposed to change the minimum group practice size from 25 to 2 accordingly with PQRS and proposed to add another criterion for being a successful electronic reporter under the program for the 2014 payment adjustment (77 FR 44984). (For the other criteria we previously adopted for the eRx GPRO Reporting Option, please see 76 FR 73412–73414). Specifically, we proposed the following criterion for being a successful electronic prescriber for purposes of the 2014 payment adjustment for group practices comprised of 2–24 eligible professionals participating under the eRx GPRO: Report the electronic prescribing measure's numerator code at least 225 times for the 6-month 2014 payment adjustment reporting period (January 1, 2013–June 30, 2013). We proposed this lower criterion for group practices participating under the eRx GPRO with 2–24 eligible professionals because we understand that their smaller sizes necessitate a lower reporting threshold. In addition, we noted that this reporting threshold is familiar to group practices, as this was the threshold established for group practices comprised of 11–25 eligible professionals that participated in the GPRO II in 2011 (75 FR 73509).

We invited public comment on the proposed criterion for being a successful electronic prescriber for the 2014 eRx payment adjustment for the 6-month payment adjustment reporting period for group practices composed of 2–24 eligible professionals. The following is a summary of comments we received regarding this proposal.

Comment: Commenters generally provided the same comments regarding this proposed criterion for becoming a successful electronic prescriber for the 2014 payment adjustment as provided for the proposed criterion for becoming a successful electronic prescriber for the 2013 incentive. Specifically, several commenters generally supported our proposal to establish criteria for becoming a successful electronic prescriber for group practices comprised of 2–24 eligible professionals. However, some commenters stated that our proposed reporting threshold for a

group practice of 2–24 eligible professionals to become a successful electronic prescriber is too high. One commenter suggested applying a percentage threshold, similar to the electronic prescribing criteria established under the EHR Incentive Program. Other commenters suggested a tiered approach similar to the criteria for becoming a successful electronic prescriber previously established under eRx GPRO II (75 FR 73509). One of these commenters also suggested that, in the alternative, the proposed threshold be lowered. Group practices of 2–24 eligible professionals should be required report the electronic prescribing measure at least 75 times to become a successful electronic prescriber for the 2014 payment adjustment.

In addition to these comments, some commenters supported our proposed criteria to report the electronic prescribing measure at least 225 times to become a successful electronic prescriber for the 2013 incentive but believed that this 225 threshold is too high for the 2014 payment adjustment, as group practices will only have 6 months as opposed to 12 months to meet this threshold. The commenters added that the threshold is especially high for dermatologists who may not see this many Medicare Part B patients during the 6-month 2014 payment adjustment reporting period.

Response: For the same reasons we discussed above with regard to the threshold for the 2013 incentive, we agree with the points raised by commenters. In addition, for reporting under the eRx GPRO, it is our desire to keep with the trend of establishing similar criteria for the incentives as payment adjustments. It is our desire to finalize the same criterion for the 2014 payment adjustment as finalized for the 2013 incentive. Therefore, based on the comments received and for the reasons we stated for establishing a lower threshold of 75 for the 2013 incentive, we are finalizing a lower threshold for reporting the electronic prescribing measure for the 2014 payment adjustment of 75 instead of 225. To be a successful electronic prescriber for the 2014 payment adjustment, group practices comprised of 2–24 eligible professionals that are participating in the eRx GPRO must report the electronic prescribing measure at least 75 times during the applicable 2014 6-month payment adjustment reporting period.

4. Analysis for the Claims-Based Reporting Mechanism

We understand that, in certain instances, it is permissible for an eligible professional to have their Medicare Part B claims reprocessed. However, we raised concerns about eligible professionals resubmitting claims for the sole reason of attaching a G-code for purposes of reporting under the eRx Incentive Program (rather than reporting such data at the time the claim was initially submitted). Therefore, we proposed to modify § 414.92 to indicate that under the eRx Incentive Program, if an eligible professional re-submits a claims for reprocessing, the eligible professional may not attach a G-code at that time. The following is a summary of comments we received on this proposal.

Comment: Some commenters disagreed with our proposal to modify § 414.92 to indicate that G-codes cannot be attached to claims that are re-submitted for reprocessing for purposes of the eRx Incentive Program. Commenters urged us to allow the reopening or resubmission of claims for the sole purpose of attaching a reporting code on a claim.

Response: To avoid the reprocessing of claims solely to report quality measure for the eRx Incentive Program, we believe such a policy is needed and therefore, we are finalizing our change to the regulation at § 414.92. In addition, we note that even though professionals may prefer this practice, it is not practically feasible to allow eligible professionals and group practices to resubmit a claim for the sole purpose of attaching a reporting code on a claim for purposes of the eRx Incentive Program. Allowing eligible professionals to resubmit claims for reporting purposes opens the potential for the reprocessing of millions of claims, which would be overly burdensome and costly for CMS. Therefore, we are finalizing our proposal to add § 414.92(f)(2)(i)(A) to indicate if an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on the electronic prescribing measure. We note that has been CMS' policy not to accept quality data from claims that were resubmitted since the inception of PQRS (where the electronic prescribing measure was first available for reporting) in 2007.

5. Proposed Significant Hardship Exemptions

Section 1848(a)(5)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment, if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. In the CY 2012 final rule with comment period, we finalized, as set forth at § 414.92(c)(2)(ii)(B), four circumstances under which an eligible professional or eRx GPRO can request consideration for a significant hardship exemption for the 2013 and 2014 eRx payment adjustments (76 FR 73413):

- The eligible professional or group practice practices in a rural area with limited high speed internet access.
- The eligible professional or group practice practices in an area with limited available pharmacies for electronic prescribing.
- The eligible professional or group practice is unable to electronically prescribe due to local, state, or Federal law or regulation.
- The eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a 6-month reporting period.

We have received feedback from stakeholders requesting significant hardship exemptions from application of the payment adjustment based on participation in the EHR Incentive Program, a program which requires a certain level of electronic prescribing activity. Under the EHR Incentive Program, eligible professionals [4] may receive incentive payments beginning in CY 2011 for successfully demonstrating ''meaningful use'' of Certified EHR Technology (CEHRT) and will be subject to payment adjustments beginning in CY 2015 for failure to demonstrate meaningful use. For further explanation of the statutory authority and regulations for the EHR Incentive Program, we refer readers to the EHR Incentive Program—Stage 1 final rule (75 FR 44314) and the EHR Incentive Program—Stage 2 final rule (77 FR 53968). As a result of such feedback, we believe that in certain circumstances it may be a significant hardship for eligible professionals and group practices who are participants of the EHR Incentive Program to comply with the successful electronic prescriber requirements of the eRx Incentive Program. Therefore, we proposed to revise the regulation at § 414.92(c)(2)(ii)(B) (77 FR 44984) to add the following two additional significant hardship exemption categories for the 2013 and 2014 payment adjustments:

- Eligible professionals or group practices who achieve meaningful use during certain eRx payment adjustment reporting periods.

[4] ''Eligible professional'' is defined for the EHR Incentive Program at 42 CFR 495.4, 495.100, and 495.304.

• Eligible professionals or group practices who demonstrate intent to participate in the EHR Incentive Program and adoption of Certified EHR Technology.

The following is a summary of general comments we received regarding our proposal to add these two additional significant hardship exemption categories for the 2013 and 2014 payment adjustments:

Comment: One commenter opposed our proposal to add two new additional significant hardship exemption categories related to participation in the EHR Incentive Program. The commenter notes that CMS implemented the eRx Incentive Program in 2009 and eligible professionals have had sufficient time in which to make arrangements to implement the program. The commenter is concerned these two new hardship exemptions may have the unintended consequence of discouraging eligible providers' rapid participation in the electronic prescribing program.

Response: We appreciate the commenter's concern and note that it is not our intention to discourage participation in the eRx Incentive Program through the establishment of these significant hardship exemption categories. We note that incentives under the eRx Incentive Program are available until 2013 and hope that the potential to earn an incentive under the eRx Incentive Program will encourage eligible professionals who are not also receiving incentives under the Medicare EHR Incentive Program to participate in the eRx Incentive Program.

With respect to the argument that eligible professionals have had adequate time to acquire systems capable for electronic prescribing, we note that although the eRx Incentive Program was established in 2009, and has transitioned from bonus incentives to payment adjustments beginning in 2012, we believe that with the establishment of the EHR Incentive Program, which also includes an electronic prescribing objective, eligible professionals and group practices choosing to participate in the eRx Incentive Program and the EHR Incentive Program may have had difficulties with regard to searching for products that had the capabilities to meet requirements for both programs. As we noted in the proposed rule (77 FR 44984), we received stakeholder feedback regarding the difficulties of choosing, purchasing, and setting up an EHR system that is capable for use for both programs. Therefore, we believe that these significant hardship exemption categories are appropriate for eligible professionals and group practices such as these.

Comment: Several commenters supported our proposed two additional significant hardship exemption categories related to participation in the EHR Incentive Program for the 2013 and 2014 payment adjustments.

Response: We agree with the commenters' general support of these two additional significant hardship exemptions. Therefore, based on the comments received and for the reasons stated previously, we are finalizing, as discussed in greater detail, these two additional significant hardship exemptions related to participation in the EHR Incentive Program for the 2013 and 2014 payment adjustments.

a. Eligible Professionals or Group Practices Who Achieve Meaningful Use During the 2013 and 2014 Payment Adjustment Reporting Periods

Under Stage 1 of meaningful use for the EHR Incentive Program, an eligible professional is required to meet certain objectives and associated measures to achieve meaningful use. One of these objectives is for the eligible professional to generate and transmit permissible prescriptions electronically, and the measure of whether the eligible professional has met this objective is more than 40 percent of all permissible prescriptions written by the eligible professional are transmitted electronically using Certified EHR Technology (§ 495.6(d)(4)). We note that the EHR Incentive Program and the eRx Incentive Program share a common goal of encouraging electronic prescribing and the adoption of technology that enables eligible professionals to electronically prescribe. This goal is advanced under each program via the respective program requirements—the electronic prescribing objective under the EHR Incentive Program and the requirement that an EP be a ''successful electronic prescriber'' under the eRx Incentive Program. Indeed, both programs require that the eligible professionals indicate their electronic prescribing activity. Under the EHR Incentive Program, an eligible professional must attest to the percentage of his or her permissible prescriptions that were generated and transmitted electronically using Certified EHR Technology during the applicable EHR reporting period, which must exceed 40 percent. Under the eRx Incentive Program, to avoid the payment adjustment, an eligible professional must be a successful electronic prescriber, which is achieved by the reporting of the eRx quality measure a certain number of instances during the applicable reporting period (each instance of reporting of the eRx quality measure, which includes reporting of specific quality data codes, signifies that the professional generated an electronic prescription for a specified service or encounter). In most cases, we believe the electronic prescribing objective of meaningful use would be a more rigorous standard for eligible professionals to meet than the standard adopted under the eRx Incentive Program (as demonstrated via the reporting of the eRx quality measure). In addition, there seems to be no added benefit with regard to reporting (presumably lower) electronic prescribing activity under the eRx Incentive Program given that the identical goals (encouraging electronic prescribing) of both programs would have been fulfilled through the eligible professional's achievement of meaningful use. For those reasons, we believe it may pose a significant hardship for eligible professionals who are meaningful EHR users to additionally comply with the requirements of being a successful electronic prescriber under the eRx Incentive program.

For the reasons stated, under this proposed significant hardship category, we proposed that individual eligible professionals (and every eligible professional member of a group practice using the eRx GPRO for the 2014 payment adjustment only) would need to achieve meaningful use of Certified EHR Technology for a continuous 90-day EHR reporting period (as defined for the EHR Incentive Program) that falls within the 6-month reporting period (January 1–June 30, 2012) for the 2013 eRx payment adjustment or the 12- or 6-month reporting periods (January 1–December 31, 2012 or January 1–June 30, 2013, respectively) for the 2014 eRx payment adjustment to be eligible for this significant hardship exemption (77 FR 44985). We also proposed that for purposes of the 2013 and 2014 eRx payment adjustments this hardship exemption category would apply to individual EPs and group practices (that is, every member of the group) who instead achieve meaningful use of Certified EHR Technology for an EHR reporting period that is the full CY 2012.

We invited public comment on this proposed significant hardship exemption category. The following is a summary of the comments received related to the proposed significant hardship exemption category: Eligible professionals or group practices who achieve meaningful use during the 2013 and 2014 payment adjustment reporting periods.

Comment: One commenter specifically supported this proposed

significant hardship exemption category. The commenter noted that establishing this significant hardship exemption category will help alleviate concerns from eligible professionals and group practices that are transitioning their EHR systems.

Response: We appreciate the commenter's positive feedback and are finalizing this significant hardship exemption category.

Comment: One commenter took exception that this significant hardship exemption category would only apply to those eligible professionals participating in the EHR Incentive Program for the first time. The commenter requested that CMS expand the applicability of this significant hardship exemption category to all eligible professionals who achieve meaningful use regardless of when an eligible professional first participated in the EHR Incentive Program.

Response: We appreciate the commenter's feedback. This significant hardship exemption category was intended to be applicable to eligible professionals and group practices who achieve meaningful use during certain 2013 and 2014 eRx payment adjustment reporting periods, regardless of whether it is the first time the EP (or EPs in a group practice) achieves meaningful use under the EHR Incentive Program. Therefore, we clarify that this significant hardship exemption category will apply regardless of whether an EP has previously achieved meaningful use under the EHR Incentive Program.

Comment: Some commenters suggested that this significant hardship exemption category include EPs who have achieved meaningful use in 2011, 2012, and 2013.

Response: We appreciate the commenters' feedback. We proposed that individual EPs or EPs within a group practice would be eligible for this significant hardship exemption category if the eligible professionals achieve meaningful use for an EHR reporting period that falls within (1) the 6-month 2013 payment adjustment reporting period (January 1–June 30, 2012) for the 2013 payment adjustment and/or (2) the 12-month (January 1–December 31, 2012) or 6-month (January 1–June 30, 2013) 2014 payment adjustment reporting period for the 2014 payment adjustment. We also proposed that for the 2013 and 2014 payment adjustments, individual EPs or EPs within a group practice would be eligible for this significant hardship exemption category if they achieve meaningful use for an EHR reporting period that is the full CY 2012. As such, our proposal covers those EPs who achieved meaningful use under the EHR Incentive Program in 2012 and the first 6 months of 2013. For expanding this significant hardship exemption category to cover EPs who have achieved meaningful use in 2011, we understand the desire for EPs who achieved meaningful use in 2011 to be exempt from the 2013 payment adjustment. Since 2011 was the 12-month payment adjustment reporting period for the 2013 payment adjustment, and as proposed this significant hardship exemption category would cover EPs who achieve meaningful use during the 12- and 6-month payment adjustment reporting periods for the 2014 payment adjustment, for the reasons previously stated for proposing this significant hardship category, we will extend this category to include individual EPs and EPs within a group practice who achieve meaningful use under the EHR Incentive Program for an EHR reporting period that fell within 2011 (that is, during the 12-month 2013 payment adjustment reporting period).

We cannot expand this significant hardship exemption category for the 2014 payment adjustment to include eligible professionals who achieve meaningful use during the last 6 months of 2013 (July 1, 2013–December 31, 2013) because the last 6 months of 2013 do not coincide with the 2014 payment adjustment reporting period.

Based on the comments received and for the reasons previously stated, we are finalizing this significant hardship exemption category—eligible professionals or group practices who achieve meaningful use during the 2013 and 2014 payment adjustment reporting periods—as follows: To qualify for a significant hardship exemption under this category for the 2013 payment adjustment, an eligible professional (or every eligible professional in a group practice participating in the eRx GPRO for the 2013 payment adjustment) must have achieved meaningful use of Certified EHR Technology under the EHR Incentive Program for a continuous 90-day EHR reporting period that fell within the 12-month (January 1, 2011–December 31, 2011) or 6-month (January 1, 2012–June 30, 2012) payment adjustment reporting period or for an EHR reporting period that is the full CY 2012. To qualify for a significant hardship exemption under this category for the 2014 payment adjustment, an eligible professional (or every eligible professional in a group practice participating in the eRx GPRO) must achieve meaningful use of Certified EHR Technology under the EHR Incentive Program for a continuous 90-day EHR reporting period that falls within the 12-month (January 1, 2012–December 31, 2012) or 6-month (January 1, 2013–June 30, 2013) payment adjustment reporting period or for an EHR reporting period that is the full CY 2012.

b. Eligible Professionals or Group Practices Who Demonstrate Intent To Participate in the EHR Incentive Program and Adoption of Certified EHR Technology

We note that we finalized at § 414.92(c)(2)(ii)(A)(*3*) a significant hardship exemption category for the 2012 eRx payment adjustment, under which eligible professionals and group practices seeking consideration for an exemption were required to register to participate in the EHR Incentive Program and adopt CEHRT (76 FR 54958). That significant hardship category addressed significant hardships relating to the selection, purchase and adoption of eRx technology (for example, potential significant financial hardship of purchasing two sets of eRx equipment for both programs) that may have occurred as a result of the timing of the release of the standards and requirements for CEHRT and the Certified Health IT Product List, the establishment of the respective program requirements for the eRx and EHR Incentive Programs, and the 2012 eRx payment adjustment reporting periods. Given that eligible professionals have had adequate time to identify EHR products that have been certified and that the requirements for these programs have been implemented and, various stages of reporting are underway, we do not believe this significant hardship exemption category would continue to be applicable for the 2013 and 2014 eRx payment adjustments. We understand, however, that although an eligible professional may now have the requisite information about requirements for CEHRT and each respective program, there may nevertheless exist a significant hardship with regard to compliance with the requirements for being a successful electronic prescriber under the eRx Incentive Program, given the nature of CEHRT and how it is used/implemented in one's practice.

When an eligible professional or eligible professional in a group practice first adopts CEHRT, we understand significant changes may be required with regard to how the eligible professional's practice operates. Further, necessary steps are involved in fully implementing CEHRT once it has been adopted, including: Installation, configuration, customization, training, workflow redesign and the establishment of connectivity with entities that facilitate electronic health

information exchange (such as for electronic prescriptions). Thus, we believe it would be difficult for an eligible professional or eligible professional in a group practice who has adopted CEHRT to be able to begin electronically prescribing on day one. Rather, we expect a natural lag time would likely occur between an eligible professional's adoption of CEHRT and the point at which CEHRT has been fully implemented such that an eligible professional could begin electronically prescribing. We believe this implementation timeline may pose a significant hardship for an eligible professional or group practice who seeks to comply with the requirements for being a successful electronic prescriber under the eRx Incentive Program and also participate for the first time in the EHR Incentive Program. Under the EHR Incentive Program, an eligible professional who is demonstrating meaningful use of CEHRT for the first time must do so for any continuous 90-day period within the calendar year (the ''EHR reporting period''). In the absence of this significant hardship exemption category, eligible professionals or group practices who choose a 90-day EHR reporting period that falls later in the year may potentially have to adopt two systems (for example, a stand-alone electronic prescribing system for purposes of participating in the eRx Incentive Program, and CEHRT for purposes of participating in the EHR Incentive Program), which could be financially burdensome. Alternatively, such eligible professionals who wish to use CEHRT for purposes of participating in both programs may potentially have to adopt and implement CEHRT well in advance of their 90-day EHR reporting period to meet an earlier reporting period for the eRx Incentive Program.

Therefore, for the 2013 and 2014 payment adjustments, we proposed a significant hardship exemption category to address this situation (77 FR 44985). We believe, however, that for this category it is necessary for eligible professionals and group practices to show they intend to participate in the EHR Incentive Program for the first time and have adopted CEHRT. Therefore, to be eligible for consideration for an exemption under this proposed significant hardship exemption category for the 2013 and 2014 payment adjustments, we proposed that eligible professionals or group practices must register to participate in the Medicare or Medicaid EHR Incentive Programs and adopt CEHRT by a date specified by CMS. We further note that, given the nature of the significant hardship at issue under this category, this proposal would be limited to eligible professionals and group practices (that is, every individual eligible professional of the group practice): (1) Who have not previously adopted CEHRT or received an incentive payment under the Medicare or Medicaid EHR Incentive Programs; and (2) who attempt to participate in the Medicare or Medicaid EHR Incentive Programs from January 2, 2012 through October 15, 2012, or the effective date of the final rule (which includes the 6-month 2013 eRx payment adjustment reporting period of January 1, 2012–June 30, 2012) for the 2013 eRx payment adjustment, or during the 6-month payment adjustment reporting period for the 2014 eRx payment adjustment (January 1, 2013 through June 30, 2013).

For eligible professionals or group practices who intend to adopt EHR technology in the future or have not yet taken the steps required to apply for this significant hardship exemption, we believe that mere intent to adopt CEHRT or attest at a later date does not sufficiently demonstrate that an eligible professional will adopt CEHRT to participate in the Medicare or Medicaid EHR Incentive Programs. Unlike those eligible professionals who would have registered for the Medicare or Medicaid EHR Incentive Programs and have adopted CEHRT available for immediate use, we would have to monitor and provide oversight over those eligible professionals who have not yet taken these steps to participate in the Medicare or Medicaid EHR Incentive Programs. We also do not believe that such eligible professionals or group practices would necessarily be facing a significant hardship as contemplated in this proposed exemption category. Accordingly, all of the proposed requirements to qualify for an exemption under this significant hardship exemption category would need to be met by the time the eligible professional requests an exemption. In section III.H1.5.b. below, we discuss the proposed deadlines and procedures for requesting consideration of an exemption under this proposed significant hardship exemption category.

We invited public comment on this proposed significant hardship exemption category for the 2013 and 2014 payment adjustments. The following is a summary of the comments received specific to this proposed significant hardship exemption category: Eligible professionals or group practices who demonstrate intent to participate in the EHR Incentive Program and adoption of Certified EHR Technology.

Comment: One commenter suggested that this significant hardship exemption category apply to eligible professionals who register for the EHR Incentive Program in 2011, 2012, and 2013.

Response: This significant hardship exemption category does not apply to eligible professionals who in 2011 demonstrated intent to participate in the EHR Incentive Program and adopted Certified EHR Technology. We note that this significant hardship exemption category was intended to apply to eligible professionals and group practices dealing with issues related to fully implementing CEHRT once it has been adopted, including: Installation, configuration, customization, training, workflow redesign and the establishment of connectivity with entities that facilitate electronic health information exchange (such as for electronic prescriptions). We believe these eligible professionals and group practices who adopted CEHRT and demonstrated intent to participate in the EHR Incentive Program in 2011 would have had ample time to fully implement their CEHRT in time for the payment adjustment reporting periods for the 2013 and 2014 payment adjustments. Therefore, this significant hardship exemption category does not apply to eligible professionals or group practices that adopted CEHRT and demonstrated intent to participate in the EHR Incentive Program in 2011.

For the 2013 payment adjustment, it was our intent to apply this significant hardship exemption category to eligible professionals or group practices that adopt CEHRT as well as demonstrate intent to participate in the EHR Incentive Program during a certain timeframe in 2012. We proposed that, for the 2013 payment adjustment, an eligible professional would be required to meet the qualifications for this significant hardship exemption category by October 15, 2012 or the effective date of this final rule, whichever is later.

For the 2014 payment adjustment, it was our intent to apply this significant hardship exemption category to eligible professionals or group practices that adopt CEHRT, as well as demonstrate intent to participate in the EHR Incentive Program during a certain timeframe in 2013. We proposed that an eligible professional would be required to meet the qualifications for this significant hardship exemption category by the end of the 6-month 2014 payment adjustment reporting period (January 1, 2013–June 30, 2013). We established this deadline as it coincides with the deadline for requesting exemptions

under the four previously established significant hardship exemption categories. Therefore, we decline to extend this significant hardship exemption category beyond June 30, 2013.

Based on the comments received and for the reasons stated above, we are finalizing this significant hardship exemption category—eligible professionals or group practices who demonstrate intent to participate in the EHR Incentive Program and adoption of Certified EHR Technology. However, to provide CMS with additional time to gather information on who qualifies for a significant hardship exemption under this category, we are extending the proposed deadline. For the 2013 payment adjustment, this significant hardship exemption category would apply to eligible professionals (or every eligible professional in a group practice participating in the eRx GPRO) who demonstrate intent to participate in the EHR Incentive Program by registering for the program between January 2, 2012 and January 31, 2013 and adopt Certified EHR Technology. We note that eligible professionals who achieved meaningful use of Certified EHR Technology under the EHR Incentive Program for an EHR reporting period that ended on or before June 30, 2012, or for an EHR reporting period that is the full CY 2012, are not eligible for this significant hardship exemption category (nor is a group practice participating in the eRx GPRO eligible if any of its member eligible professionals achieved meaningful use during those timeframes).

For the 2014 payment adjustment, this significant hardship exemption category applies to eligible professionals (or every eligible professional in a group practice participating in the eRx GPRO) who demonstrate intent to participate in the EHR Incentive Program by registering for the program between January 1, 2013 and June 30, 2013 and adopting Certified EHR Technology. Eligible professionals who achieve meaningful use of Certified EHR Technology under the EHR Incentive Program for an EHR reporting period that ends on or before June 30, 2013, or for an EHR reporting period that is the full CY 2013, are not eligible for this significant hardship exemption category (nor is a group practice participating in the eRx GPRO eligible if any of its member eligible professionals achieve meaningful use during those timeframes). Please note that, should the deadline for submitting requests for the four previously established significant hardship exemption categories be extended for any reason, it is our intent that the deadline for this significant hardship exemption category would be extended accordingly with all other significant hardship exemption categories to the 2014 payment adjustment.

c. Deadlines and Procedures for Requesting Significant Hardship Exemptions

In the CY 2012 final rule with comment period, we established a process whereby eligible professionals would submit significant hardship exemptions for the existing significant hardship exemption categories for the eRx payment adjustments (76 FR 54963). Unfortunately, for submitting these proposed significant hardship exemptions for the 2013 payment adjustment, it would not be operationally feasible to accept significant hardship exemption requests in the manner we previously established. Therefore, we proposed that, to request a significant hardship under the two proposed significant hardship exemption categories for the 2013 eRx payment adjustment, CMS would analyze the information provided to us in the Registration and Attestation System under the EHR Incentive Program to determine whether the eligible professional or group practice (that is, every EP member of the group practice) has either (1) achieved meaningful use under the EHR Incentive Program during the applicable reporting periods we noted previously, or (2) registered to participate in the EHR Incentive Program via the Registration and Attestation system for the EHR Incentive Program (located at *https://ehrincentives.cms.gov/hitech/login.action*) and adopted CEHRT, or both, if applicable. We understand that providing an eligible professional's CEHRT product number is an optional field in the Registration Page. We noted that if requesting a significant hardship exemption under proposed category 2, the eligible professional must provide its CEHRT product number when registering for the EHR Incentive Program. In the event that it is not operationally feasible to accept this information via the Registration and Attestation system for the EHR Incentive Program, we proposed that we would accept requests for significant hardship exemptions under these two proposed categories via a mailed letter to CMS to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850.

We also proposed that eligible professionals would be required to submit this significant hardship request by October 15, 2012 or the effective date of the final rule for this provision, whichever is later. For those eligible professionals who request a significant hardship exemption based on achieving meaningful use under the EHR Incentive Program during the 12- or 6-month reporting periods for the 2013 payment adjustment, we also proposed that the eligible professional would be required to have attested under the EHR Incentive Program by October 15th of 2012 (or if later, the effective date of the final rule), to qualify for a significant hardship exemption for the 2013 payment adjustment. For those eligible professionals requesting a significant hardship exemption for the 2013 eRx payment adjustment under the second proposed significant hardship exemption category (that is, intent to participate in the EHR Incentive Program and adoption of CEHRT), we proposed that these eligible professionals who intend to participate in the EHR Incentive Program from January 1, 2011 through October 15, 2012 or the effective date of the final rule would be required to register for the EHR Incentive Program and adopt CEHRT by the same deadline noted above, to qualify for a significant hardship exemption for the 2013 payment adjustment. We note that we proposed a later deadline of October 15, 2012 (or the effective date of the final rule, if later) for the submission of these requests because the deadline for submitting requests under other previously established significant hardship exemption categories to the 2013 eRx payment adjustment (June 30, 2012) has passed and other similar dates we might choose would likely have passed by the time the final rule is effective.

For submitting exemption requests for the two significant hardship exemption categories for the 2014 payment adjustment, we proposed the following method for submitting a request for a significant hardship exemption: Via the Communication Support Page (which is the method established for submitting the established significant hardship exemption categories).

In addition, we considered accepting significant hardship exemption requests for the two proposed significant hardship exemption categories for the 2014 payment adjustment by CMS receiving eligible professionals' information through the Registration and Attestation System for the EHR Incentive Program (similar to our proposed submission process for the

2013 payment adjustment) and via a mailed letter to CMS using the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850. We invited public comment on these considered submission options.

We proposed that the deadline for submitting these significant hardship exemption requests for the 2014 payment adjustment would be June 30, 2013, which is the same deadline established for submitting a significant hardship exemption request for the existing significant hardship exemption categories. Additionally, and consistent with our proposal for the 2013 payment adjustment, we proposed that an eligible professional or group practice (that is, all members of the practice) that achieves meaningful use under the EHR Incentive Program during the 6- or 12-month reporting periods for the 2014 payment adjustment would be required to attest by June 30, 2013. Similarly, for eligible professionals requesting a significant hardship exemption for the 2014 payment adjustment under the second proposed significant hardship exemption category (that is, intent to participate in the EHR Incentive Program and adoption of CEHRT), we proposed that eligible professionals who intend to participate in the EHR Incentive Program during the last 6 months of 2013 would be required to register for the EHR Incentive Program and adopt CEHRT by June 30, 2013, to qualify for a significant hardship exemption for the 2014 payment adjustment. We noted that we understood that these deadlines may exclude some eligible professionals who attested or registered for the EHR Incentive Program at later dates, but these deadlines were necessary to avoid the reprocessing of claims. We note, however, that these proposed deadlines would not extend any deadlines applicable under the EHR Incentive Program. That is, for purposes of the EHR Incentive Program, an eligible professional would still be required to attest to being a meaningful user by the deadline established under the EHR Incentive Program, even if such deadline fell prior to the proposed eRx Incentive program significant hardship exemption deadline.

We noted that we only proposed submission of requests for significant hardship exemptions under these two categories under an individual eligible professional level only because it is not technically feasible for us to operationally analyze information on the EHR Incentive Program's Registration and Attestation page using the TIN, as the information stored in this system is stored by NPI. However, we stated we would not preclude eligible professionals in an eRx GPRO for 2012 from submitting requests for significant hardship exemptions under these two categories. Therefore, to allow the submission of significant hardship requests for the 2013 eRx payment adjustment under these two proposed categories, we proposed that eligible professionals within an eRx GPRO must each request a significant hardship exemption under these two categories.

We invited public comment on this proposed process for submitting significant hardship exemption requests under these two proposed categories. The following is a summary of the comments received related to these proposals.

Comment: Several commenters requested that CMS utilize information contained in the EHR Incentive Program's Registration and Attestation page to determine who would qualify for the two additional significant hardship exemption categories for the 2013 and 2014 payment adjustment. Another commenter recommended that the process for requesting a significant hardship exemption under these two categories be streamlined. One commenter requested that CMS provide as many options as possible for eligible professionals to submit requests for significant hardship exemptions under the two proposed categories. One commenter suggested that requests be submitted electronically, not via U.S. mail. Overall, most commenters believe that using information already collected by CMS from the EHR Incentive Program's Registration and Attestation page to exempt eligible professionals from the 2013 and 2014 payment adjustment would reduce burden on eligible professionals and group practices as they would not be required to actively request a significant hardship exemption via the web.

Response: We agree that basing applicability of these two significant hardship exemption categories on information collected from the EHR Incentive Program's Registration and Attestation page for the 2013 and 2014 payment adjustments would relieve burden on eligible professionals as they would not be required to actively request a significant hardship exemption via the web. Based on the comments received, we are finalizing our proposal to use information collected from the EHR Incentive Program's registration and attestation page to exempt eligible professionals from the 2013 payment adjustment under these two additional significant hardship exemption categories. In addition, based on the comments received, we will use this same method to exempt eligible professionals from the 2014 payment adjustment under these two additional significant hardship exemption categories rather than requiring eligible professionals to request exemptions under these two significant hardship exemption categories via the web. We are not finalizing any other options for requesting an exemption under these two categories, because we believe that this method is the most efficient way to exempt eligible professionals. We note that we are able to internally analyze this data for the two additional significant hardship exemption categories, and not the other previously established four significant hardship exemption categories, because, unlike the previous four categories, CMS already has access to the information needed under the EHR Incentive Program's Registration and Attestation page to make our determination on whether an eligible professional should be exempt from the 2013 and/or 2014 payment adjustments under these two significant hardship exemption categories.

Comment: Some commenters requested that CMS extend the proposed deadline to submit requests for significant hardship exemptions under these two additional categories. One commenter requested that eligible professionals and group practices be allowed at least 90 days to submit such a request. Other commenters suggested a deadline of October 31, 2012 to apply exemptions under these two proposed significant hardship exemptions for the 2013 payment adjustment. In addition, since the proposed deadlines for qualifying for these two additional significant hardship exemption categories are later than the established deadline for the four previously established significant hardship exemption categories, the commenter requested that the deadline for requesting exemptions under the four previously established significant hardship exemption categories be extended to coincide with the established deadline for these two additional significant hardship categories.

Response: For applying these two proposed significant hardship exemptions for the 2013 payment adjustment, we proposed a deadline of October 15, 2012 or the effective date of the rule, whichever is later. Since our proposed deadline date of October 15,

2012 as well as the commenter's proposed deadline date of October 31, 2012 has passed, we considered finalizing our proposed deadline of the effective date of the CY 2013 Medicare PFS final rule. However, it is our understanding that certain eligible professionals that achieve meaningful use may have until February 28 of the following year to attest that they met the CQM component of achieving meaningful use. Although it is not practically feasible to extend the deadline for qualifying for the first significant hardship exemption category (related to achieving meaningful use under the EHR Incentive Program) due to the need to minimize the reprocessing of claims, it is feasible to extend the deadline for qualifying for this significant hardship exemption category to January 31, 2013. To afford eligible professionals with more time to qualify for this exemption, we are therefore finalizing a deadline of January 31, 2013 to qualify for this significant hardship exemption category related to achieving meaningful use under the EHR Incentive Program. So that the deadlines for qualifying for these two additional significant hardship exemptions coincide, we are also finalizing a deadline of January 31, 2013 to qualify for the second significant hardship exemption category related to demonstrating intent to participate in the EHR Incentive Program. Therefore, for the 2013 payment adjustment, eligible professionals must qualify for consideration under these two additional significant hardship exemption categories by January 31, 2013.

We received no public comment regarding the proposed deadline for qualifying for an exemption under these two additional significant hardship exemption categories for the 2014 payment adjustment. Based on the reasons stated previously, we are finalizing this proposal. We note, however, that in the event that the deadlines for requesting a significant hardship exemption under the four previously established exemption categories are extended, we intend to extend this deadline to coincide with the deadline for requesting exemptions under these other four categories. Additionally, we may extend this deadline should we run into operational concerns, such as receiving data from the EHR Incentive Program's Registration and Attestation page.

With respect to extending the deadline to submit exemption requests under the four previously established significant hardship exemption categories for the 2013 payment adjustment, we will allow the extension of the deadline to request exemptions under these four previously established exemption categories to January 31, 2013. We finalized a deadline of June 30, 2012 to submit requests for exemptions under these four significant hardship categories primarily to avoid having to reprocess claims. Since we are extending this deadline to January 31, 2013, we anticipate that, in some cases, particularly in instances where eligible professionals submit significant hardship exemption requests closer towards the deadline, we may not be able to complete our review of the requests before the claims processing systems updates are made to begin reducing eligible professionals' and group practices' PFS amounts in 2013. In such cases, if we ultimately approve the eligible professional or group practice's request for a significant hardship exemption after January 1, 2013, we would need to reprocess all claims for services furnished up to that point in 2013 that were paid at the reduced PFS amount, which we anticipate may take several months. To avoid the reprocessing of claims, we encourage eligible professionals who would be submitting a significant hardship exemption request under these four significant hardship exemption categories to do so as soon as possible, rather than waiting until the deadline to submit such a request.

We note that we would like to be able to process all such requests before we begin making the claims processing systems changes to adjust eligible professionals' or group practices' payments starting on January 1, 2013 or 2014. However, we anticipate that, in some cases, particularly in instances where eligible professionals submit significant hardship exemption requests closer towards the deadline, we may not be able to complete our review of the requests before the claims processing systems updates are made to begin reducing eligible professionals' and group practices' PFS amounts in 2013. In such cases, if we ultimately approve the eligible professional or group practice's request for a significant hardship exemption after January 1, 2013 or 2014, we would need to reprocess all claims for services furnished up to that point in 2013 that were paid at the reduced PFS amount, which we anticipate may take several months. To avoid the reprocessing of claims, we encourage eligible professionals who would be submitting a significant hardship exemption request under these two categories to do so as soon as possible, rather than waiting until the deadline to submit such a request.

Tables 125 and 126 provide a summary of the significant hardship exemption categories that are available to eligible professionals and group practices for the 2013 and 2014 payment adjustments.

TABLE 125—SUMMARY OF SIGNIFICANT HARDSHIP EXEMPTION CATEGORIES FOR THE 2013 eRx PAYMENT ADJUSTMENT

Significant hardship exemption category	Method of submission	Deadline for submitting exemption request
The eligible professional or group practice practices in a rural area with limited high speed internet access.	Web-based Communication Support Page.	Extended to January 31, 2013.
The eligible professional or group practice practices in an area with limited available pharmacies for electronic prescribing.	Web-based Communication Support Page.	Extended to January 31, 2013.
The eligible professional or group practice is unable to electronically prescribe due to local, state, or Federal law or regulation.	Web-based Communication Support Page.	Extended to January 31, 2013.
The eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a 6-month reporting period.	Web-based Communication Support Page.	Extended to January 31, 2013.
* Eligible professionals or group practices who achieve meaningful use during the 2013 12- and 6-month eRx payment adjustment reporting periods (that is, January 1, 2011–June 30, 2012).	EHR Incentive Program's Registration and Attestation Page.	January 31, 2013.

TABLE 125—SUMMARY OF SIGNIFICANT HARDSHIP EXEMPTION CATEGORIES FOR THE 2013 eRX PAYMENT ADJUSTMENT—Continued

Significant hardship exemption category	Method of submission	Deadline for submitting exemption request
* Eligible professionals or group practices who demonstrate intent to participate in the EHR Incentive Program and adoption of Certified EHR Technology.	EHR Incentive Program's Registration and Attestation Page.	January 31, 2013.

* Eligible professionals participating in the eRx Incentive Program under the eRx GPRO are eligible for these significant hardship exemption categories. However, each eligible professional in the eRx GPRO wishing to have this exemption applied must individually have provided the requisite information on the EHR Incentive Program's Registration and Attestation page.

TABLE 126—SUMMARY OF SIGNIFICANT HARDSHIP EXEMPTION CATEGORIES FOR THE 2014 eRX PAYMENT ADJUSTMENT

Significant hardship exemption category	Method of submission	Deadline for submitting exemption request
The eligible professional or group practice practices in a rural area with limited high speed internet access.	Web-based Communication Support Page.	June 30, 2013.
The eligible professional or group practice practices in an area with limited available pharmacies for electronic prescribing.	Web-based Communication Support Page.	June 30, 2013.
The eligible professional or group practice is unable to electronically prescribe due to local, state, or Federal law or regulation.	Web-based Communication Support Page.	June 30, 2013.
The eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a 6-month reporting period.	Web-based Communication Support Page.	June 30, 2013.
* Eligible professionals or group practices who achieve meaningful use during the 2014 12- and 6-month eRx payment adjustment reporting periods (that is, January 1, 2012–June 30, 2013).	EHR Incentive Program's Registration and Attestation Page.	June 30, 2013.
* Eligible professionals or group practices who demonstrate intent to participate in the EHR Incentive Program and adoption of Certified EHR Technology.	EHR Incentive Program's Registration and Attestation Page.	June 30, 2013.

* Eligible professionals participating in the eRx Incentive Program under the eRx GPRO are eligible for these significant hardship exemption categories. However, each eligible professional in the eRx GPRO wishing to have this exemption applied must individually have provided the requisite information on the EHR Incentive Program's Registration and Attestation page.

6. Informal Review

To better facilitate issues surrounding the issuance of incentives and payment adjustments, we proposed to establish an informal review process for the eRx Incentive Program (77 FR 44987). We proposed an informal review process similar to the informal review process established for the PQRS (76 FR 73390), because eligible professionals and group practices are already familiar with this process. We proposed the informal review process would only be available for the 2013 incentive payments and the 2014 payment adjustment.

For an informal review regarding the 2013 incentive, we proposed that an eligible professional or group practice must request an informal review within 90 days of the release of his or her feedback report, irrespective of when an eligible professional or group practice actually accesses his/her feedback report.

For an informal review regarding the 2014 payment adjustment, we proposed that an eligible professional or group practice must request an informal review by January 31, 2013 (77 FR 44988). We believed this deadline would provide ample time for eligible professionals and group practices to discover that their respective claims are being adjusted due to the 2014 payment adjustment and seek informal review.

We proposed that the request be submitted in writing and summarize the concern(s) and reasons for requesting an informal review. In his or her request for an informal review, an eligible professional may also submit other information to assist in the review. We proposed that an eligible professional may request an informal review through the web. We believe use of the web would provide a more efficient way for CMS to record informal review requests, as the web would guide the eligible professional through the creation of an informal review requests. For example, the web-based tool would prompt an eligible professional of any necessary information he or she must provide. Should it be technically not feasible to receive requests for informal reviews via the web, we proposed that an eligible professional would be able to request an informal review via email (77 FR 44988).

We further proposed that we would make our determination and provide the eligible professional or group practice with a written response to his or her request for an informal review within 90 days of receiving the request.

Based on our informal review and once we have made a determination, we proposed that we would provide the eligible professional or group practice a written response. Where we find that the eligible professional or group practice did successfully report for the 2013 incentive, we would provide the eligible professional or group practice with the applicable incentive payment. Where we find that the eligible professional or group practice did successfully report (that is, meet criteria for being a successful electronic prescriber) for purposes of the 2014 payment adjustment, we would cease application of the 2014 payment adjustment and reprocess all claims that have been adjusted. We further proposed that decisions based on the informal review would be final, and there would be no further review or appeal.

We invited public comment on our proposals for the eRx Incentive Program informal review process for the 2013 incentive and the 2014 payment adjustment. The following is a summary of comments we received on these proposals:

Comment: Several commenters supported our proposal to establish an informal review process for the 2013

incentive and 2014 payment adjustment.

Response: We appreciate the commenters' feedback and are finalizing our proposal to establish an informal review process for the 2013 incentive and 2014 payment adjustment.

Comment: One commenter urged CMS to create a more formal appeals process that provides eligible professionals with concurrent feedback on reporting.

Response: We appreciate the commenter's feedback. We note that the informal review process we have proposed has deadlines and a process similar to formal review processes. We believe the informal review process we are establishing is appropriate for this program and is an adequate venue for eligible professionals and group practices to seek a review of their eRx incentive or payment adjustment applicability. With respect to providing concurrent feedback on reporting, for the 2012 and 2013 incentives, feedback reports will be available to eligible professionals and group practices prior to the start of the informal review process. With respect to the 2013 and 2014 payment adjustments, with respect to reporting during the 12-month 2013 and 2014 payment adjustment reporting periods (that is, January 1, 2011–December 31, 2011 and January 1, 2012–December 31, 2012 respectively), we note that these feedback reports, which are the same feedback reports given for the 2011 and 2012 incentives respectively, will be provided prior to the start of the informal review process. While it may not be technically feasible to have feedback reports for the 6-month 2013 and 2014 payment adjustment reporting periods (that is, January 1, 2012–June 30, 2012 and January 1, 2013–June 30, 2013 respectively), we note that we anticipate that payment adjustment status notifications to eligible professionals who report the electronic prescribing measure will be made available prior to the start of the informal review process.

Comment: One commenter urged that we align the PQRS and eRx informal review processes.

Response: To the extent possible, it is our intention to align the informal review processes for the eRx Incentive Program and PQRS. We established the same deadline for requesting an informal review under the eRx Incentive Program and PQRS. However, we stress that these two programs are separate and require separate methods of review. For example, the eRx Incentive Program involves the reporting of one measure, whereas PQRS involves the reporting of hundreds of measures. Therefore, the PQRS informal review process would require more intensive resources than the eRx Incentive Program's informal review process.

Comment: In addition to supporting our proposal to establish an informal review process for the 2013 eRx incentive and 2014 eRx payment adjustment, some commenters urged us to establish a similar informal review process for the 2012 eRx incentive and 2012 and 2013 eRx payment adjustments. The commenters believed that extending this informal review process would allow eligible professionals or group practices who have had administrative, operational, or technological issues to present their case to CMS.

Response: We understand the desire to establish a similar informal review process for the 2012 eRx incentive and 2012 and 2013 eRx payment adjustments. As for establishing an informal review process for the 2012 eRx payment adjustment, we note that we have already reviewed cases where an eligible professional or group practice has sought a review of their 2012 eRx payment adjustment applicability. We also note that it is not operationally feasible to establish an informal review process for the 2012 eRx payment adjustment until 2013, after the cessation of the application of the 2012 eRx payment adjustment for eligible professionals who were not successful electronic prescribers. However, we believe it will be operationally feasible to establish an informal review process for the 2012 eRx incentive and 2013 eRx payment adjustment. Therefore, we are finalizing an informal review process for the 2012 and 2013 eRx incentives and 2013 and 2014 eRx payment adjustments. The process and deadlines for the informal review process for the 2012 eRx incentive and 2013 eRx payment adjustment will mirror our established process and deadlines for the 2013 eRx incentive and 2014 eRx payment adjustment.

Comment: Some commenters recommended that eligible professionals be given until March 31, 2014 to request an informal review relating to issues surrounding the 2012 and 2013 eRx incentives and 2012, 2013 and 2014 eRx payment adjustments. The commenters noted that eligible professionals and group practices need ample time to keep up with informal review deadlines that vary from program to program.

Response: We understand the need to provide eligible professionals with ample time to learn about the informal review process. However, it is not operationally feasible to establish an informal review request deadline of March 31, 2014 for the 2012 and 2013 eRx incentives and 2012, 2013, and 2014 eRx payment adjustments. This would be overly burdensome and costly for CMS, as CMS would then have to potentially process claims from 2012–2014 for those who receive a favorable decision. To minimize the reprocessing of claims, the informal review process (which includes the time for submitting a request as well as the processing time to review these requests) would need to occur within the year the eligible professional or group practice's payments are being adjusted (for example, in 2013 for the 2013 payment adjustment). However, we believe it is feasible to extend the deadline for requesting an informal review past January 31. Therefore, we are finalizing a deadline of February 28, 2013 to request an informal review related to issues surrounding the 2012 eRx incentive and 2013 eRx payment adjustment. We are finalizing a deadline of February 28, 2014 to request an informal review related to issues surrounding the 2013 eRx incentive and 2014 eRx payment adjustment. Please note that February 28 is the same deadline we established for the PQRS payment adjustment informal review process, thereby alleviating the issue of eligible professionals and group practices needing to keep up with different informal review request deadlines.

Comment: Some commenters supported our proposal to receive informal review requests via the web.

Response: We appreciate the commenter's feedback. Unfortunately, it is not technically feasible for us to accept informal review requests via an online tool. However, we believe that accepting informal review requests electronically will be the most efficient way to facilitate the informal review process as opposed to receiving mailed requests. Therefore, we will accept informal review requests via an email to CMS.

To summarize what we have finalized, we are establishing an informal review process for the 2012 and 2013 eRx incentives and 2013 and 2014 eRx payment adjustments. As such, we are also finalizing our proposed modifications to § 414.92 that address the informal review process we are establishing. Eligible professionals and group practices wishing to request an informal review must do so via email. For the 2012 eRx incentive and 2013 eRx incentives, eligible professionals and group practices must submit a request for an informal review 90 days after the receipt of the

respective feedback reports. For the 2013 and 2014 eRx payment adjustments, eligible professionals and group practices must submit a request for an informal review by February 28, 2013 and February 28, 2014, respectively. CMS will provide a written response to each informal review request. More information regarding this informal review process will be available on the eRx Incentive Program's Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ERxIncentive/index.html?redirect=/ERXincentive*.

H2. The PQRS-Medicare EHR Incentive Pilot

The Medicare EHR Incentive Program provides incentive payments to eligible professionals (EPs) who demonstrate meaningful use of certified EHR technology (CEHRT). EPs who fail to demonstrate meaningful use will be subject to payment adjustments beginning in 2015. We established a phased approach to meaningful use, which we expect will include three stages (77 FR 53973), and all EPs are currently in Stage 1. In the CY 2012 Medicare PFS final rule, we established the PQRS-Medicare EHR Incentive Pilot in an effort to pilot the electronic submission of CQMs for the Medicare EHR Incentive Program and move towards the alignment of quality reporting requirements between Stage 1 of the Medicare EHR Incentive Program and the PQRS (76 FR 73422). We refer readers to the final rule for further explanation of the requirements of the Pilot (76 FR 73422–73425). Specifically, we established that an EP participating in the PQRS-Medicare EHR Incentive Pilot would be able to report clinical quality measures (CQMs) data extracted from Certified EHR Technology via use of a PQRS qualified direct EHR product or PQRS qualified EHR data submission vendor (76 FR 73422). We proposed to modify § 495.8 to extend this Pilot for CY 2013 as it was finalized for CY 2012. We also proposed to remove from § 495.8(a)(2)(v) the cross-reference to § 495.6(d)(10) to conform to the proposed changes to § 495.6(d) that were included in the EHR Incentive Program—Stage 2 NPRM (77 FR 53976). This proposal includes the following:

- For 2013 only, EPs intending to participate in the PQRS-Medicare EHR Incentive Pilot may use a PQRS qualified EHR data submission vendor that would submit CQM data extracted from the EP's CEHRT to CMS. Under this option, identical to the submission process used for the Pilot in 2012, the PQRS qualified EHR data submission vendor would calculate the CQMs from the EP's CEHRT and then submit the calculated results to CMS on the EP's behalf via a secure portal for purposes of this Pilot.
- For 2013 only, identical to the submission process used for the Pilot in 2012, EPs intending to participate in the PQRS-Medicare EHR Incentive Pilot may use a PQRS qualified direct EHR product to submit CQM data directly from his or her CEHRT to CMS via a secure portal using the infrastructure of the PQRS EHR-based reporting mechanism.

In addition, for 2013, we proposed to extend the use of attestation as a reporting method for the CQM component of meaningful use for the EHR Incentive Program. For 2013, EPs would be able to continue to report by attesting CQM results as calculated by CEHRT, as they did for 2011 and 2012. For further explanation of the CQM reporting criteria for EPs and reporting by attestation, we refer readers to the EHR Incentive Program—Stage 2 final rule (77 FR 54049 through 54089) and the EHR Incentive Program—Stage 1 final rule (75 FR 44386–44411, 44430–44434).

We invited public comment on our proposal to extend to 2013 the PQRS-Medicare EHR Incentive Pilot as it was established for 2012 as well as reporting CQMs by attestation. The following is a summary of the comments we received regarding our proposals.

Comment: Several commenters supported our proposal to extend the PQRS-Medicare EHR Incentive Pilot to 2013. The commenters do not believe that there was sufficient participation in 2012 to move beyond the Pilot stage in 2013. The commenters noted that the extension of the Pilot will continue to encourage the adoption of health information technology (HIT).

Response: We appreciate the commenters' feedback and agree with the commenters. Based on the comments received and for the reasons previously stated, we are finalizing our proposal to extend the PQRS-Medicare EHR Incentive Pilot to CY 2013 as proposed. We are also finalizing our proposal to extend the use of attestation to CY 2013 as a reporting method for the CQM component of meaningful use for the EHR Incentive Program. We are also finalizing our proposed revisions to § 495.8 as proposed. Please note we are only extending the Pilot for 2013 because in the EHR Incentive Program—Stage 2 final rule (77 FR 53968), we established a policy that will require all EPs participating in the Medicare EHR Incentive Program that are beyond their first year of meaningful use to electronically submit CQM data.

I. Medicare Shared Savings Program

1. Medicare Shared Savings Program and Physician Quality Reporting System Payment Adjustment

Under section 1899 of the Act, CMS has established a Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in healthcare costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule implementing the Shared Savings Program appeared in the **Federal Register** on November 2, 2011 (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

Section 1899(b)(3)(D) of the Act affords the Secretary discretion to ''* * * incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 * * *'' and permits the Secretary to ''use alternative criteria than would otherwise apply [under section 1848 of the Act] for determining whether to make such payments.'' Under this authority, we incorporated certain Physician Quality Reporting System (PQRS) reporting requirements and incentive payments into the Shared Savings Program (76 FR 67902). In the Shared Savings Program final rule, we finalized the following requirements with regard to PQRS incentive payments under the Shared Savings Program: (1) The 22 GPRO quality measures identified in Table 1 of the final rule (76 FR 67889–67890); (2) reporting via the GPRO web interface (76 FR 67893); (3) criteria for satisfactory reporting (76 FR 67900); and (4) January 1 through December 31 as the reporting period. The regulation governing the incorporation of PQRS incentives and reporting requirements under the Shared Savings Program is set forth at § 425.504.

Under § 425.504(a)(1), ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using the GPRO web interface established by CMS, to qualify on behalf

of their eligible professionals for the PQRS incentive under the Shared Savings Program. ACO providers/suppliers that are eligible professionals constitute a group practice for purposes of qualifying for a PQRS incentive under the Shared Savings Program. Under § 425.504(a)(2)(ii), an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report the measures determined under the Shared Savings Program during the reporting period according to the method of submission established by CMS to receive a PQRS incentive under the Shared Savings Program. For the years in which a PQRS incentive is available, if eligible professionals that participate in an ACO as ACO providers/suppliers qualify for a PQRS incentive payment under the Medicare Shared Savings Program, the ACO participant TIN(s) under which those ACO providers/suppliers bill, will receive an incentive payment based on the allowed charges of those ACO providers/suppliers. Under § 425.504(a)(4), ACO participant TINs and individual ACO providers/suppliers who are eligible professionals cannot earn a PQRS incentive outside of the Medicare Shared Savings Program. The PQRS incentive under the Medicare Shared Savings Program is equal to 0.5 percent of the Secretary's estimate of the ACO's eligible professionals' total Medicare Part B PFS allowed charges for covered professional services furnished during the calendar year reporting period from January 1 through December 31, for years 2012 through 2014.

As discussed in section III.G of this final rule with comment period, as required by section 1848(a)(8) of the Act, a payment adjustment will apply under the PQRS beginning in 2015. For eligible professionals who are not satisfactory reporters, the PFS amount for covered professional services furnished by the eligible professional during 2015 shall be equal to 98.5 percent (and 98 percent for 2016 and each subsequent year) of the fee schedule amount that would otherwise apply to such services. Therefore, consistent with our authority under section 1899(b)(3)(D) of the Act, we proposed to amend § 425.504 to incorporate reporting requirements for the PQRS payment adjustment under the Shared Savings Program for eligible professionals that are ACO providers/suppliers (77 FR 44989).

We proposed to incorporate requirements for the PQRS payment adjustment that are consistent with requirements for PQRS incentives that we previously adopted in the Shared Savings Program final rule. Specifically, for purposes of the PQRS payment adjustment, we proposed to incorporate the same PQRS GPRO under the Shared Savings Program that is currently used for purposes of the PQRS incentive under the Shared Savings Program. Under this proposal, eligible professionals that are ACO providers/suppliers would constitute a group practice that would report quality measures via the GPRO data collection tool for purposes of both the PQRS incentive under the Shared Savings Program and the PQRS payment adjustment under the Shared Savings Program (77 FR 44989).

For purposes of the payment adjustment, we proposed to use the final GPRO quality measures adopted under the Shared Shavings Program that appear in Table 1 of the Shared Savings Program final rule (76 FR 67899–67890). We further proposed to incorporate the same criteria for satisfactory reporting that were finalized for the PQRS incentive under the Shared Savings Program, which are described in the Shared Savings Program final rule (76 FR 67900). Specifically:

- An ACO on behalf of its eligible professionals must report on all measures included in the GPRO data collection tool under the Shared Savings Program final rule.
- Beneficiaries would be assigned to the ACO using the methodology described in § 425.400. As a result, the GPRO tool would be populated based on a sample of the ACO-assigned beneficiary population. ACOs must complete the tool for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each domain, measures set, or individual measure if a separate denominator is required such as in the case of preventive care measures which may be specific to one sex. If the pool of eligible assigned beneficiaries is less than 411, the ACO must report on 100 percent of assigned beneficiaries for the domain, measures set, or individual measure.
- The GPRO data collection tool must be completed for all domains, measure sets and measures described in Table 1 of the of the Shared Savings Program final rule (76 FR 67889–67890).

Under this proposal, ACOs would need to satisfactorily report the 22 GPRO quality measures identified in Table 1 of the Shared Savings Program final rule (76 FR 67889–67890) and would not need to report the other 11 Shared Savings Program quality performance measures for purposes of satisfactory reporting for the PQRS payment adjustment. However, under this proposal, the ACO would still be required to satisfy the ACO quality performance standards for purposes of determining eligibility for shared savings, as described in § 425.502.

We note that the proposal that ACOs report the same quality measures for purposes of satisfactory reporting for both the PQRS payment adjustment and incentive payments under the Shared Savings Program was consistent with the proposal under the traditional PQRS GPRO Web Interface reporting option that the criteria for satisfactory reporting for the payment adjustments align with the satisfactory reporting requirements for the incentive payments (77 FR 44824).

Comment: We received a number of comments supporting the proposal to incorporate the same PQRS GPRO measures used for the PQRS incentive payment under the Shared Savings Program and Shared Savings Program quality performance standards. We also received support for accepting quality data at the ACO level rather than requiring each ACO provider and supplier who is an eligible professional to submit measure data separately to PQRS outside of the Medicare Shared Savings Program. We did not receive any comments opposing our proposal or suggesting alternatives.

Response: We appreciate commenters' support and are finalizing our proposal to use the final GPRO quality measures adopted under the Shared Shavings Program that appear in Table 1 of the Shared Savings Program final rule (76 FR 67899–67890) for purposes of the PQRS payment adjustment satisfactory reporting criteria with the following modifications. Instead of requiring ACOs to report on all of the ACO GPRO quality measures for purposes of satisfactory reporting for the 2015 PQRS payment adjustment under the Shared Savings Program, ACOs must only report one of the ACO GPRO measures that were finalized for the PQRS incentive under the Shared Savings Program, as described above and in the Shared Savings Program final rule (76 FR 67900). As the intent of our proposal was to align with the traditional PQRS GPRO Web Interface reporting option policy regarding the PQRS payment adjustment, this policy for ACOs participating in PQRS under the Shared Savings Program, as finalized under § 425.504(b), is consistent with the criteria for satisfactory reporting that we are finalizing for group practices that select the PQRS GPRO Web Interface reporting option, for the 2015 payment adjustment, as discussed in section III.G. of this final rule. We believe that aligning the satisfactory reporting

requirements for the 2015 PQRS payment adjustment under the Medicare Shared Savings Program with the satisfactory reporting requirements for the payment adjustment under the traditional PQRS GPRO Web Interface reporting option is important for encouraging participation in the Medicare Shared Savings Program. That is, we do not wish to create a disincentive for eligible professionals to join an ACO or participate in the Medicare Shared Savings Program by setting the satisfactory reporting criteria for the 2015 PQRS payment adjustment at a higher level under the Medicare Shared Savings Program than under the traditional PQRS. We believe it is appropriate to set the satisfactory reporting criteria higher for purposes of the PQRS incentive than for the PQRS payment adjustment, under the Shared Savings Program, for the same reasons discussed in section III.G. of this final rule.

While satisfactorily reporting one measure would be required for purposes of avoiding the 2015 PQRS payment adjustment under the Medicare Shared Savings Program, we note that ACOs are still required to report all 22 GPRO measures for purposes of the PQRS incentive under the Shared Savings Program and for purposes of assessing ACOs' quality performance under the Shared Savings Program and determining the percentage of shared savings that ACOs are eligible to receive. In addition, under the Shared Savings Program regulations at § 425.500(e)(3), ACOs are required to report on all of the quality measures established by CMS, and the failure to report on those quality measures accurately, completely, and timely may subject the ACO to termination or other sanctions. Therefore, we expect PQRS eligible professionals who are ACO providers/suppliers to meet the satisfactory reporting criteria for the 2015 PQRS payment adjustment, since they would need to continue to report beyond the one measure for purposes of the PQRS incentive payment and Shared Savings Program shared savings. Satisfactory reporting criteria for the PQRS payment adjustment under the Shared Savings Program for 2016 and beyond will be discussed in future rulemaking.

Although we proposed to use the same timeframe of January 1 through December 31 that we adopted for the PQRS incentive under the Shared Savings Program as the reporting period for the PQRS payment adjustment, we proposed that the timing of the reporting period would differ for purposes of the PQRS payment adjustment (77 FR 44990). Specifically, we proposed that the reporting period for the payment adjustment would fall 2 years prior to when the payment adjustment would be assessed. For example, under the Shared Savings Program, the reporting period for the 2015 payment adjustment would be from January 1, 2013 through December 31, 2013.

We also noted that this policy results in overlapping reporting periods for both the PQRS incentive and payment adjustment. For example, the measure data collected for the 2013 calendar year reporting period (January 1, 2013–December 31, 2013) would be used for purposes of both the Physician Quality Reporting System 2013 incentive and 2015 payment adjustment under the Shared Savings Program. We believed that using the same reporting period for purposes of both the incentive and payment adjustment would result in less reporting burden and that ACOs would perceive this as more efficient than requiring one set of measures reported during one timeframe for purposes of the PQRS incentive and another set during another timeframe for purposes of the payment adjustment.

Comments: We received several comments in support of the reporting period proposed for assessing the PQRS payment adjustment under the Shared Savings Program. Some of these commenters supported the proposal, because it aligned with the same reporting period proposed for group practices participating in the PQRS GPRO. We did not receive any comments opposing this proposal or suggesting alternatives.

Response: We appreciate the commenters' support and are finalizing our proposal that the reporting period for the payment adjustment fall 2 years prior to when the payment adjustment is assessed. For example, under the Shared Savings Program, the reporting period for the 2015 payment adjustment is from January 1, 2013 through December 31, 2013.

It is necessary for us to use a reporting period that precedes the year in which the payment adjustment is applicable to avoid retroactive payments and the reprocessing of claims. In addition, it is not operationally feasible for us to use a full calendar year reporting period that falls closer to the year in which the payment adjustment is applicable because we need sufficient time to determine if the requirements for satisfactory reporting have been met and to adjust our claims systems prior to the start of the applicable year. We note that the length and timing of the reporting period that we are finalizing for the PQRS payment adjustment under the Shared Savings Program is consistent with the one finalized for the traditional PQRS (76 FR 73392).

Since the publication of the Shared Savings Program final rule, we have received a number of inquiries regarding whether ACO participant TINs need to self-nominate or register to participate in PQRS GPRO under the Shared Savings Program, since there are such registration and self-nomination requirements under the traditional PQRS GPRO. We wish to clarify that no registration or self-nomination is required for ACO providers/suppliers that are eligible professionals to earn a PQRS incentive or avoid the payment adjustment under the Shared Savings Program.

Finally, just as ACO providers/suppliers that are eligible professionals in an ACO may only participate under their ACO participant TIN as a group practice under the PQRS GPRO under the Shared Savings Program for purposes of receiving an incentive under that TIN (76 FR 67903), we proposed that ACO providers/suppliers that are eligible professionals within an ACO must participate under the ACO participant TIN as a group practice under the PQRS GPRO under the Shared Savings Program for purposes of the PQRS payment adjustment (77 FR 44990). Thus, ACO providers/suppliers who are eligible professionals may not seek to avoid the payment adjustment by reporting either as an individual under the traditional PQRS or under the traditional PQRS GPRO.

We recognize that some eligible professionals may move across programs and reporting options from year to year. For instance, an eligible professional that is an ACO provider/supplier and participates in the PQRS under the Shared Savings Program in 2013 may later exit the Shared Savings Program and participate in PQRS individual reporting in 2014. Alternatively, a group practice participating in the traditional PQRS GPRO in 2013 may be an ACO participant in 2014. In instances in which eligible professionals change their PQRS reporting option from year to year, we believe that as long as the eligible professional satisfactorily reported for purposes of the payment adjustment during the applicable reporting period, then the eligible professional should not be subject to the payment adjustment even if the eligible professional was reporting under a different reporting method than at the time the payment adjustment would be assessed.

Comment: We received one comment applauding our recognition that providers may shift across programs and reporting options from year to year. Several commenters supported our proposal that as long as an eligible professional satisfactorily reported for purposes of the payment adjustment during the applicable reporting period, then the eligible professional would not be subject to the payment adjustment even if the eligible professional was reporting under a different reporting method than at the time the payment adjustment would be assessed. We did not receive any comments against our proposal or suggesting alternatives.

Response: We appreciate commenters' support and are finalizing our proposal that ACO providers/suppliers that are eligible professionals must participate under the ACO participant TIN as a group practice under the PQRS GPRO under the Shared Savings Program for purposes of the PQRS payment adjustment and that such ACO providers/suppliers who are eligible professionals may not seek to avoid the payment adjustment by reporting either as an individual under the traditional PQRS or under the traditional PQRS GPRO. For group practices and ACOs that may reorganize and individual providers and groups of providers that may move in and out of ACOs from year to year, as long as the eligible professional satisfactorily reported for purposes of the payment adjustment during the applicable reporting period, then the eligible professional will not be subject to the payment adjustment even if the eligible professional was reporting under a different reporting method than at the time the payment adjustment is assessed, as long as that eligible professional is still billing under the same TIN at the time the payment adjustment is assessed as they were during the applicable reporting period. We believe this approach offers maximum flexibility for eligible professionals and groups of providers to make appropriate decisions regarding their participation in an ACO and allows ACOs to recruit new participants, by eliminating any risk that eligible professionals will be assessed with the payment adjustment as a result of such changes. We also believe it would be unfair to assess the payment adjustment on an eligible professional on the basis of the decision to either join or leave an ACO, if the eligible professional had satisfactorily reported during the applicable reporting period.

Accordingly, we are finalizing the proposed amendment to the regulations at § 425.504(b) with two modifications. We have revised § 425.504(b)(2)(ii) to provide that an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report one of the GPRO measures during the reporting period according to the method of submission established by CMS under the Shared Savings Program for purposes of the 2015 Physician Quality Reporting System payment adjustment. Satisfactory reporting criteria for the PQRS payment adjustment under the Shared Savings Program for 2016 and beyond will be discussed in future rulemaking.

Please note that, in this final rule with comment period, we also address final policies for ACO data to be publicly reported on Physician Compare in section III.G. of this final rule with comment period and under Medicare Shared Savings Program regulations at § 425.308. ACOs and the Value-Based Modifier are discussed in section III.I of this final rule with comment period.

J. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a demonstration for up to 2 years to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Current Medicare coverage for chiropractic services is limited to treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act provided such treatment is legal in the state or jurisdiction where performed. The demonstration expanded Medicare coverage to include: ''(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and (B) diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided.'' The demonstration was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of MMA mandates the Secretary to ensure that ''the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration projects under this section were not implemented.''

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess budget neutrality (BN) and the method for adjusting chiropractor fees in the event the demonstration resulted in costs higher than those that would occur in the absence of the demonstration. We stated that BN would be assessed by determining the change in costs based on a pre-post comparison of total Medicare costs for beneficiaries in the demonstration and their counterparts in the control groups and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We also stated that our analysis would not be limited to only review of chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs for other services.

In the CY 2010 PFS final rule with comment period (74 FR 61926), we discussed the evaluation of this demonstration conducted by Brandeis University and the two sets of analyses used to evaluate BN. In the ''All Neuromusculoskeletal Analysis,'' which compared the total Medicare costs of all beneficiaries who received services for a neuromusculoskeletal condition in the demonstration areas with those of beneficiaries with similar characteristics from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was $114 million higher costs for beneficiaries in areas that participated in the demonstration. In the ''Chiropractic User Analysis,'' which compared the Medicare costs of beneficiaries who used expanded chiropractic services to treat a neuromusculoskeletal condition in the demonstration areas, with those of beneficiaries with similar characteristics who used chiropractic services as was currently covered by Medicare to treat a neuromusculoskeletal condition from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was a $50 million increase in costs.

As explained in the CY 2010 PFS final rule, we based the BN estimate on the ''Chiropractic User Analysis'' because of its focus on users of chiropractic services rather than all Medicare beneficiaries with neuromusculoskeletal conditions, as the latter included those who did not use chiropractic services

and who may not have become users of chiropractic services even with expanded coverage for them (74 FR 61926 through 61927). Users of chiropractic services are most likely to have been affected by the expanded coverage provided by this demonstration. Cost increases and offsets, such as reductions in hospitalizations or other types of ambulatory care, are more likely to be observed in this group.

As explained in the CY 2010 PFS final rule (74 FR 61927), because the costs of this demonstration were higher than expected and we did not anticipate a reduction to the PFS of greater than 2 percent per year, we finalized a policy to recoup $50 million in expenditures from this demonstration over a 5-year period, from CYs 2010 through 2014 (74 FR 61927). Specifically, we are recouping $10 million for each such year through adjustments to the chiropractic CPT codes. Payment under the PFS for these codes will be reduced by approximately 2 percent. We believe that spreading this adjustment over a longer period of time will minimize its potential negative impact on chiropractic practices.

For the CY 2012 PFS, our Office of the Actuary (OACT) estimated chiropractic expenditures to be approximately $470 million, which reflected the statutory 29.4 percent reduction to physician payments scheduled to take effect that year. As noted above, the statute was subsequently amended to impose a zero percent update for CY 2012 instead of the 29.4 percent reduction. OACT now estimates CY 2012 chiropractic expenditures to be approximately $630 million. We are currently recouping $10 million through adjustments to the chiropractic CPT codes in CY 2012, and the percent of this reduction is approximately 1.5 percent.

We are continuing the implementation of the required BN adjustment by recouping $10 million in CY 2013. Our Office of the Actuary estimates chiropractic expenditures in CY 2013 will be approximately $470 million based on Medicare spending for chiropractic services for the most recent available year and reflecting an approximate 30.9 percent reduction to physician payments scheduled to take effect under current law. To recoup $10 million in CY 2013, the payment amount under the PFS for the chiropractic CPT codes (CPT codes 98940, 98941, and 98942) will be reduced by approximately 2 percent. We are reflecting this reduction only in the payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the relative value units (RVUs). Avoiding an adjustment to the RVUs would preserve the integrity of the PFS, particularly since many private payers also base payment on the RVUs.

Therefore, as finalized in the CY 2010 PFS regulation and reiterated in the CYs 2011–2012 PFS regulations, we are implementing this methodology and recouping from the chiropractor fee schedule codes set forth above. Our methodology meets the statutory requirement for BN and appropriately impacts the chiropractic profession that is directly affected by the demonstration.

The following is a summary of the comments we received and our responses.

Comment: One commenter, representing chiropractors, indicated that they continue to oppose our methodology for assuring budget neutrality under the demonstration. Instead of the application of an adjustment to the national chiropractor fee schedule, the commenter believes the Congressional intent was for CMS to make an adjustment to the totality of services payable under the Part B Trust Fund because of the language in Section 651(f)(A) of the MMA, which directs the Secretary to ''provide for the transfer from the Federal Supplementary Insurance Trust Fund * * * of such funds as are necessary for the costs of carrying out the demonstration projects under this section.''

Response: Section 651(f)(1)(B) of the MMA requires that the Secretary ''shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration projects under this section were not implemented.'' The statute does not specify a particular methodology for ensuring budget neutrality, but leaves that decision to the Secretary. In the CY 2010 Payment Policies under the Physician Fee Schedule and other Revisions to Part B for CY 2010 final rule with comment period (74 FR 61738, 61926–61928), we discussed our strategy for assessing budget neutrality and finalized the methodology for reducing the payment amount of the chiropractic CPT codes under the Physician Fee Schedule in order to ensure the demonstration is budget neutral. See also the CY 2006, 2007, and 2008 Physician Fee Schedule final rules with comment period (70 FR 70266–70267, 71 FR 69707–69708, 72 FR 66325–66326, respectively). Our methodology for reducing the payment of the chiropractic CPT codes (98940, 98941, and 98942) ensures budget neutrality, meets the statutory requirements in § 651(f)(1) of the MMA, and appropriately impacts the chiropractic profession that is directly affected by the demonstration. The final evaluation report, which describes, among other things, our methodology for calculating budget neutrality for this demonstration, is located on our Web site at *http://www.cms.gov/reports/downloads/Stason_ChiroDemoEvalFinalRpt_2010.pdf*.

Comment: The commenter referenced in the previous comment also noted that the increase in costs from the demonstration was completely due to the Illinois site, and not the other four sites. The commenter ''has concerns that the Chicago area did not meet the criteria for an appropriate demonstration site for this project.'' The commenter believes it is ''premature to use demonstration findings to estimate the cost of a national roll out of the expansion of chiropractic services without further analysis of the demonstration project data.''

Response: Section 651(c)(1) of the Act required the demonstration be conducted in 4 geographically diverse sites, specifically two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). We discussed the design of this demonstration with the chiropractic industry and others prior to implementation. Based on these discussions, we included additional criteria for site selection in the design of this demonstration. The Chicago area met the site selection criteria for this demonstration. We refer readers to the January 28, 2005 Notice (70 FR 4130) for a discussion of our site selection criteria and the sites selected for participation based on these criteria.

Regardless of the differences in the costs associated with the demonstration areas, the evaluation conducted by Brandeis University found that expanding coverage for chiropractic services under the demonstration resulted in increased Medicare expenditures, and the Secretary must recoup these costs in order to meet the budget neutrality requirement of the law.

In response to the comment suggesting that the data from this demonstration should not be used to estimate the cost of a national rollout of the expansion of chiropractic services, we note the following. At the time of the final Report to Congress on the Chiropractic Services Demonstration, we estimated the costs of a national rollout of the expansion of chiropractic services. We based our estimate on the best available data at the time which

was data from the demonstration. Further, data from the demonstration was the only information CMS had at the time of the Report to Congress for estimating the costs of a national rollout.

After consideration of the public comments received, we are continuing the implementation of the required budget neutrality adjustment by recouping $10 million in CY 2013 by reducing the payment amount under the PFS for chiropractic codes (that is, CPT codes 98940, 98941, and 98942) by approximately 2 percent.

K. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

1. Overview

Section 1848(p) of the Act requires that we establish a value-based payment modifier and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015 and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, the section 1848(p)(7) of the Act provides the Secretary discretion to apply the value-based payment modifier to eligible professionals as defined in section 1848(k)(3)(B) of the Act. Based on our initial experience with the program, we will consider whether to expand the application of the value-based payment modifier to additional eligible professionals as permitted by the Act.

We proposed to apply the value-based payment modifier (a) to groups of physicians of 25 or more eligible professionals, (b) to align quality measurement for purposes of the value-based payment modifier with the reporting requirements for data on quality measures under the Physician Quality Reporting System (PQRS), and (c) to implement the value-based payment modifier so that it does not affect payment for those groups that satisfactorily report information on quality measures under the PQRS unless the group of physicians expressly elect further assessment using a quality-tiering option. The statute requires the value-based payment modifier to be budget neutral.

We are finalizing our overall approach to the value-based payment modifier in which the value-based payment modifier adjustment is based on participation in the PQRS. Although we are refining many of the proposed value-based payment modifier policies in response to comments received, the major change from our proposals is that we will apply the value-based payment modifier to groups of physicians of 100 or more eligible professionals rather than to groups of physicians of 25 or more eligible professionals. We believe this change in policy is necessary in order for us to gain additional experience with, and to be able to produce data to enhance physician acceptance of, our methodologies and approach. We emphasize that even with this change we are committed to applying the value-based payment modifier to all physicians and groups of physicians by 2017 as required by Section 1848(p) of the Act. We urge solo practitioners and physicians in smaller groups to participate in the PQRS now, because when we propose in future rulemaking to apply the value-based payment modifier to smaller groups and solo practitioners, we anticipate basing the quality composite on PQRS quality data reported by such physicians. We also anticipate that we would propose to increase the amount of payment at risk under the value-based payment modifier as we gain additional experience with the methodologies used to assess the quality of care furnished, and the cost of care, by physicians and groups of physicians.

2. Value-Based Payment Modifier Overview

In the CY 2013 PFS proposed rule, we stated that the value-based payment modifier has the potential to help transform Medicare from a passive payer to an active purchaser of higher quality, more efficient and effective healthcare by providing upward payment adjustments under the PFS to high performing physicians (and groups of physicians) and downward adjustments for low performing physicians (and groups of physicians) (77 FR 44993). We recognize, however, that physicians are at the forefront of care delivery and that changes in payment policy can directly affect the medical care that physicians furnish to Medicare beneficiaries. Consistent with the National Quality Strategy, our aim is to promote preventive care and improve, rather than impede, the care that beneficiaries currently receive, especially for the chronically ill and those with the most complicated cases.

We explained in the CY 2013 PFS proposed rule (77 FR 42908) that Medicare is beginning to implement value-based payment adjustments for other types of services, including inpatient hospital services. We have also outlined in reports to Congress strategies to implement value-based purchasing for skilled nursing facilities, home health services, and ambulatory surgical center services. In implementing value-based purchasing initiatives generally, we would meet the following goals:

- Recognize and reward high quality care and quality improvements.

++ Value-based payment systems and public reporting should rely on a mix of standards, processes, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, we would move as quickly as possible to the use of outcome and patient experience measures. To the extent practicable and appropriate, we believe these outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

++ To the extent possible, and recognizing differences in payment system readiness and statutory requirements and authorities, measures should be aligned across Medicare and Medicaid's public reporting and payment systems. We would seek to evolve a focused core set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

++ The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we will continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

++ To the extent practicable, the measures we use should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

- Promote more efficient and effective care through the use of evidence based measures, less rework and duplication, and less fragmented care.

++ Providers should be accountable for the costs of care, being both rewarded for reducing unnecessary expenditures and responsible for excess expenditures.

++ In reducing excess expenditures, providers should continually improve and maintain the quality of care they deliver.

++ To the extent possible, and recognizing differences in payers' value-based purchasing initiatives, providers should redesign care processes to deliver higher quality and more efficient care to their entire patient population.

Because of the centrality of physicians to high-quality, efficient, patient-

centered care furnished in multiple settings, we believe that in the long run the value-based payment modifier should rely on measuring physician performance (both quality of care and cost) at four levels (to the extent practicable)—the individual physician level, the group practice level, the facility level (for example, hospital), and the community level. Physicians make decisions on a patient-by-patient basis as to what services are indicated and furnished. These decisions are made independently by physicians within multiple settings (that is, individual office practice, group practice, and hospital) and are dependent, in part, on how care is organized in a community. Consequently, physicians have the potential to drive both quality of care and costs at all levels of the health system and these decisions have an impact on patient outcomes and costs for populations of patients. We envision a physician value-based payment modifier in the future that blends performance at each of these levels (as applicable) and reinforces our objectives to encourage and reward physicians for furnishing high-quality, efficient, patient-centered clinical care.

Given this long range objective, we proposed that the following specific principles should govern the implementation of the value-based payment modifier.

- *A focus on measurement and alignment.* It is difficult to maintain high quality care and improve quality and performance without measurement. Therefore, the value-based payment modifier should incorporate performance on more quality measures than those that we finalized in the CY 2012 PFS final rule (76 FR 73429 through 73432). These additional measures for the value-based payment modifier should consistently reflect differences in performance among physicians and physician groups and reflect the diversity of services furnished. These measures should be consistent with the National Quality Strategy and other CMS quality initiatives, including the PQRS, the Medicare Shared Savings Program, and the Medicare EHR Incentive Program.
- *A focus on physician choice.* Physicians should be able to choose the level at which their performance will be assessed reflecting physicians' choice over their practice configurations. The choice of level should align with the requirements of other physician quality reporting programs, such as the PQRS and the Medicare EHR Incentive program to reduce administrative burden and encourage greater program participation.
- *A focus on shared accountability.* CMS has a role in fostering high value care for individual beneficiaries, but also focusing on how that beneficiary interacts with the healthcare system generally. We believe that the value-based payment modifier can facilitate shared accountability by assessing performance at the group practice level and by focusing on the total costs of care, not just the costs of care furnished by an individual physician.
- *A focus on actionable information.* In conjunction with adjusting payment based on performance, CMS should provide meaningful and actionable information to help physicians identify clinical areas where they are doing well as well as areas in which performance could be improved. The Physician Feedback reports can serve this purpose and we plan to continue to provide groups of physicians with feedback reports on the quality and cost of care they furnish to their patients.
- *A focus on a gradual implementation.* We believe that the value-based payment modifier should focus initially on outliers (that is, those groups of physicians that are demonstrably high or low performers as compared to their peers that treat like beneficiaries). We also believe that groups of physicians should be able to elect how the value-based payment modifier would apply to their payment under the PFS starting in 2015 as we phase-in the value-based payment modifier. As we gain more experience with physician measurement tools and methodologies, we can broaden the scope of measures assessed to organize them around medical condition, refine physician peer groups to focus on how like beneficiaries are treated, create finer payment distinctions that focus on increasing value, and provide greater payment incentives for high performance.

We solicited comments on these principles as guides to our implementation of the value-based payment modifier. The following is a summary of the comments we received and our response.

Comment: Commenters generally supported the five principles that we proposed would govern the implementation of the value-based payment modifier. However, some commenters expressed concerns that the proposed implementation of the value-based payment modifier did not support all of the principles.

One commenter stated that the proposed value-based modifier program was designed for large multispecialty group practices, not small single specialty groups. Another commenter indicated that long term care physicians currently lack the infrastructure to be able to achieve the proposed principles within the timeline proposed. Other commenters were concerned about the lag between the performance year (2013) and the application of the payment adjustment (2015) and urged CMS to further explore ways to realistically achieve the goal cited under ''Focus on actionable information.'' One of the commenters also raised several concerns related to group reporting of the quality data.

Some of the commenters' recommendations included providing the Physician Feedback reports to all physicians sooner so they have information before implementation of the value-based payment modifier; making group reporting optional; expanding the reporting options for large groups; and evaluating the implementation proposals on small single specialty group practices and settings such as long term care settings.

Response: We appreciate the commenters' support of the five principles that we believe should govern the implementation of the value-based payment modifier. We address the narrower concerns raised by commenters later in this final rule with comment period, but continue to believe that the five principles we have identified here should guide the implementation of the value-based payment modifier.

3. Proposals for the Value-Based Payment Modifier

In the proposed rule, we described our proposals for each component of the value-based payment modifier (77 FR 44995). In this final rule with comment period, we discuss our proposed policies for each component of the value-based payment modifier, the comments received, our responses to the comments, and a brief statement of our final policy.

a. Application of the Value-Based Payment Modifier

Section 1848(p)(4)(B)(iii) of the Act requires the Secretary to apply the value-based payment modifier to items and services furnished under the Medicare Physician Fee Schedule beginning on January 1, 2015, for specific physicians and groups of physicians the Secretary determines appropriate, and beginning not later than January 1, 2017 for all physicians and groups of physicians. For purposes of the value-based payment modifier we are finalizing in this final rule with comment period, physicians are defined in section 1861(r) of the Act to include

doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.

(1) Definition of a Group, Group Size, and Application of the Value-Based Payment Modifier to the Paid Amount

We proposed to apply the value-based payment modifier beginning in calendar year 2015 to all groups of physicians with 25 or more eligible professionals (77 FR 44995). For purposes of establishing group size, we proposed to use the definition of an eligible professional as specified in section 1848(k)(3)(B) of the Act. This section defines an eligible professional as any of the following: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist or a qualified speech-language pathologist; or (4) a qualified audiologist. We proposed to define a group of physicians as ''a single Tax Identification Number (TIN).'' We chose this definition in order to align with the reporting requirements for group practices and the definitions used in the PQRS. We also proposed to assess whether a group of physicians has 25 or more eligible professionals at the time the group of physicians is selected to participate under the PQRS GPRO.

In addition, we proposed to apply the value-based payment modifier to the Medicare paid amounts for the items and services billed under the PFS at the TIN level so that beneficiary cost-sharing would not be affected. We also proposed to apply it to the items and services billed by physicians under the TIN, not to other eligible professionals that also may bill under the TIN. Application of the value-based payment modifier at the TIN level means that we would not ''track'' or ''carry'' an individual physician's performance from one TIN to another TIN. In other words, if a physician changes groups from TIN A in the performance period (calendar year 2013) to TIN B in the payment adjustment period (calendar year 2015), we would apply TIN B's value-based payment modifier to the physician's payments for items and services billed under TIN B during 2015. We made this proposal for two reasons (77 FR 44995). First, payment at the group practice (TIN level) promotes shared accountability for the quality of care furnished at the group practice level. Second, we believed it will be more straightforward for groups of physicians to understand how the value-based payment modifier affects their TIN's payment in the payment adjustment period if all physicians billing under the TIN received the same value-based payment modifier.

Comment: Some commenters supported CMS' proposal to apply the value-based payment modifier to only groups of 25 or more eligible professionals. They typically based their support on their agreement with the points CMS made in the proposed rule, stating that it would be premature to extend the value modifier to groups smaller than 25. However, many other commenters recommended that CMS apply the value-based payment modifier only to larger, multi-specialty groups, such as those with 100 or more physicians (MDs/DOs). Some of these commenters suggested that if single specialty or smaller groups were to be included, they should be limited to those groups that specifically request to be included. They reasoned that it would be important for CMS to devote resources to ensuring the program is successful with large groups before including smaller groups and solo practitioners. They stated that several issues are still untested and thus in need of further development (for example, attribution for cost purposes, new quality reporting methods, cost measure comparisons, and physician awareness). These commenters expressed concern, based on prior experience with CMS' confidential feedback reports, about the ability of CMS to notify and sign up a large number of groups by the proposed deadline. They stated that applying the value-based payment modifier initially only to larger groups would reduce the number of physicians and groups that would need to be notified and would focus on practices that are most likely to follow the federal regulatory process and have staff devoted to value-based performance initiatives. Further, those commenters opined that tying the group size determination to the number of MDs and DOs rather than to all PQRS-eligible professionals would also eliminate potential misunderstanding about the groups that are subject to the value-based payment modifier. Commenters also suggested that removing single specialty groups could mitigate a number of problems such as a lack of relevant quality measures available for many specialties under the group reporting options.

On the other hand, a few commenters suggested we apply the value-based payment modifier to additional physicians, such as those in groups of 10 or more. This suggestion was based on a view that increasing participation in the value-based payment modifier for the first 2 years of the program could facilitate a smoother transition to all physicians in 2017 (as required by law) and gain physician participation in the first few years. Another commenter recommended that CMS allow smaller practices to participate in the modifier in 2015 if they meet certain criteria, such as being Meaningful Users (MU) of certified Electronic Health Records (EHRs), or practicing in a rural state or other area where there are relatively few groups with 25 or more eligible professionals (for example, Health Professional Shortage Areas). These commenters reasoned that incorporating smaller practices into the value-based payment modifier would encourage all physicians, not only larger groups, to focus on high-quality, affordable care, reinforcing current private and other payers' payment incentives. Commenters stated a belief that a broader definition of physician group is imperative if the value-based payment modifier is to promote value on a wide scale, given that most physicians practice in groups of less than 10 physicians. Further, they argued that it would be feasible to include smaller practices in the value-based payment modifier because many of these smaller practices are participating in the EHR Incentive Program and they are currently reporting many of the same measures that are available to eligible professionals under the PQRS. In addition, it was also noted that some states with a high proportion of rural and other under-served areas may have comparatively few groups of 25 or more eligible professionals and thus be under-represented in the value-based payment modifier unless smaller groups are included.

Response: We are persuaded by the commenters that recommended we apply the value-based payment modifier only to larger groups. We agree with commenters that suggested the minimum group size be defined as groups of physicians with 100 or more eligible professionals as a first step. We believe it would be reasonable to focus on groups with 100 or more eligible professionals before expanding the application of the value-based payment modifier to more groups. We believe that increasing the group size from 25 to 100, we would be addressing the concerns raised by commenters regarding attribution, new group reporting mechanisms, and cost comparisons. We also agree with commenters that we will be more successful in notifying and informing these large groups about the requirements of the value-based payment modifier than if we were to include groups of less than 100 eligible

professionals. We do not agree, however, that the group size should be determined only by the number of physicians (MDs, DOs), because we still seek to align with the quality measure reporting criteria in the PQRS; that is, under the PQRS, group practices are defined by the number of eligible professionals as defined under section 1848(k)(3)(B), not just physicians. We believe it would be confusing to have the same group size (for example, 100) be calculated different ways (one way for the PQRS and another way for the value-based payment modifier), because the group's participation in the PQRS informs how they are treated for the value-based payment modifier.

Comment: Some commenters believed it was essential for CMS to provide additional flexibility to allow groups to define themselves rather than using our proposed definition of a group of physicians as ''a single Tax Identification Number (TIN).'' For example, some commenters urged us to allow groups to aggregate TINs for the value modifier, indicating that due to a variety of business reasons unrelated to quality reporting, some practices have multiple TINs. In these practices, such as some faculty practice plans, the departments share common services and are perceived by the public as being part of the same practice. Other commenters suggested that CMS allow certain practices, such as large practices that operate under a single TIN, an option to disaggregate the TIN into separate component sub-groups in a way that represents how the groups functionally operate.

Response: We are finalizing our proposal to identify the group by its Medicare-enrolled TIN. Using TINs makes it possible for us to take advantage of infrastructure and methodologies already developed for PQRS group-level reporting and evaluation. We believe this approach affords us flexibility and statistical stability for monitoring and evaluating quality and outcomes for beneficiaries assigned to the group for quality reporting purposes. In contrast, adopting approaches suggested by some commenters to allow the disaggregation of a TIN (or aggregation of a collection of TINs) would create much greater operational complexity by requiring us to establish and maintain additional organizational IDs under each TIN (for disaggregation purposes) or among TINs (for aggregation purposes). It would be difficult operationally to maintain such an approach to accommodate future organizational changes among physicians and their practices. TINs are relatively stable over time, but still allow for some flexibility as individual physicians make choices about what TINs they establish. Despite these challenges and our decision to define a group of physicians as a ''single TIN,'' we intend to examine whether it is possible in future years to allow for the aggregation or disaggregation of TINs in order to better reflect physician group organization as suggested by the commenters.

Comment: Some commenters disagreed with the proposal to apply the value-based payment modifier to the items and services billed by eligible professionals who are physicians under the TIN and not to other eligible professionals that also may bill under the TIN. They reasoned it is inconsistent to apply the value-based payment modifier only to items or services billed by eligible professionals who are physicians, given that under the proposal CMS would count all eligible professionals for purposes of determining group size. These commenters generally requested consistency between the assessment of group size and application of the value-based payment modifier. By contrast, we also received suggestions that we ought to exclude non-physicians in the group size determination but apply the modifier to all eligible professionals within a medical group practice. These commenters argued that this approach would be more consistent with the view that high quality and coordinated care is a team effort.

Response: Section 1848(p)(7) of the Act requires us to apply the value-based payment modifier beginning in 2015 only to physicians as defined in section 1861(r) of the Act. On or after January 1, 2017, the Act provides the Secretary discretion to apply the value-based payment modifier to a broader set of eligible professionals (as defined in section 1848(k)(3)(B) of the Act). Thus, we are unable at this time to apply the value-based payment modifier to Medicare FFS payments paid to eligible professionals who are not physicians as suggested by the commenters. Based on our initial experience with the value-based payment modifier, we plan to consider whether to expand its application to additional eligible professionals in future years. As discussed previously, we believe it is important to use the same definition of group size (that is, eligible professionals) as the PQRS both to align the two programs (the PQRS and the value-based payment modifier) and to help avoid physicians' confusion as they determine the method by which they will participate in the PQRS.

Comment: We received few comments on our proposals to apply the value-based payment modifier to the Medicare paid amounts for the items and services billed under the PFS so that beneficiary cost-sharing or coinsurance would not be affected. These commenters generally agreed with the proposal to apply the value-based payment modifier to the Medicare paid amounts for the items and services billed under the PFS at the TIN level so that beneficiary cost-sharing would not be affected.

Response: We agree with these comments. We continue to believe it is important that beneficiary cost-sharing not be affected by the value-based payment modifier.

Comment: Several commenters requested clarification of when and how we would determine group size if the group of physicians did not participate in the PQRS. This determination is important, they reasoned, because these groups would be subject to the -1.0 percent value-based payment downward adjustment under the value-based payment modifier if they were a group of physicians meeting the value-based payment modifier size requirement and they had not participated in the PQRS.

Response: We had proposed to assess the size of a group of physicians at the time the group of physicians is selected to participate under the PQRS GPRO. As discussed above with respect to the PQRS GPRO self-nomination process (section III.G.1) and below with respect to the election of the quality-tiering approach, we have extended to October 15, 2013, the time period for groups of physicians to submit their self-nomination statement to select their PQRS reporting method and to elect the quality-tiering methodology. As such, we will query Medicare's Provider Enrollment, Chain, and Ownership System (PECOS) as of October 15, 2013, to identify the groups of physicians with 100 or more eligible professionals. This query will produce a list of the groups of physicians that are subject to the value-based payment modifier. To ensure that the groups of physicians on this list have 100 or more eligible professionals during the performance period, we will analyze the group's (TIN's) claims submitted for services furnished during the performance year, including at least a 60-day claims runout (that is, we will analyze claims submitted through at least February 28, 2014 for services furnished during the calendar year 2013 performance year). We will remove a group of physicians from this list if the group does not have at least 100 eligible professionals that billed under the group's TIN during the performance period. We note that we

will not add groups to the October 15 list based on this claims analysis, rather we will only remove groups that, based on claims, do not have 100 or more eligible professionals. We also will engage in education and outreach during the performance year to encourage all groups of physicians, not just those to which the value-based payment modifier applies during 2015, to participate in the PQRS.

In response to the comments, we are finalizing that beginning in calendar year 2015 we will apply the value-based payment modifier to groups of physicians of 100 or more eligible professionals. We also are finalizing the following proposed policies related to the definition of a group and group size:

- For purposes of establishing group size only, we use the definition of an eligible professional as specified in section 1848(k)(3)(B) of the Act;
- We apply the value-based payment modifier to the Medicare paid amounts for the items and services billed under the PFS at the TIN level so that beneficiary cost-sharing is not be affected; and
- We apply the value-based payment modifier to the items and services billed by physicians under the TIN, not to other eligible professionals that also may bill under the TIN.
- We identify the groups of physicians subject to the value-based payment modifier (groups of 100 or more eligible professionals) based on a query of PECOS on October 15, 2013, and we remove any groups from this October 15 list if, based on a claims analysis, the group of physicians did not have 100 or more eligible professionals that submitted claims during the performance period.

(2) Approach to Setting the Value-Based Payment Modifier Adjustment Based on PQRS Participation and the Quality-Tiering Option

We explained in the proposed rule that our proposals would allow groups of 25 or more eligible professionals to decide how the value-based payment modifier would be applied to their PFS payments (77 FR 44995). We proposed that in light of our desire to align CMS quality improvement programs, the value-based payment modifier methodology relies, in part, on the data submitted on quality measures by groups of physicians through the PQRS. We explained that quality measurement is necessary, but not sufficient, for quality improvement and a focus on value. Thus, we proposed to categorize groups of physicians eligible for the value-based payment modifier into two categories depending upon whether they had met the criteria for satisfactory reporting of data on the PQRS GRPO quality measures for the 2013 and 2014 incentive payments under the PQRS or the criteria for satisfactory reporting using the administrative claims-based reporting mechanism, which was proposed for the 2015 and 2016 PQRS payment adjustment. For those groups of physicians that met either of these PQRS satisfactory reporting criteria and requested that their value-based payment modifier be calculated using a quality-tiering approach, we proposed to use the performance rates on the quality measures reported through any of these PQRS reporting mechanisms available to them.

We proposed that the second category include those groups of physicians with 25 or more eligible professionals that have not met the PQRS satisfactory reporting criteria identified above (77 FR 44996). Because we would not have quality measure performance rates on which to assess the quality of care furnished by these groups, we proposed to apply a value-based payment modifier of −1.0 percent, meaning they would receive 99.0 percent of the paid amounts for the items and services billed under the PFS in CY 2015.

We explained that we were concerned, however, that some groups of physicians may attempt to submit data on PQRS quality measures and fail to meet the criteria for satisfactory reporting for the PQRS incentive and thus be placed into the second category of groups of physicians and, therefore, be subject to the −1.0 percent value-based payment modifier downward adjustment. To address this issue, we solicited comments on whether to assess performance on the measures included in the PQRS administrative claims-based reporting option as a default if a group of physicians attempts to participate in one of the PQRS GPRO reporting mechanisms and does not meet the PQRS criteria for satisfactory reporting.

Comments: The majority of commenters supported CMS' use of the PQRS system as the foundation for the measurement of performance rates for physician groups for the value-based payment modifier. Many commenters stated this approach was a way to better align reporting requirements across physician programs and decrease burden. They also believed it was reasonable to phase-in the value-based payment modifier using this two-category structure. By contrast, some commenters suggested that applying the −1.0 percent downward adjustment to groups of physicians in the second category was penalizing these groups twice (once by the PQRS payment adjustment and once by the value-based payment modifier) for the same action, namely failure to report satisfactorily under the PQRS. Other commenters opposed allowing the use of performance rates on the quality measures reported through PQRS reporting mechanisms. They expressed concern that PQRS reporting methods are ''overwhelming given the multiple methods of reporting, varying reporting periods, differing reporting requirements for each reporting mechanism.'' One commenter stated that while it supported streamlining CMS quality programs, it had longstanding concerns with the PQRS program and as a result, opposed the concept of tying participation in the value-based payment modifier to participation in the PQRS. One commenter requested a value-based modifier of 0.0 percent be applied in 2015 for pathologists as there would be no applicable PQRS measures.

Response: We continue to believe that the two-category approach is a reasonable way to phase-in the value-based payment modifier in 2015. It is difficult to maintain high-quality care and improve quality and performance without measurement. We agree with commenters who stated that we should seek to align quality reporting mechanisms across physician programs. CMS has one physician quality reporting system and we intend to use it as the foundation for the value-based payment modifier. Although not satisfactorily reporting data under the PQRS will subject physicians and groups of physicians to a PQRS payment adjustment, the lack of quality data also prevents us from fully assessing the quality of care furnished compared to cost. At the same time, we also believe we should not affect the payment of those groups of physicians that have taken steps to participate in the PQRS and have developed systems within their practices to report data for quality measurement. Thus, in response to comments, we have decided to modify the two categories that we proposed and instead, we are finalizing a policy to apply the −1.0 percent downward value-based payment modifier adjustment only to those groups of physicians that do not participate in the PQRS in CY 2013 as described below.

Comment: Many commenters urged CMS to hold groups harmless from the −1.0 percent value-based payment modifier downward adjustment if the group of physicians attempts, but is not a satisfactory reporter for the PQRS incentive payment. Commenters felt this was a good way to transition physician

groups with little experience with PQRS reporting to do so without the threat of being subject to the value-based payment modifier and PQRS payment adjustments. Also, commenters stated that given the complexity of the PQRS, medical groups would be deterred from reporting data if they did not have a safety net to avoid being subject to both the value-based payment modifier and PQRS payment adjustments.

Response: We agree with commenters that we should encourage groups of physicians to participate in the PQRS GPRO. Accordingly, we are expanding the first category of groups of physicians to which we would apply a value-based payment modifier adjustment of 0.0 percent to include those groups that self-nominate for the PQRS GPRO and report at least one measure. Further, if such group of physicians had elected the quality-tiering option and did not meet the satisfactory reporting criteria for the PQRS payment incentive using the reporting method they selected in their self-nomination statement under the PQRS GPRO (such that we would not have performance information to create a quality composite), we will develop and use the group's performance on the administrative claims-based reporting option as the basis for determining the group's quality composite for purposes of the value-based payment modifier. We believe this policy will encourage groups to put systems in place in their practices to become satisfactory PQRS reporters.

Based upon the comments received, we are adopting our proposed policy, with one modification, to categorize groups of physicians eligible for the value-based payment modifier into two categories. Specifically, the first category of groups of physicians includes those that (a) have self-nominated for the PQRS as a group and reported at least one measure or (b) have elected the PQRS administrative claims option for CY 2013 We note that groups in category (a) also include those groups that have self-nominated and have met the satisfactory reporting criteria for the PQRS incentive payment. The value-based payment modifier for the groups of physicians in this first category (both (a) and (b)) will be 0.0 percent, meaning no payment adjustment will be applied to physicians in these groups for CY2015. For those groups of physicians within this first category that have requested that their value-based payment modifier be based on quality-tiering and have either met the satisfactory reporting criteria for the PQRS incentive or have chosen the administrative claims-based option, we will use the performance rates on the quality measures reported through these reporting mechanisms (that is, GPRO registries, web-interface, or administrative claims) to calculate their value-based payment modifier. Otherwise, we will use the group's performance on the administrative claims measures for quality-tiering, because although the group self-nominated and reported at least one measure, we would not have sufficient quality information to construct a quality composite under the quality-tiering approach.

The second category includes those groups of physicians with 100 or more eligible professionals that do not fall within either of the two subcategories of category 1 described above. The value-based payment modifier for these groups of physicians will be −1.0 percent in CY 2015.

Comment: Commenters requested that we clarify whether physicians that are reporting PQRS measures at the individual level and are members of groups subject to the value-based payment modifier would be able to continue to report as individuals using their currently preferred PQRS option at the individual level. They explained that they already have systems in place and staff that understands how to report under the PQRS at the individual level. They also opined that such flexibility allowed physicians in the group to choose PQRS measures that were most applicable to their practice and patients.

Response: We appreciate commenters' support for the use of the PQRS as the foundation for quality reporting for the value-based payment modifier. We agree with the commenters that we should continue to encourage physicians in groups subject to the value-based modifier and who are already satisfactorily reporting PQRS measures as individuals to have the option to remain individual PQRS reporters. We wish to clarify that in our proposals we did not intend to preclude individual participation in the PQRS. We specifically proposed that groups of physicians subject to the value-based payment modifier could elect the PQRS administrative-claims based option. Therefore, we are adopting a policy that physicians in groups of 100 or more eligible professionals that wish to report data for quality measures in the PQRS as individuals rather than as a group for the PQRS payment incentive must, as a group, elect the administrative claims-based reporting method under the PQRS by October 15, 2013. By doing so, the group of physicians would fall with category 1(b) and avoid the −1.0 percent downward value-based payment modifier. In future rulemaking, we anticipate proposing whether and how to combine quality measures reported at the individual level into a group quality score for the value-based payment modifier.

Comment: We received a substantial number of comments in support of the optional nature of having us evaluate performance based on the quality of care performance. One commenter recommended that quality-tiering remain voluntary until CMS has more confidence in its measures and composites. But we also received several comments that quality-tiering should not be optional.

Response: We agree with commenters that application of the quality-tiering methodology for calculating the value-based payment modifier should be optional. There will be many groups of physicians participating in the PQRS for the first time in 2013, many of them using the new group reporting mechanisms under the PQRS that are described in Table 92 above. We believe it is reasonable for them to gain experience in reporting data for quality measurement under the PQRS. In addition, we will be establishing national benchmarks for the first time for the quality measures in the PQRS and we will be using these benchmarks in the quality-tiering calculation. We believe groups of physicians should have time to understand how their performance compares to these benchmarks, and to have time to adjust their performance based on these comparisons, before their payment is adjusted. Although we recognize the need to improve the quality of care furnished compared to cost, we believe it is unreasonable to make quality-tiering mandatory in the first year of the phase-in for the value-based payment modifier. We anticipate for future years, as we collectively learn from our experiences with quality measurement and the value-based payment modifier, we will consider making quality-tiering mandatory.

(3) Individual Physicians

We proposed that, starting in 2017, we would apply the value-based payment modifier to all physicians and groups of physicians as required by the statute (77 FR 44996). We also solicited comments on whether we should offer individual physicians and groups of physicians with fewer than 25 eligible professionals an option that their value-based payment modifier be calculated using a quality-tiering approach starting in 2015 (77 FR 44996). If we did so, we indicated that we could calculate a value-based payment modifier for groups of physicians with as few as two

eligible professionals and apply the value-based payment modifier at the TIN level in the manner described in these proposals for groups of 25 or more eligible professionals. Likewise, we solicited comments on how to adapt our proposals to calculate a value-based payment modifier at the TIN level for physicians in solo practices (TINs comprised of one NPI).

Comment: There were a few commenters that supported application of the value-based payment modifier to individual physicians or EPs. For example, a commenter indicated that we should allow individuals that meet PQRS reporting requirements the option to participate in the quality-tiering option as early as possible as all physicians will be subject to the payment adjustment in 2017. However, most commenters agreed with the proposal to only apply the value-based payment modifier to groups at this time for the reasons outlined in the proposed rule (77 FR 44996).

Response: We appreciate the comments that were provided on this issue and will consider them further as we develop future plans to apply the value-based payment modifier to individual physicians.

As discussed above, we are adopting a policy to apply the value-based payment modifier to groups of physicians of 100 or more eligible professionals. We will not offer smaller groups of physicians and individual physicians the ability to elect quality-tiering for the 2015 value-based payment modifier as suggested by some commenters. Although we recognize that we must apply the value-based payment modifier to all physicians and groups of physicians starting January 1, 2017, we believe it is important to phase-in the value-based payment modifier to larger groups of physicians as we gain experience with the methodologies used in the value-based payment modifier. We want to emphasize, however, that in future rulemaking we anticipate proposing for smaller groups and for individual physicians a value-based payment modifier structure similar to the policies we are adopting for groups of physicians of 100 or more eligible professionals. Importantly, we expect the value-based payment modifier structure for smaller groups and individuals would also be aligned with the PQRS. Thus, we strongly encourage smaller groups of physicians and individual physicians to participate in the PQRS so that they can prepare themselves and their practices for the application of value-based payment modifier in later years.

(4) Hospital-Based Physicians

We also solicited comments on whether we should develop a value-based payment modifier option for hospital-based physicians to elect to be assessed based on the performance of the hospital at which they are based (77 FR 44996). In particular, hospital performance could be assessed using the measure rates for the quality measures in the Inpatient Quality Reporting (IQR) and the Outpatient Quality Reporting (OQR) programs. We solicited comments on which IQR and OQR measures (and applicable reporting period) would be appropriate to include in such an option and a way to identify and verify whether physicians are hospital-based.

The following is a summary of the comments we received regarding whether we should develop a value-based payment modifier option for hospital-based physicians.

Comment: A few commenters, including some that represent or employ physicians that practice in hospital settings, submitted comments on this issue. These commenters generally agreed that CMS should develop a value-based payment modifier option for hospital-based physicians, some noting that this option should be voluntary and based on self-nomination. They believed this hospital-based option could create a shared incentive between hospital-based physician groups and their institutions to augment physician involvement in quality improvement initiatives relating to inpatient care. This alignment, particularly for hospitalists who are directly involved in the quality improvement efforts of the hospital, could enhance and refine the safety and quality of hospital care.

Some commenters urged CMS to be judicious when selecting measures from the IQR and OQR programs to ensure that hospitalist care is measured in a valid way. Some potential areas for performance measures were identified, such as to include transitions of care/discharges and common diagnoses like congestive heart failure (CHF), acute myocardial infarction (AMI), pneumonia and stroke. A number of these commenters requested that physicians and group practices should be able to identify themselves as ''hospitalists'' ensuring that they are compared to like-groups within the value-based payment modifier. Some commenters were concerned that our proposed beneficiary attribution approach and our total per capita cost measures could result in hospitalists being inaccurately measured, as they could be attributed the total cost of the patients' stay at a hospital, when the hospitalist may have only been responsible for discharging the patient. Therefore, a commenter recommended that an attribution methodology be developed to accurately capture the role of hospitalists in patient care.

Response: We appreciate the comments received and will consider them as we develop future proposals for the value-based payment modifier as they relate to hospital-based physicians.

(5) Quality-Tiering Election Process

We solicited comments on how best to ascertain whether a group of physicians subject to the value-based payment modifier requests the option that their value-based payment modifier be calculated using a quality-tiering approach (77 FR 44996). We are seeking to establish a system that is as simple as possible to reduce administrative burden on physicians and enable these groups of physicians to indicate how they plan to submit data on quality measures through the PQRS for purposes of the value-based payment modifier. We described three possible approaches to accomplish these objectives: (a) Build off of the self-nomination process that we have proposed for groups of physicians to participate in the PQRS GPRO and which requires groups to submit a self-nomination application by January 31, 2013 for the 2013 performance period, (b) create a separate web-based registration system that permits groups of physicians to, throughout calendar year 2013, request that their value-based payment modifier be calculated using the quality-tiering approach, or (c) require that groups of physicians submit a letter (in a prescribed format) to CMS in a timely manner.

Comment: Commenters indicated that they appreciated that CMS is seeking to reduce administrative burden when identifying the way groups of physicians would indicate that they request their value-based payment modifier to be calculated using a quality-tiering approach. These commenters generally support using a web-based registration system or other simple online approach to opt into the quality-tiering that allows for ongoing registration by groups throughout the relevant calendar year.

Response: We thank commenters for their comments. To ease administrative burden and to align the quality-tiering election process with the self-nomination processes under the PQRS (as described in section III.G.1.b.(2) and III.G.1.c above), we are finalizing a web-based system for groups of physicians to

request the quality-tiering methodology. Under this policy, groups of physicians would access the same web-based system to request the quality-tiering approach that they use either to submit their PQRS GPRO self-nomination statement or to elect administrative claims option. We also are finalizing a contingency plan to accept groups of physicians' statements indicating their quality-tiering election via mail in the event the web-based functionality is not available in time to accept these statements, or in the event we experience issues with accepting self-nomination statements via the web. For the same reasons we discussed above with regard to other deadlines we are adopting under the PQRS, such quality-tiering elections must be received by October 15, 2013. We believe utilizing the same processes and deadlines finalized by the PQRS will ease administrative burden and facilitate the election of the quality-tiering option.

We want to emphasize that if a group of physicians with 100 or more eligible professionals does not self-nominate to participate in the PQRS GPRO or elect the administrative claims option for groups for CY 2013, its value-based payment modifier in CY 2015 will be −1.0 percent.

(6) Participants in the Medicare Shared Savings Program and Center for Medicare and Medicaid Innovation initiatives

We proposed that groups of physicians that are participating in the Medicare Shared Savings Program or the testing of the Pioneer ACO model, assuming they meet the PQRS satisfactory reporting criteria, would not have the option that their value-based payment modifier be calculated using the quality-tiering approach (77 FR 44996–44997). We made this proposal because we were mindful that the physicians and groups of physicians that are, or will be, participating in the Shared Savings Program and the testing of the Pioneer ACO model have made sizable investments to redesign care processes based on the incentives created by these programs and did not wish to unintentionally disturb these investments. Therefore, we solicited comments on ways to structure the value-based payment modifier starting in 2017 so it does not create incentives that conflict with the goals of the Shared Savings Program and the Pioneer ACO model. We also solicited comments on whether groups of physicians that are participating in these two initiatives should have the option that their value-based payment modifier be calculated using a quality-tiering approach and applied to their payments under the PFS starting in 2015.

Comment: Many commenters supported the proposal. A few commenters, especially those that supported broader opportunities for participation in the value-based payment modifier, likewise recommended that ACOs of both types (Shared Savings Program and Pioneer ACO model) should be permitted, but not required, to participate in the value-based payment modifier. Some recommended that ACOs be permitted to participate in the value-based payment modifier starting January 1, 2015. Such commenters believed that to the extent these groups furnish high-quality, low-cost care, they should have the opportunity to be rewarded for the value they furnish. They also believed that having a broader array of participants in the early years of the value-based payment modifier would facilitate the full-scale implementation in later years. Some commenters also noted that providing ACOs this option would also promote alignment with the Hospital Value-Based Purchasing Program in which hospitals participating in ACOs are permitted to participate. Another commenter encouraged CMS to further explore how to apply a value modifier to ACO-participating groups' PFS payments prior to 2017; for example, perhaps CMS could apply a value modifier to PFS payments for all patients who are not attributed to the ACO. A commenter noted that they were aware of several commercial plans with ACO-type contracts that simultaneously maintain ACO and pay-for-performance initiatives. In one case, the type of incentive follows the patient: providers receive the ACO program's incentives for patients attributed to that arrangement, and pay-for-performance incentives are based on care furnished to other patients the practice treats, but who do not meet the ACO's attribution criteria. The commenter believed this approach would avoid CMS's concern about unintentionally disturbing providers' ACO investments while encouraging a single standard of high-quality, affordable care for all patients seen by the practice. Several commenters that are participating in the Innovation Center's Comprehensive Primary Care Initiative also suggested that we not apply the value-based payment modifier to them and/or not offer the quality-tiering approach, because they are collecting quality information, are eligible for shared savings, and are being held to a different programmatic structure with different incentives.

Response: We are finalizing and clarifying our proposal not to apply the value-based payment modifier for 2015 and 2016 to groups of physicians that are participating in the Shared Savings Program or the testing of the Pioneer ACO model. This policy means that such groups of physicians also will not have the option to elect quality-tiering because we will not apply the value-based payment modifier to them. At this early stage of the Medicare Shared Savings Program and the Innovation Center initiatives, we do not wish to unintentionally disturb their investments in implementing these programs. In addition, we also will not apply the value-based payment modifier in 2015 and 2016 to groups of physicians that are participating in other Innovation Center initiatives, such as the Comprehensive Primary Care initiative, or other CMS programs which also involve shared savings and participants making substantial investments to report quality measures and to furnish higher quality, more efficient and effective healthcare.

In sum, we will not apply the value-based payment modifier for 2015 and 2016 to groups of physicians that are participating in the Medicare Shared Savings Program, the testing of the Pioneer ACO model, or other similar Innovation Center or CMS initiatives.

b. Performance Period

We previously finalized CY 2013 as the initial performance period for the value-based payment modifier that will be applied in CY 2015 (76 FR 73436). This means that we will use performance on quality and cost measures during CY 2013 to calculate the value-based payment modifier that we would apply to items and services for which payment is made under the PFS during CY 2015. Likewise, we proposed that performance on quality and cost measures in CY 2014 be used to calculate the value-based payment modifier that is applied to items and services for which payment is made under the PFS during CY 2016 (77 FR 44997).

As we explained in the CY 2012 PFS final rule with comment period (76 FR 73435), we explored different options to close the gap between the performance period (that is, 2013) and the payment adjustment period (that is, 2015), but found that none of them would have permitted sufficient time for physicians and groups of physicians to report measures or have their financial performance measured over a meaningful period, or for us to calculate

a value-based payment modifier and notify physicians and groups of physicians of their quality and cost performance and value-based payment modifier prior to the payment adjustment period. We also explained that a system that adjusted payments to take into account the value-based payment modifier after claims have been paid would be onerous on physicians and beneficiaries. We continued to explore ways to provide more timely feedback to physicians and to narrow the gap between the performance period and the payment adjustment period and solicited comments on practical alternatives that we could implement to do so. We solicited comments on our proposal to use CY 2014 as the performance period for the 2016 value-based payment modifier (77 FR 44997).

Comment: Although we did not seek comment on the use of 2013 as the performance period for the value-based payment modifier starting in 2015, a number of commenters expressed concern that it was premature to use 2013 as the initial performance period for the 2015 value-based modifier. These commenters suggested that under the proposal, CMS in effect advanced the statutory implementation date by 2 years. They expressed concern that there will be insufficient time for CMS to communicate to all of the affected physicians and groups that they must sign-up to participate in the PQRS GPRO in the 3-month span between the publication of this final rule and the proposed self-nomination deadline for participating in the PQRS GPRO. In addition, some commenters stated that additional testing and analysis is required to further refine the methodology and ensure that the modifier is fair and reliable. They suggested that CMS could and should use the time between now and 2015 to do further testing and refinement of the modifier's components rather than establish 2013 as the initial performance period. In addition, commenters objected to the lag between the performance period (2013 or 2014) and the payment adjustment period (2015 or 2016, respectively).

Response: As previously noted, we already finalized our proposal to use 2013 as the performance period for the value-based payment modifier in 2015. For the reasons noted above and below, we are finalizing calendar year 2014 as the performance period for the value-based payment modifier in 2016. We have taken steps to phase-in the value-based payment modifier in a very gradual and cautious manner, as further evidenced by the fact that we are adjusting our policy to apply the value-based payment modifier to groups of physicians of 100 or more eligible professionals (rather than to groups of physicians of 25 or more eligible professionals) and the policy to allow such groups to select whether the quality-tiering approach would apply to the calculation of the value-based payment modifier. As we discussed above, our first principle guiding implementation of the value-based payment modifier is a focus on measurement. Thus, we believe it is essential to encourage greater reporting and we believe this activity should not be delayed. Although we agree with commenters suggestions to analyze different ways to structure and implement the value-based payment modifier, we need data on quality to do so. Thus, we believe it is imperative to begin phasing in the value-based payment modifier with an emphasis on encouraging all physicians and groups of physicians to participate in the PQRS. Moreover, given that all physicians will have to report data on quality measures under the PQRS or else be subject to the PQRS payment adjustment, we believe it is reasonable to align the programs to encourage greater reporting participation. Finally as discussed above in section III.G.1.b above, we have extended to October 15, 2013 the time period during which groups of physicians subject to the value-based payment modifier can indicate their preferred PQRS reporting mechanism and whether they choose the quality-tiering approach. Therefore, we are finalizing our proposal to use CY 2014 as the performance period for the 2016 value-based payment modifier.

c. PQRS Quality Reporting Methods and Quality Measures

In this section we discuss our policies to align quality measure reporting for the value-based payment modifier with the PQRS reporting methods, and to expand the range of quality measures that we will use for the value-based payment modifier.

(1) Alignment of Quality Reporting Options With the PQRS

In the proposed rule we proposed to categorize groups of physicians eligible for the value-based payment modifier into two categories depending upon their participation in the PQRS (77 FR 44997). We further elaborated on these proposals and proposed that groups of physicians subject to the value-based payment modifier would be able to submit data on quality measures using one of the following proposed PQRS reporting mechanisms: PQRS GPRO using the web-interface, claims, registries, or EHRs; or PQRS administrative claims-based option. We also sought comment on which PQRS reporting mechanisms we should offer to individual physicians if we were to apply the value-based payment modifier to their payments under the PFS starting in 2015 and 2016.

Comment: As discussed previously, the majority of commenters supported CMS' use of the PQRS as the foundation for measurement of the performance rates for groups of physicians subject to the value-based payment modifier. Several commenters, however, suggested using one PQRS reporting mechanism (rather than multiple mechanisms with varying criteria for becoming a satisfactory reporter for the PQRS incentive payment. They cited ''significant problems when comparing data submitted via claims-based CPT II codes and data gathered from an EHR data submission vendor or a registry'' due to the difference in reporting requirements.

Response: We appreciate the commenters' suggestions. We agree with commenters who stated that we should seek to align quality reporting mechanisms across physician programs. We intend to use the PQRS as the foundation for the value-based payment modifier. We also believe that if a group of physicians subject to the value-based payment modifier reports data for quality measurement using one of the available reporting mechanisms under the PQRS, then we should use performance on those quality measures for the value-based payment modifier. Thus, the PQRS reporting mechanisms available to groups of physicians subject to the value-based modifier will be available for these groups to report measures for purposes of the value-based payment modifier. Although we proposed to include four methods for groups of physicians to participate in the PQRS GPRO (web-interface, claims, registries, and EHRs), as discussed in section III.G (Table 92), we are finalizing for the PQRS the web-interface and registries methods for CY2013. Thus, to align with the PQRS, we will finalize the same reporting methods for the value-based payment modifier. We recognize commenters' concern about the comparability of performance rates on measures reported through different reporting mechanisms. We intend to examine this issue more fully, especially as more physicians and groups of physicians utilize EHRs, to determine whether we should adjust our policies in future rulemaking.

In summary, we are finalizing and clarifying our proposal that the groups

of physicians subject to the value-based payment may utilize the PQRS GPRO reporting mechanisms available to them in Tables 92, as well as the PQRS administrative claims option as a group, for purposes of the value-based payment modifier. In addition, if physicians in a group of physicians subject to the value-based payment modifier wish to report data for quality measures in the PQRS as individuals for the PQRS payment incentive rather than as a group practice, the group must elect the PQRS administrative claims-based reporting method as a group by October 15, 2013 in order for the group to avoid the −1.0 percent downward value-based payment modifier adjustment.

(2) Quality Measure Alignment With the PQRS

We proposed to include all individual measures in the PQRS GPRO web-interface, claims, registries, and EHR reporting mechanisms for 2013 and beyond for the value-based payment modifier. We proposed to include the measures in the PQRS administrative claims-based reporting option as well (77 FR 44998). We also proposed that four of the quality measures in the PQRS administrative claims-based reporting option (the four outcome measures) be used in the value-based payment modifier for all groups of physicians subject to the value-based payment modifier (77 FR 45001–02). Finally, we solicited comments on the quality measures that we should propose for individual physicians if we were to provide individual physicians the ability to elect to have the value-based payment modifier apply to their payments under the PFS starting in 2015 or 2016 (77 FR 44998). In addition, we sought comment on the inclusion of community level measures in the value-based payment modifier (77 FR 45002).

Comment: The majority of commenters appreciated the flexibility of choice in reporting individual measures. The clinical community cited that allowing physician groups to report on the entire spectrum of PQRS measures ''recognizes the diversity of services provided among physicians and physician groups and allows for more appropriate assessments of quality.'' Other commenters objected to the PQRS system because groups can ''cherry pick'' measures and consequently felt that PQRS did not provide a strong enough incentive for improving performance. A couple of commenters did not support including all measures from the 2013 GPRO interface in the value-based payment modifier and suggested we exclude both measures new to the GPRO web interface and measures which were not NQF-endorsed for physicians or group practices. One of these commenters also expressed concern about measures in the web interface with absolute thresholds and measures that do not allow a clinician to indicate that a patient has declined the service. Other commenters cited a lack of measures for many specialties and sub-specialties within PQRS as a cause for concern in using performance rates from PQRS quality measures in 2015.

Response: We agree with the majority of commenters that physician groups should have flexibility in which measures to report for the value-based payment modifier. We are finalizing all of the individual measures under the PQRS for 2013 and beyond for the value-based payment modifier. These measures are discussed in Tables 94, 95, 123, and 124 in section III.G above. We disagree with the commenters' suggestion to exclude measures new to the GPRO web interface, measures which were not NQF-endorsed, measures with absolute thresholds, and measures that do not allow a clinician to indicate the patient has declined the service in the value-based payment modifier. We believe we have provided groups of physicians with sufficient flexibility to choose the quality reporting method as well as the measures on which to report information. Moreover, we reiterate that the quality-tiering election we are finalizing is optional, thus ensuring no payment consequences for potentially poor performance on such quality measures.

In addition as we described above in section III.G.6, we plan on expanding the specialty measures available in the PQRS in order to more accurately measure the performance on quality of care furnished by specialists. The expansion of the GPRO to registries in 2013 and to EHRs in 2014 means that sub-specialists may participate in the PQRS as members of a group practice, such that the group can report data on measures of broad applicability. We believe group reporting can ameliorate the commenters' concerns that the current set of PQRS measures does not capture all of the clinical care that some specialists and sub-specialists furnish. We also recognize that the rules governing the PQRS are flexible in terms of the quality measures physicians and groups of physicians report and the methods by which they report them. Although some commenters stated this flexibility would lead to ''cherry-picking'' measures, we believe these two features of the PQRS are beneficial given that the first principle governing the value-based payment modifier is to encourage greater reporting of information for quality purposes by physicians and groups of physicians.

Comment: CMS received many comments about how to phase-in the value-based payment modifier at the individual level (for example, a solo practitioner) to allow them to report measures within any of the PQRS mechanisms for individual reporting (claims, registry, EHR) or by the method they had systems in place to report. Commenters supported the idea of flexibility of choice in reporting measures as stated above.

Response: The vast majority of commenters have agreed with the application of the value-based payment modifier at the group level for the initial implementation of the program. We are not finalizing an option for solo practitioners to participate in the value-based payment modifier for 2015. We plan to make proposals for how the value-based payment modifier would apply to individual physicians and to smaller groups in future rulemaking.

d. Cost Measures

Section 1848(p)(3) of the Act requires us to evaluate costs, to the extent practicable, based on a composite of appropriate measures of costs. In the CY 2012 PFS final rule with comment period (76 FR 73434), we finalized use of total per capita cost measures and per capita cost measures for beneficiaries with four specific chronic conditions (chronic obstructive pulmonary disease, heart failure, coronary artery disease, and diabetes) for the value-based payment modifier. Total per capita costs include payments under both Part A and Part B. Total per capita costs do not include Medicare payments under Part D for drug expenses. We proposed to use at least a 60-day claims run out with a completion factor from our Office of the Actuary (for example, claims paid through March 1 of the year following December 31, the close of the performance period) to calculate the total per capita cost measures (77 FR 45002).

As described more fully in the composite scoring methodology discussion below, we proposed to make cost comparisons among groups of physicians using a similar beneficiary attribution methodology such that we make ''apples to apples'' comparisons. We believe that this would be an appropriate approach to using the total per capita cost measure in the value-based payment modifier. We sought comment on these proposals.

The following is a summary of the comments we received regarding these proposals.

Comment: A number of commenters expressed support for CMS' proposal to implement the total per capita cost measure and per capita cost measures for the four chronic conditions. One commenter noted that the four chronic conditions align with the proposed quality measures. Some commenters who expressed support for the proposed cost measures encouraged CMS to refine and improve its cost measures in a transparent manner, including by working with specialty societies and other interested parties to fine tune the existing measures and potentially add other chronic conditions. One commenter encouraged CMS to continue looking into how to incorporate Medicare Part D data into physician cost measures.

One commenter expressed concerns that the value-based payment modifier was based on ''crude'' per capita measures, while a number of specialists expressed concern that the cost measures are inappropriate for some specialties, particularly single specialty practices. A number of specialists objected to basing physician cost measures on total amount billed per patient, since the specialist is assumed to be held responsible for care and treatment decisions of the patient for which they have little control and for which they have limited ability to modify their practice to reduce costs. Commenters indicated that attribution of no costs or little costs to specialists is possible under any attribution method since the majority of specialists do not treat one of the four chronic conditions, so measuring costs using per capita measures would not create incentives to change behavior. Some commenters stated that Medicare Part A costs should be excluded from cost comparisons, because physicians cannot control Part A (for example, hospital) costs. A number of specialists supported CMS working closely with physicians to refine the cost measures prior to implementation of the value-based payment modifier.

Response: In the CY 2012 PFS final rule, we established a policy to use total per capita cost measures and per capita cost measures for beneficiaries with four specific chronic conditions (COPD, coronary artery disease, diabetes, and heart failure) in the value-based payment modifier to be implemented in 2015. We continue to believe that these measures are useful measures of the total volume of healthcare services furnished to Medicare beneficiaries attributed to a group of physicians. Moreover, use of total per capita cost measures reinforces one of the five principles governing implementation of the value-based payment modifier to encourage shared accountability for beneficiary care. We agree with specialty societies and other interested parties that suggested we continue to look for ways to refine the current measures and potentially add other chronic conditions. We will continue to explore the feasibility of including Part D data in the cost measures.

Comment: Many commenters suggested that CMS focus on episode-based cost measures in the value-based payment modifier, and some explicitly mentioned the importance of CMS' work related to development of the Medicare Episode Grouper. A number of commenters agreed with CMS' recommendation to first incorporate episode costs from the Medicare Episode Grouper in the Physician Feedback program prior to applying the measures to the value-based payment modifier. Some commenters recommended that CMS focus on chronic or high priority episode types during the initial states of the value-based payment modifier. Commenters suggested that CMS meet with specialty groups and other stakeholders to obtain feedback on the development and application of the Medicare Episode Grouper data and urged transparency through means other than just rulemaking.

Response: We agree with commenters about the potential value of episode-based cost measures in the value modifier, and we also agree with those that support our recommendation to first incorporate episode costs from the Medicare Episode Grouper in the Physician Feedback program before applying these measures to the value-based payment modifier. CMS plans to engage stakeholders through events that will provide details of the episode grouper methodology and to obtain feedback on episode based costs and utilization.

Comment: Several commenters noted that it would be useful to look at costs over a sufficiently long time period (for example, several years) to ensure that the full benefits of using the technology, diagnostic testing, or drug were captured. Some commenters also noted that per capita cost measures do not reflect savings in Medicare Part A that are due to the physician's or groups' care. Other commenters suggested that cost measures should be aligned with appropriate outcomes or quality measures.

Response: We agree that it would be useful to incorporate benefits of technology and drugs that might be realized in future years, and we may examine ways to measure costs, and changes in cost, over multiple years in the future for the value-based payment modifier. We believe that Part A savings during the performance year will be reflected in lower total per capita costs, and thus we disagree with the comments that suggest we should not include Part A costs in the total per capita cost measures.

Comment: A number of commenters recommended that all value-based payment modifier cost measures be submitted to NQF for endorsement. Some commenters stated that CMS should include only NQF-endorsed cost measures in the value-based payment modifier. They also suggested that CMS delay implementation of the value-based payment modifier until measure testing and the NQF process was complete.

Response: We plan to submit the total per capita cost measures and the four chronic condition-focused per capita measures for NQF endorsement. Although we generally agree that NQF-endorsed measures are preferable, we do not agree that we should only use NQF-endorsed measures for the value-based payment modifier. The development of cost measures is in its infancy and we believe that conditioning use of cost measures for the value-based payment modifier on NQF-endorsement would unduly delay implementation of the value-based payment modifier.

Comment: We received no comments specifically on using at least a 60-day claims run out, but one supporter of the five per capita cost measures noted that the run out period should be established such that an extension of the time period would only minimally improve accuracy.

Response: We are finalizing our proposal to use at least a 60-day run out with a completion factor from CMS' Office of the Actuary to calculate the total per capita cost measures, because we believe it will provide an accurate calculation of these measures.

As a result of the comments and for the reasons we articulated previously, we are finalizing the total per capita cost measures and per capita cost measures for beneficiaries with four specific chronic conditions (COPD, coronary artery disease, diabetes, and heart failure) in the 2015 value-based payment modifier and to use at least a 60-day claims run out.

(1) Proposed Payment Standardization Methodology for Cost Measures

Section 1848(p)(3) of the Act requires that ''* * * costs shall be evaluated, to

the extent practicable, based on a composite of appropriate measures of costs established by the Secretary (such as the composite measure under the methodology established under section 1848(n)(9)(C)(iii)) that eliminate the effect of geographic adjustments in payment rates (as described in subsection (e)) * * *'' We have interpreted this directive to require us to standardize Medicare payments to ensure fair comparisons of costs across geographic areas.

Payment standardization removes local or regional price differences that may cause cost variation a physician cannot influence through practicing efficient care. In Medicare, an effective payment standardization methodology would exclude Medicare geographic adjustment factors such as the geographic practice cost index (GPCI) and the hospital wage index so that, for example, per capita costs for beneficiaries in Atlanta, Georgia can be compared to those of beneficiaries in Lincoln, Nebraska. Payment standardization, therefore, allows fair comparisons of resource use costs for physicians to those of peers who may practice in locations or facilities where Medicare payments are higher or lower.

With industry input, we developed a Medicare payment standardization methodology that excludes such geographic payment rate differences. We update this methodology annually to reflect any change in CMS payment systems. We proposed to use the same standardization methodology as in the 2011 Physician Feedback reports and the Medicare Spending per Beneficiary (MSPB) measure that is used in CMS' feedback reports to hospitals (77 FR 45003).

The following is a summary of the comments we received regarding the payment standardization proposal.

Comment: Commenters expressed support for removing geographic and other adjustments when calculating cost measures. Several commenters agreed that cost measures in the value-based payment modifier must be standardized and explicitly supported the removal of indirect medical education (IME) and disproportionate share hospital (DSH) payments from the inpatient resource calculations.

Multiple commenters expressed concern about the Geographic Price Cost Indices (GPCIs). They stated that the GPCI results in downward adjustments that do not reflect the actual cost of physician practice. Some commenters referred to concerns about CMS cost measurement methodology issues that were raised in the May 2011 and July 2012 Institute of Medicine reports that questioned CMS policies regarding geographic adjustment.[5] These commenters claimed that, although the standardization method reverses the effects of the GPCI, it results in the perpetuation of some of the inaccuracies of the GPCI inputs that reduce payments for some regions. Some commenters stated that payment standardization does not account for regional differences in spending, so CMS should establish cost measures at the regional and national level. One commenter described concerns about efforts of poor physician supply on local cost measures. Several commenters noted that some areas might have high costs but lower rates of spending growth than nationally.

Response: We agree that standardization is important to ensure that groups of physicians' cost measures are not higher or lower due to geographic differences and other adjustments (IME, DSH, etc.) that affect actual Medicare Part A and Part B payments. We note that the effects of the GPCIs are removed from payments under the CMS payment standardization methodology,[6] so services that would be subject to the GPCIs under Medicare payment rules are priced at the same level across all physicians within the same setting, regardless of geographic area in which they practice. Commenters' concerns about the effectiveness of our geographic adjustment policies in general are outside the scope of this rulemaking. Commenters' concern about the proposed standardization methodology not taking account of regional differences in spending appears to misinterpret our approach to standardization. The per capita cost measures themselves will show regional differences in Medicare spending, but the standardization process ensures that differences in cost measures do not reflect differences in Medicare's price indices such as the GPCI. Finally, standardization is not meant to measure growth in spending.

As a result of the comments and for the reasons specified above, we are finalizing our proposal to apply the CMS payment standardization methodology, and any annual updates to the methodology, to the cost measures used for the value-based payment modifier.

(2) Risk Adjustment Methodology for Cost Measures

Section 1848(p)(3) of the Act requires that costs be adjusted to ''* * * take into account risk factors[,] such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive interventions) and other factors determined appropriate by the Secretary.''

Risk adjustment accounts for differences in patient characteristics not directly related to patient care, but that may increase or decrease the costs of care. In the Physician Feedback reports, after standardizing per capita costs for geographic factors, we also adjusted them based on the unique mix of patients attributed to the physician or group of physicians. Costs for beneficiaries with high risk factors (such as a history of chronic diseases, disability, or increased age) are adjusted downward, and costs for beneficiaries with low risk factors are adjusted upward. Thus, for individual physicians or physician groups who have a higher than average proportion of patients with serious medical conditions or other higher-cost risk factors, risk adjusted per capita costs are lower than the unadjusted costs, because costs of higher-risk patients are adjusted downward. Similarly, for individual physicians or physician groups who treated comparatively lower-risk patients, risk adjusted per capita costs were higher than unadjusted costs, because costs for lower-risk patients were adjusted upwards.

We proposed to use the HCC model, which assigns prior year ICD–9–CM diagnosis codes to 70 high-cost clinical conditions (each with similar disease characteristics and costs) to capture medical condition risk (77 FR 45003–45004). The HCC risk scores also incorporate patient age, gender, reason for Medicare eligibility (age or disability), and Medicaid eligibility status, which is in part a proxy for socioeconomic status and reflects the greater resources typically used by beneficiaries eligible for both Medicare and Medicaid. The risk adjustment model also includes the beneficiary's end stage renal disease (ESRD) status. More information about the risk adjustment model is on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/122111_Slide_Presentation.pdf.*

[5] See *http://iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx* (May 2011; revised September 2011) and *http://iom.edu/eports/2012/Geographic-Adjustment-in-Medicare-Payment-Phase-II.aspx* (July 2012).

[6] See Quality Net, Measure Methodology Reports, available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

We proposed to use the same risk adjustment model for risk adjusting total per capita costs and the total per capita costs for beneficiaries with four chronic diseases (coronary artery disease, COPD, diabetes, and heart failure) as we have used for the group and individual 2010 Physician Feedback reports.

The following is a summary of the comments we received regarding the risk adjustment proposal.

Comment: A number of commenters supported the HCC risk adjustment methodology, with one commenter stating that the risk adjustment approach that was used for the 2010 physician feedback reports is the best currently available approach to risk adjustment of the value-based payment modifier with the best proxies for health status and socioeconomic status being used. Other commenters noted the need for or importance of risk adjustment of cost measures without explicitly stating support of the CMS method, with one commenter urging CMS to proceed with caution so that risk adjustment does not penalize physicians that treat sicker, more costly patients.

Many commenters expressed concerns about the proposed risk adjustment method. Some commenters indicated that they had long-standing concerns with the HCC risk adjuster that should be addressed before the value-based payment modifiers is applied to small and mid-sized practices, and they urged CMS to consider new approaches that have been suggested by MedPAC and by the Medicare Episode Grouper contractor. Some concerns about the HCC model that commenters expressed include that it does not fare as well with acute costs associated with surgeries that are not predictable. Some commenters argued that socioeconomic factors and compliance are not adequately captured in the model, and that the Medicaid dual eligible status alone does not capture these differences in risk. Commenters suggested including different factors to capture socioeconomic status, including poverty status, education, literacy, race, ethnicity, English proficiency, homelessness, and religion. A number of commenters urged that CMS do further analysis in testing and refining risk adjusters that address comorbid conditions or new disease onset, and suggested that CMS work with physician groups.

Response: We continue to believe that the current risk adjustment methodology, which is based on the HCC model [7] and supported by a number of commenters, should be used in the value-based payment modifier. The HCC model is calibrated on Medicare fee for service beneficiaries and is accurate in predicting these costs. Moreover, one of the benefits of the HCC model is that CMS updates it regularly to reflect changes in treatment patterns and costs. In addition, CMS is exploring how to incorporate additional aspects of coding completeness and quality. The result of these efforts would inform how to weigh the future model design to predict costs and to capture conditions that are present in clinical conditions.[8]

Commenters did not present evidence that the risk adjustment model systematically disadvantages physicians or groups that see certain patient types, nor did they present reliable data sources we could use in our risk adjustment model to account for recommended factors such as socioeconomic status, education, literacy, English proficiency, homelessness, and religion. We agree with commenters that patient compliance could be a relevant issue, but commenters did not present a method about how to incorporate such compliance into the risk adjustment model using existing beneficiary data.

After consideration of the comments and for the reasons discussed above, we are finalizing our proposed approach to risk adjustment of the cost measures included in the value-based payment modifier.

e. Attribution of Quality and Cost Measures

Calculation of administrative claims-based quality and cost measure performance rates requires us to attribute Medicare beneficiaries to groups of physicians. We proposed to use a plurality of care method to attribute beneficiaries to a group of physicians (77 FR 45005). In this method, we attributed Medicare FFS beneficiaries to the group practice that billed a larger share of office and other outpatient Evaluation and Management (E/M) services (based on dollars) than any other group of physician practice (that is, the plurality). In addition, beneficiaries had to have at least two E/M services furnished by the group of physicians.

We sought comments on two possible alternative attribution approaches for the value-based payment modifier (77 FR 45005). First, we sought comment on whether we should use an attribution approach based on the methodology used in the Medicare Shared Savings Program to assign a beneficiary to an Accountable Care Organization (ACO). As discussed in the CY 2013 proposed FFS rule (77 FR 44819), this attribution approach would involve a two-step process that emphasizes primary care services furnished by a physician or group of physicians. Second, we sought comment on whether we instead should apply the ''degree of involvement'' attribution method. We used the ''degree of involvement'' method to attribute beneficiaries for cost purposes to individual physicians in the CY 2010 Physician Feedback reports. Under this attribution method, we classified the patients for which a physician submitted at least one Medicare FFS Part B claim into three categories (directed, influenced, and contributed) based on the amount of physician involvement with the patient.[9] For directed and influenced patients, the physician billed for 35 percent or more of the patient's office or other outpatient evaluation and management (E/M) visits or for 20 percent or more of the patient's total professional costs, whereas for contributed patients, the physician billed for fewer than 35 percent of the patient's outpatient E&M visits and for less than 20 percent of the patient's total professional costs.

The following is a summary of the comments we received regarding the attribution proposal.

Comment: We received several comments on attribution. Of the many commenters who expressed a preference for one of the attribution methods, the majority expressed support for the plurality of care method or the plurality of primary care services method used in the Medicare Shared Savings Program (Shared Savings Program). Arguments in favor of a plurality of care attribution method include consistency with 2010 group feedback reports, administrative simplicity, transparency, credibility, understandability, and its emphasis on role of treatment of chronic conditions. One commenter supported using a plurality of care method, but stated that CMS should encourage beneficiaries to choose a primary care physician and adopt an attribution method that includes greater consideration of annual wellness visits. Another commenter suggested that CMS adopt either a plurality of care or plurality of primary

[7] See RTI, ''Evaluation of the CMS–HCC Risk Adjustment Methodology,'' (March 2011), available at: *https://www.cms.gov/MedicareAdvtgSpecRateStats/downloads/Evaluation_Risk_Adj_Model_2011.pdf.*

[8] See ''Advance Notice of Methodological Changes for Calendar Year (CY) 2013 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2013 Call Letter.''

[9] CMS, ''Detailed Methodology for Individual Physician Reports'' (2012), available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/QRURs_for_Individual_Physicians.pdf.*

care services as included in the Shared Savings Program, as it would provide a better transition to episodes of care than the degree of involvement method.

Although commenters were more favorable of the plurality of care or plurality of primary care method than the degree of involvement attribution method, some commenters expressed concerns about using an attribution method based on plurality of care. Some commenters agreed with CMS that the plurality of care method, which depends on E/M frequency, would not work for certain specialists, with one commenter stating that plurality unfairly attributes costs to certain specialties over others and other commenters agreeing with CMS that plurality will not be applicable to single specialty groups. One commenter expressed concern that the plurality method may be too restrictive for some practices. Another commenter noted that plurality of care attribution in the performance year is a problem when used with risk adjustment that is based on claims that are submitted in years prior to the performance year, and noted that multiple attribution or degree of involvement may alleviate some, but not all, of the issues. One commenter asked how the plurality of care method accommodates specialists who do not furnish the plurality of a patient's care.

CMS asked for comment on the plurality of primary care attribution approach that is similar to what is used in the Shared Savings Program. Although fewer commenters discussed this method than the plurality of care method, most who did discuss this method expressed general support for this approach, either as their preferred attribution method or one that was at least at the same level of acceptability as the plurality of care method. Some commenters stated that, while the plurality of care method would be consistent with the attribution method proposed for the PQRS GPRO web-interface, the plurality of primary care attribution method is comparable to that used in the Shared Savings Program and would create consistency across these programs. One specialist group indicated that a patient that sees a specialist for management of chronic conditions and receives a plurality of primary care services from the specialist would be appropriately attributed under this method. One medical center supported the Shared Savings Program-like approach over the plurality of care method because most group reporting measures are primary care based, so attribution under this method would be to the primary care physician whereas, under plurality of care attribution, the beneficiaries could be assigned incorrectly to higher cost specialists.

Response: We are persuaded by the comments that we should not finalize the plurality of care method, but should instead align the attribution methodology with the methodology used for the Shared Savings Program. Given that we are applying the value-based payment modifier to groups of physicians of 100 or more eligible professionals, we believe it is important to align attribution methods with the one being used for the Shared Savings Program and the PQRS. Because the cost measures we are using for the value-based payment modifier focus on total per capita costs, we believe it is reasonable to attribute beneficiaries to those groups of physicians that are most responsible for the delivery of primary care services and have the ability to furnish it in a cost-effective manner.

We recognize that certain large single specialty groups—such as those limited to emergency medicine, diagnostic radiology, pathology, and anesthesiology—will not be attributed beneficiaries under this attribution methodology. Indeed, neither the plurality of care attribution methodology nor the Shared Savings Program methodology would attribute beneficiaries to certain single specialty groups. However, after we have had the opportunity to examine the issue further and gain more experience with the value-based payment modifier we anticipate addressing this issue in future rulemaking. We believe that as we continue to phase in the value-based payment modifier, we will refine our attribution methods to assign beneficiaries to these physicians and groups of physicians within these specialties.

Comment: Support for the degree of involvement method was mixed, with a high percentage of commenters of this method suggesting that it needed to be studied further and explained to physicians. Some commenters argued that the degree of involvement method was more comprehensive and a better alternative in the long run; allows physicians who contribute to the care of a patient to be recognized for their services; and is preferable for attribution for individual physicians (rather than groups). One commenter supported the degree of involvement method, but disagreed with the idea of combining the directed and influenced categories because of the differences in accountability between the two categories. Similarly, another commenter indicated that if CMS selected the degree of involvement method over its preferred method of plurality of care, only the directed category should be used, since influenced patients are not sufficiently under the physicians' care. Another commenter suggested that CMS study the effects of the degree of involvement method and consider whether to exclude certain specialists from attribution because they should not be treating patients with certain conditions.

A number of commenters expressed either concern or confusion about the degree of involvement attribution method. Several commenters suggested that CMS use data from the Physician Feedback reports to examine the impact of different methods on groups' cost and quality scores. Some commenters questioned how the degree of involvement classification would translate into how much would be attributed to a physician or a group. One commenter indicated that the degree of involvement method would be problematic in many cases and would need to evolve over time, with consideration for physicians who see patients at multiple facilities. Emergency physicians expressed concern about their ability to influence overall costs through coordination, although they might be attributed the costs under this method.

Response: We thank commenters for their views on the degree of involvement attribution methodology, but as discussed above, we are finalizing the attribution methodology used in the Medicare Shared Savings Program. We will continue to study this methodology for it may continue to have applicability when we make proposals to apply the value-based payment modifier to individual physicians.

Comment: Some commenters expressed concerns about attribution methods in general, stating that the current models do not address attribution appropriately when a patient sees multiple physicians, with some costs within a physician's control and other costs not within the physician's control. Another commenter suggested that CMS explore the option of a set of billing codes to make explicit the scope and nature of responsibility between the physician and patient. Another commenter indicated that attribution methods for specialists must account for care furnished because the original physician did not take sufficient preventive steps or because the patient was referred to a specialist. One commenter stated that attribution of the entire cost of surgeries should be attributed to the performing surgeon.

Response: We thank commenters for their views and will consider them

when developing future proposals to design an attribution methodology for those groups of physicians that will not have beneficiaries attributed to them under the finalized attribution methodology discussed above for the 2013 performance period.

Comment: Many commenters indicated that CMS should study the impact of different attribution methods on physicians/physician groups' costs and share the results to solicit stakeholder feedback, possibly through future rulemaking. A number of commenters expressed a willingness to work with CMS on attribution. Commenters wanted to understand how the results change when the attribution methodology changes, and some suggested that CMS delay the value-based payment modifier until CMS has tested and implemented a meaningful system for attribution to specialists. Some commenters discussed the RAND study to prove their point that the attribution methodology can affect how physicians and groups of physicians are characterized for cost and quality purposes. This study, which used claims on adults age 18–65 that were continuously enrolled in four Massachusetts commercial plans in the years 2004 and 2005, created 12 attribution rules and found that about 22 percent of physicians would be assigned to the wrong cost category given a change in attribution rules.[10]

Response: We agree with commenters that it would be informative to study the results of different attribution methods using the same data and share the results with physicians. We do not agree with the commenters' suggestion to delay implementation of the value-based payment modifier. We believe it is critical for physicians and groups of physicians to report data for quality measures through the PQRS. A delay of the value-based payment modifier would undermine this objective. Moreover, because the quality-tiering calculation methodology is optional, we believe we have provided a reasonable way to implement the value-based payment modifier so that groups of physicians can obtain information on how their payment could be modified in the future and take appropriate action.

As a result of the comments, we are not finalizing the proposed plurality of care method, but instead, as described above, we will apply the same attribution rule as that used for the Medicare Shared Savings Program and the PQRS GPRO web interface. This methodology is described at *http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf*. See also 45 CFR 425.400 through 425.402.

f. Composite Scores for the Value-Based Payment Modifier

Section 1848(p)(2) of the Act requires that quality of care be evaluated, to the extent practicable, based on a composite of measures of the quality of care furnished. Likewise, section 1848(p)(3) of the Act requires that costs in the value-based payment modifier be evaluated, to the extent practicable, based on a composite of appropriate measures of costs.

(1) Quality of Care and Cost Domains

We proposed to align the quality measures used in the value-based payment modifier with the national priorities established in the National Quality Strategy (77 FR 45006). The National Quality Strategy outlined six priorities including:

- Make care safer by reducing harm caused in the delivery of care (patient safety).
- Ensure that care engages each person and family as partners (patient experience).
- Promote effective communication and coordination of care (care coordination).
- Promote the most effective prevention and treatment practices for leading causes of mortality (clinical care).
- Work with communities to promote wide use of best practice to enable healthy living (population/community health).
- Make quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models (efficiency).[11]

We proposed to classify each of the quality measures that we proposed for the value-based payment modifier into one of these six domains. We proposed to weight each domain equally to form a quality of care composite. We believe this is a straightforward approach that recognizes the importance of each domain. Within each domain, we proposed to weight each measure equally so that groups of physicians have equal incentives to improve care delivery on all measures. To the extent that a domain does not contain quality measures, the remaining domains would be equally weighted to form the quality of care composite. For example, if only three domains contain quality information, each domain would be weighted at 33.3 percent to form the quality composite while the remaining three domains would not be included.

In terms of the cost composite, we finalized in the CY 2012 PFS final rule (76 FR 73434) five per capita cost measures: Total per capita costs (Parts A and B) and total per capita costs for beneficiaries with four chronic diseases (diabetes, CAD, COPD, heart failure). We proposed to group these five per capita cost measures into two separate domains: Total overall costs (one measure) and total costs for beneficiaries with specific conditions (four measures). A separate domain for costs for beneficiaries with specific conditions highlights our desire to incentivize efficient care for beneficiaries with these conditions.

Similar to the quality of care composite, we proposed to weight each cost domain equally to form the cost composite and within the cost domains we proposed to weight each measure equally. In those instances in which we cannot calculate a particular cost measure, for example, due to too few cases, we proposed to weight the remaining cost measures in the domain equally.

Comment: We received comments both in support of and in opposition to our proposed composite score methodology. Some commenters expressed support for quality of care and cost composites, with one noting their view that composite scores are more meaningful for purchasers than are other measures. Some commenters expressed concerns with the proposed composite measures. For example, one commenter observed that quality of care and cost composites might mask significant variation in performance across disease categories. That is, a physician could demonstrate high quality and low costs for one disease category, but lower quality and higher costs for others; however, this would not be detected within a composite measure. This commenter also recommended that the internal validity of measures should be demonstrated before multiple measures are combined into a single composite. Another commenter expressed concern that few measures within the composites were applicable to their particular specialty.

Comments on our proposed domains and weighting methodology were also mixed. One commenter expressed support for our proposal to equally weight domains, but recommended that attention be given to the number of measures in each domain so that they were weighted to support our policy

[10] See RAND, Is Physician Cost Profiling Ready for Prime Time? Available at: *http://www.rand.org/pubs/research_briefs/RB9523-1/index1.html.*

[11] National Quality Strategy, *http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf.*

goals. Another commenter expressed concern about establishing separate domains when some of these had no measures in place (for example, population/community health) while others had only a handful of measures, which could cause differential weighting among measures.

We also received varying views on how to weight various measures. One commenter suggested that quality outcome measures should receive more weight than other measure types; another comment suggested that outcome measures be weighted lower than the PQRS measures as the latter are likely to be more direct indicators of a physician's performance, particularly for specialty physicians. Alternatively, one commenter suggested that CMS weight existing PQRS measures within the efficiency domain for those who successfully report or assess costs on a measure-by-measure basis.

Response: We appreciate the comments in support of, and suggestions to improve upon, our proposals. We believe that forming each group of physicians' quality and cost composites by equally weighting quality measures in equally weighted domains makes the most sense when groups of physicians have flexibility to choose which measures they will report. It also is a transparent method and easily understood by physicians. We recognize that some groups may not report measures in certain proposed domains, such as community/population health, efficiency, and patient experience. We wish to clarify that our proposal intended to establish an overall framework for how we would weight measures, and that as more measures are included in this and the PQRS programs, they would be incorporated into our framework. As we stated in the proposed rule (77 FR 45006), in cases where a group does not report measures in one or two of the domains the remaining domains will be weighted equally. If the group only reports measures in a single domain, the domain would be weighted 100 percent. Moreover, all measures in a domain would be equally weighted.

We agree with the commenters' recommendation that we continue to monitor and examine our policy to form the quality and cost composites. We believe this monitoring will be facilitated with the data reported by those participating in value-based payment modifier and the PQRS programs. As part of this monitoring, we will be able to examine whether the quality and cost composites are masking performance variation within a group as suggested by the commenters.

Accordingly, we are finalizing our proposal to construct the quality composite by classifying each group's quality measures into one of the six National Quality Strategy domains, to weight each measure equally within each domain, and to weight the domains equally to form the quality composite. Likewise, we are finalizing our proposals to construct the cost composite by classifying each group's per capita cost measures into two domains—all patients and all patients with four specific chronic conditions, to weight each measure equally within each domain, and to weight the domains equally to form the cost composite.

(2) Value-Based Payment Modifier Scoring Methods

We proposed a scoring approach that focuses on how the group of physicians' performance differs from the benchmark on a measure-by-measure basis because we proposed to provide flexibility to groups of physicians as to the quality measures they report (77 FR 45007). We explained that the scoring methodology needs to be able to compare ''apples to apples.'' For each quality and cost measure, we proposed to divide the difference between a group of physicians' performance rate and the benchmark by the measure's standard deviation. The benchmarks, as further described below, are the national means of the quality or cost measure. This step produces a score for each measure that is expressed in standardized units.

Comment: The comments we received on this issue supported our proposal to establish standardized scores for performance measures to ensure fair comparisons among groups of physicians.

Response: After consideration of the comments, we are finalizing our proposal to establish standardized scores for the value-based modifier performance measures. We believe that this approach achieves our policy objective to distinguish clearly between high and low performance and to allow us to create composites of quality of care for groups of physicians that report different quality measures. We will be considering the effects of our methodology over the next several years as we implement this program and may consider changes to the policy through future rulemaking.

(3) Benchmarks and Peer Groups for Quality Measures

We proposed that the benchmark for each quality measure be the national mean of each measure's performance rate during the performance period (77 FR 45008). We proposed to unify the calculation of the benchmark by weighting the performance rate of each physician and group of physicians submitting data on the quality measure by the number of beneficiaries used to calculate the performance rate so that group performance is weighted appropriately.

In addition, we proposed that the benchmarks for quality measures in the PQRS administrative claims-based reporting option be the national mean of each quality measure's performance rate calculated at the TIN level. We proposed to calculate the national mean by including all TINs of groups of physicians with 25 or more eligible professionals. We proposed to weight the TIN's performance rate by the number of beneficiaries used to calculate the quality measure.

To help groups of physicians understand how their quality measure performance affects their quality of care composite score, we proposed to publish the previous years' performance rates (and standardized scores) on each quality measure.

Comment: We received several comments supporting our proposed national benchmark. Some commenters highlighted their view that national benchmarks were a fair way to both (1) reward high-quality, low-cost groups of physicians while (2) providing targets for improvement to underperforming groups of physicians. Although generally supporting our proposal, one commenter expressed the concern that benchmarks might be skewed and inconsistent across years because physicians could choose the measures on which they reported rather than requiring that they report on the full distribution of performance. Accordingly, this commenter recommended that all groups of physicians should report on a common set of measures.

Other commenters reported concerns about the proposed national benchmark and, as an alternative, suggested that comparisons should be within regions, physician or to some other appropriate peer group, for example, considering patient risk. One commenter encouraged CMS to set performance standards higher in subsequent years.

Some commenters suggested that CMS explore and conduct analyses on a variety of benchmarking options. For example, one suggested that CMS examine the advantages of initially using a regional or blended benchmark that gradually moves to a national benchmark. In their view, this could be a means to encourage physician buy-in while not disadvantaging certain regions

based on their historical performance levels.

One commenter suggested that for a pay-for-performance system to be effective, it must have clarity and credibility with front-line practitioners. This commenter observed that under our proposals, physicians receiving a payment adjustment are unlikely to understand why their payments are getting adjusted and what they need to do to improve their value modifier.

Response: We appreciate the comments we received in support of our proposed national benchmarks as well as suggested alternatives. Given that Medicare is a national program, we concur with comments that a national benchmark is most appropriate. Medicare beneficiaries should receive high quality and low cost care regardless of their location. Moreover, we use national benchmarks for other Medicare programs aimed at improving the quality and cost of care, for example, the Medicare Shared Savings program.

Because we are allowing flexibility on the quality measures that groups of physicians can report, we believe the most appropriate peer group consists of other physicians and physician groups reporting the same measure regardless of specialty. Under this approach, we expect physicians and physician groups will report data on the quality measures that best reflect the care they furnish.

We also believe that the optional nature of the quality-tiering approach to calculating the value-based payment modifier will encourage physician buy-in while not disadvantaging certain regions based on their historical performance levels, thus we will not develop regional benchmarks for each quality measure.

Further, we believe transparency is a key component to establish credibility among physicians, namely, physicians need to understand why their payments are being adjusted in order to improve their performance. Thus, we are modifying our proposal to establish benchmarks based on the year prior to the performance year so that groups of physicians have information on national benchmarks prior to the end of the performance year. For example, the benchmark for the 2013 performance year will be based on 2012. We intend that these benchmarks would be available publicly to inform a group of physicians' choice of PQRS reporting method for the applicable performance year.

Accordingly, we are finalizing our proposal for national benchmarks and we will unify the calculation of the benchmark by weighting the performance rate of each physician and group of physicians submitting data (through any PQRS reporting method) on the quality measure by the number of beneficiaries used to calculate the performance rate. In addition, the benchmarks for quality measures in the PQRS administrative claims-based reporting option are the national mean of each quality measure's performance rate calculated at the TIN level. We will weight the TIN's performance rate by the number of beneficiaries used to calculate the quality measure. We also will use the year prior to the performance year as the year for calculating the benchmark. If a measure is new to the PQRS, we will be unable to calculate a benchmark, and hence, performance on that measure will not be included in the quality composite. We will be considering the effects of our policies over the next several years as we implement this program and may consider changes and refinements through future rulemaking.

(4) Benchmarks and Peer Groups for Cost Measures

To ensure fair cost comparisons that identify groups of physicians that are outliers (both high and low), we proposed that the methodology used to attribute beneficiaries to a group of physicians be the same as the methodology used to attribute beneficiaries in the peer group (77 FR 45008). We explained that we seek to compare like groups of physicians that use the same cost attribution methodology to ensure we are making ''apples to apples'' comparisons among groups of physicians. As discussed above, we are finalizing a cost attribution methodology that we use in the Medicare Shared Savings Program and that relies on a two-step process. We sought comment, however, on whether the cost measure peer groups should change if we adopted the ''degree of involvement'' methodology for groups of physicians other than groups of physicians using the PQRS GPRO web-interface to submit data on quality measures. We also solicited comments on establishing cost benchmarks on a quality measure-by-quality measure basis.

Comment: As discussed above, we received comments in support of our proposal for a national benchmark. We also received several suggestions that we implement regional cost benchmarks rather than national ones to account for regional variations in spending.

Response: Consistent with our discussion above regarding the national basis of this program, we are finalizing our proposal to establish national benchmarks for the five cost measures based on data from the current performance year. Given that we are standardizing Medicare payments to eliminate regional payment differences to ensure fair national comparisons, we do not believe it is appropriate to establish regional benchmarks for the value-based payment modifier. We will be considering the effects of this policy over the next several years as we implement this program and may consider changes to these policies through future rulemaking.

(5) Reliability Standard

We believe it is crucial that the value-based payment modifier be based on quality of care and cost composites that reliably measure performance. Statistical reliability is defined as the extent to which variation in the measure's performance rate is due to variation in the quality (or cost) furnished by the physicians (or group of physicians) rather than random variation due to the sample of cases observed. Potential reliability values range from zero to one, where one (highest possible reliability) signifies that all variation in the measure's rates is the result of variation in differences in performance across physicians (or groups of physicians). Generally, reliabilities in the 0.40–0.70 range are often considered moderate and values greater than 0.70 high.

Therefore, we proposed to establish a minimum number of cases in order for a quality or cost measure to be included in the quality of care or cost composite (77 FR 45009). To the extent that a group of physicians fails to meet the minimum number of cases for a particular measure, the measure would not be counted and the remaining measures in the domain would be given equal weight. To the extent that we cannot develop either a reliable quality of care composite or cost composite because we do not have reliable domain information, we proposed that we would not calculate a value-based payment modifier and payment would not be affected.

Based on an analysis of the individual CY 2010 Physician Feedback reports and on recent literature, we proposed a minimum case size of 20 for both quality and cost measures to ensure high statistical reliability. We explained that the average reliability of the total per capita cost measure assessed at the individual level for physicians in all specialties was high (greater than 0.70) when the minimum case size was 20 or more. We also stated that reliability was high for nine of the 15 administrative claims based quality measures that we are proposing for purposes of the value-

based payment modifier for the PQRS administrative claims-based reporting option when the minimum case size was 20 or greater. We anticipate that statistical reliability of the quality and cost measures will increase when we assess physicians at the TIN level rather than NPI level, because, on average, a TIN will be attributed more beneficiaries than an NPI.

Comment: We received a few comments on this proposal expressing support for strong reliability standards or a minimum case size threshold. We received a couple of comments recommending a higher minimum case size, for example, 30 rather than 20. One commenter sought clarification of our analysis of the reliability of the administrative claims based quality measures from the 2010 Individual Physician Feedback reports.

Response: We appreciate the comments we received in support of strong reliability standards. Based upon our statistical analysis that we discussed in the proposed rule (77 FR 45009), we believe a minimum case size of 20 is sufficient for this purpose. As we stated in our proposal, nine of the 15 administrative claims quality measures were highly reliable at the individual level. The other six were either moderately reliable at the individual level or assessed clinical care in high priority areas. We anticipate that reliability will not be an issue given that our analysis was at the individual level and not for groups of 100 or more eligible professionals. Accordingly, we are finalizing our proposal for 20 cases as the minimum case size; however, we will monitor and examine this issue as we implement this program and may consider changes to this policy through future rulemaking as we broaden the value-based payment modifier to reach all physicians and groups of physicians in 2017.

g. Payment Adjustment Amount

Section 1848(p) of the Act does not specify the amount of physician payment that should be subject to the adjustment for the value-based payment modifier; however, section 1848(p)(4)(C) of the Act requires the payment modifier be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups of physicians based on high performance and decrease for others based on low performance, but the aggregate amount of Medicare spending in any given year for physicians' services will not change as a result of application of the value-based payment modifier.

In making proposals about the amount of Medicare payment made under the PFS at risk for the value-based payment modifier, we considered that there are two other payment adjustments affecting physicians' Medicare payment in 2015 that could further decrease physician payments in 2016. Specifically, under the PQRS, a physician who does not submit data on quality measures to meet the satisfactory reporting criteria for the PQRS payment adjustment during the applicable reporting period in 2013 will have his or her fee schedule amount reduced by 1.5 percent for services furnished in 2015. This PQRS downward payment adjustment to the fee schedule will increase to 2 percent in 2016 (and thereafter) based on reporting periods that fall in CY 2014 (and thereafter, reporting period or periods that fall two years prior to the year in which the PQRS payment adjustment is assessed). The second payment adjustment is for physicians who do not achieve meaningful EHR use under the EHR Incentive program. Section 1848(a)(7) of the Act provides for a downward payment adjustment of 1 percent in 2015, 2 percent in 2016, and 3 percent in 2017 . We note that the adjustment in 2015 for not achieving meaningful use is increased by 1 percentage point (to −2 percent) if the physician was subject to the eRx Incentive Program payment adjustment for 2014.

As discussed above, we have finalized our policy to allow groups of physicians of 100 or more eligible professionals to elect whether to have their value-based payment modifier based on the quality-tiering methodology. For those groups that elect quality-tiering, we proposed that the maximum payment adjustment be −1.0 percent for poor performance (75 FR 45010). We stated that due to the budget neutrality requirement, we did not propose the exact amount of the upward payment adjustments for high performance under the quality-tiering approach because the upward payment adjustments (in the aggregate) will have to balance the downward payment adjustments in order to achieve budget neutrality. Thus, we proposed to determine the projected aggregate amount of downward payment adjustments and then calculate the upward payment adjustment factor based on the amount of the projected aggregate upward payment adjustments.

For groups of physicians subject to the value-based payment modifier that have not met the PQRS criteria for satisfactory reporting as described above (including those groups that have not participated in any of the PQRS reporting mechanisms), we proposed to set their value-based payment modifier at −1.0 percent (77 FR 45010). We arrived at our proposal for a −1.0 percent downward adjustment using the following rationale: Section 1848(p)(1) of the Act requires us to differentiate payment based on a comparison of quality of care furnished compared to cost. Because we do not have performance rates on which to assess the quality of care furnished by these groups, we can differentiate payment based on costs only rather than quality and cost as required by statute. Due to the fact that the value-based payment modifier is just starting in 2015, we do not wish to apply a greater downward payment adjustment for non-satisfactory reporters than we are proposing for the low quality/high cost groups that request that their value-based payment modifier be calculated using a quality-tiering approach.

Comment: Commenters expressed general support for our proposal to limit the downside risk to −1.0 percent for groups not participating in the PQRS and to ensure that those groups that elected quality-tiering would not be penalized more than those who did not participate in the PQRS. For example, one commenter noted that absent a specified maximum penalty, practices would be unwilling to risk having their payments significantly cut under a voluntary program. Another commenter expressed appreciation for our proposal to limit payment reductions to 1 percent, but also noted that with the potential for additional reductions for PQRS, e-Rx, and a 2 percent sequester-related reduction, the proposed 1 percent reduction still poses some risk. Similarly, some commenters requested a higher floor on downward payment adjustments, for example, −0.5 percent rather than −1.0 percent or even no negative adjustment for practices that opt into quality-tiering. One commenter raised a question as to whether participants in quality-tiering should be penalized at all given they had taken the minimum step of reporting PQRS data. As an alternative, this commenter recommended that CMS consider upward adjustments for groups that perform well with no adjustment for the remainder. Another commenter offered the view that with the possibility of a downward payment adjustment, only high quality/low cost physicians will participate in the program, which would result in a narrow range of comparisons that could be made and high performers being classified as being low. In their view, this would limit the ability to learn from the program.

In contrast, however, we received many comments suggesting that the

proposed payment adjustments were insufficient to motivate change at the physician level. Hence, one commenter recommended that quality-tiered scoring be mandatory for groups that report PQRS measures in 2013 as not doing so effectively creates a one-year opt out. Further, they recommended that the maximum downward adjustment be increased to −3.0 percent as it would both motivate change among lower performing physicians while better making available a sufficiently meaningful reward for good performance. Some commenters recommended that CMS apply higher payment differentials, some as high as ± 10 percent or more either in 2015 or subsequent years.

Related to this, some commenters expressed concern that since the upward payment adjustment was yet unspecified, there was little incentive or clarity in terms of the advantages and risks for participating in the program. One commenter sought clarity on whether budget neutrality meant that groups that elect quality-tiering would be ''vying to receive an upward modifier adjustment from a pool of funds derived from groups that received the −1.0 percent adjustment or would be competing against one another.

Response: While we appreciate comments suggesting larger payment adjustments to more strongly encourage quality improvements, we are finalizing our proposed adjustments as we believe they better align with our goal to gradually phase in the value-based payment modifier. We anticipate that as we gain more experience with our value-based payment modifier methodologies, we will consider ways to increase the amount of payment at risk.

We also appreciate concerns expressed about the uncertain of the amount of the upward payment adjustment; however, given statutory requirements for budget neutrality, we have not identified a way to specify an upward amount until all downward adjustments have been determined. We are open to comments on how we might be able to provide an upward payment amount for future rulemaking. We also wish to clarify that the total amount of upward payment adjustments is a fixed amount that is equal the amount made available through downward payment adjustments.

In summary, we are finalizing our proposal to establish a −1.0 value-based payment modifier adjustment for those groups of physicians of 100 or more eligible professionals that fall into category 2, which are those that neither (a) self-nominate for the PQRS as a group and report at least one measure nor (b) elect the PQRS administrative claims option for CY 2013. We also are finalizing our proposal to limit the downside payment adjustment for groups of physicians that elect the quality-tiering option at −1.0 percent.

h. Value-Based Payment Modifier Scoring Methodology

Section 1848(p)(1) of the Act requires the Secretary to establish a payment modifier that provides for differential payment to a physician or group of physicians under the fee schedule based upon the quality of care furnished compared to cost during a performance period. As noted previously, the statute requires that quality of care furnished and cost shall be evaluated, to the extent practicable, based on composites of quality of care furnished and cost.

In making our proposals, we developed two models that compare the quality of care furnished to costs: A quality-tiering model and a total performance score model. We proposed the quality-tiering model for the value-based payment modifier, and solicited comments on the total performance score model (77 FR 44010–12).

(1) Quality-Tiering Model

The quality-tiering model compares the quality of care composite with the cost composite to determine the value-based payment modifier. To make this comparison, we proposed to classify the quality of care composites scores into high, average, and low quality of care categories based on whether they are statistically above, not different from, or below the mean quality composite score. We seek to ensure that those groups of physicians classified as high or low performers have performance that is meaningfully different from average performance (to be sure that no group of physicians is disadvantaged for performance only slightly different from the benchmark) and is precisely measured (to ensure that no group of physicians is disadvantaged by an inaccurate performance assessment). We proposed to assess meaningful differences as those performance scores that are at least one standard deviation from the mean. We proposed to assess precision by requiring a group of physicians' score to be statistically different from the mean at the 5.0 percent level of significance (that is, a 95 percent confidence interval).

Likewise, we proposed to identify those groups of physicians that have cost composite scores that are statistically different from the mean cost composite score of all groups of physicians. We proposed to classify these groups of physicians into high, average, and low cost categories based on whether they are significantly above, not different from, or below the mean cost composite score as described above with reference to quality composite. We proposed to assess meaningful differences as those performance scores that are at least one standard deviation from the mean and we proposed to assess precision at the 5.0 percent level of significance.

We proposed to compare quality of care composite classification with the cost composite classification to determine the value-based payment modifier adjustment according to the amounts in Table 126.

TABLE 126—VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost
High quality	+ 2.0x *	+ 1.0x *	+ 0.0%
Average quality	+ 1.0x *	+ 0.0%	−0.5%
Low quality	+ 0.0%	−0.5%	−1.0%

* Groups of physicians eligible for an additional +1.0x if reporting measures and average beneficiary risk score in the top 25 percent of all risk scores.

We proposed to establish the upward payment adjustment factor (''x'') after the performance period has ended based on the aggregate amount of downward payment adjustments. We also proposed to aggregate the downward payment adjustments in Table 126 with the downward adjustment for groups of physicians subject to the value-based payment modifier that are not satisfactory PQRS reporters and then to solve for the upward payment

adjustment factor (''x''). For example, after determining the aggregate projected amount of the downward payment adjustments, CMS could calculate that the payment adjustment factor (''x'') would be 0.75 percent such that high quality/low cost groups of physicians would receive a 1.5 percent (2×0.75) upward payment adjustment during the payment adjustment period.

We also proposed that the scoring methodology provide a greater upward payment adjustment (+1.0x) for groups of physicians that care for high-risk patients (as evidenced by the average HCC risk score of the attributed beneficiary population) and submit data on PQRS quality measures through PQRS via the GPRO using the web-interface, claims, registries, or EHRs. We proposed to increase the upward payment adjustment to +3x (rather than +2x) for groups of physicians classified as high quality/low cost and to +2x (rather than +1x) for groups of physicians that are either high quality/average cost or average quality/low cost if the group of physicians' attributed patient population has an average risk score that is in the top 25 percent of all beneficiary risk scores. In other words, we did not propose this additional upward payment adjustment (+1.0x) for groups of physicians that select the PQRS administrative claims-based reporting option.

A second approach to scoring the value-based payment modifier is a total performance score approach. We sought comment on this approach. This approach allows us to develop a unique value-based payment modifier for each group of physicians. This approach results in a range of continuous payment adjustments rather than the thresholds proposed in the quality tier approach. This method would be similar to the approach we use in the Hospital Value-Based Purchasing program where we use a linear exchange function to develop a unique payment for each hospital. This approach results in a continuous array of unique value-based payment modifiers such that there are no longer cut-off points between high and low performing groups of physicians.

Comment: We received several comments in support of the quality-tiering model. In some cases, commenters noted their support for quality-tiering as it was readily understandable or could provide an incentive to care for difficult-to-treat beneficiaries. MedPAC indicated support for CMS' proposal to apply the value modifier bonus or penalty only when a physician group's performance is significantly different from the national mean. Further, MedPAC indicated that it has supported an ''outlier'' approach for cost measures as a reasonable way to identify physicians or groups with extraordinarily higher or lower costs than average. In some cases, commenters suggested that we apply the quality-tiering model initially, but consider moving to the total performance score model over time. One commenter noted they had general concerns with quality-tiering, but would take a wait-and-see approach as long as it was voluntary rather than mandatory.

We also received many comments supporting the total performance score methodology. Several commenters expressed their view that this methodology better aligned with the hospital value-based purchasing methodology than did quality-tiering or that it would be most appropriate for hospital-based physicians.

Many of these commenters suggested that the total performance score methodology: (1) Offered greater incentives for groups to participate in the program or to improve their performance because they could be rewarded for either achievement or improvement; and (2) avoided ''cut off problems'' where groups are placed in high and low performing categories that occur under the quality-tiering approach. One commenter offered their view that applying a cutoff such as one standard deviation is crude in that a physician performing at 0.99 standard deviations below the mean would be considered average while another performing at 1.01 standard deviations below the mean would be considered low. Another commenter observed that since quality-tiering applies to only physician groups above or below one standard deviation, the methodology effectively removes two-thirds of practices from its effects. Another suggested that a focus on outliers does little to improve care as variation in performance within groups is hidden.

Commenters also noted that CMS might not have sufficient historical data on all physicians to implement this methodology, and suggested that it could evolve from quality-tiering over time.

Response: We appreciate the comments in support of the quality-tiering model, and are finalizing our proposal to adopt this model. We agree with the commenters that this approach is a reasonable way to phase in the value-based payment modifier, especially as more groups of physicians report quality data and we can fine tune our methodology to identify high and low performers. Although we recognize the beneficial aspects of the total performance score model mentioned by the commenters (for example, incentives for continuous improvement and no cut-off issues), we believe that model may be inappropriate when groups of physicians have the ability to select the quality measures on which they report such that there is not a uniform yardstick by which to assess performance improvement. Moreover, at this initial stage of the value-based payment modifier, we believe a more reasonable approach is to focus on outliers rather than trying to adjust the payment of every group of physicians, despite the fact that a focus on outliers may mask performance variation within a group of physicians.

Comment: Also, assuming adoption of the quality-tiering model, some commenters suggested a more stringent criterion than one standard deviation from the mean to differential outliers. For example, some commenters suggested that two or three standard deviations be used as a threshold for distinguishing groups. In particular, one commenter noted that a more stringent threshold should be used if and when the risk for downward adjustments increases.

In other cases, commenters suggested alternatives to distinguishing groups by statistical comparison. For example, one commenter suggested that CMS explore a concept of ''meaningful clinical difference'' that is used in the domain of patient self-reported health status.

Response: We thank this commenter for their suggestions on how to distinguish outliers, that is high and low performers, but are finalizing our proposal to use one standard deviation with a 5 percent level of confidence. We believe distinguishing outliers in this way provides substantial confidence to physicians that we will not misclassify groups as high or low performers when they actually are not. Allowing groups of physicians the option to elect quality-tiering also addresses the issues that we are being too stringent in identifying high and low performers. We will be considering the effects of this policy over the next several years as we implement this program and may consider changes to these policies through future rulemaking.

Comment: Commenters were generally supportive of our proposal to offer additional incentives for groups caring for high-risk beneficiaries. Some commenters suggested that the high-risk incentives be expanded to include additional physician groups, for example, to those groups with average or high costs who also have average or above average quality scores. Another commenter recommended that we apply

the high-risk beneficiary upward adjustment to all practices participating in quality-tiering—not just those categorized as high quality/low-cost, high quality/average cost, or average quality/low cost tiers—particularly, if a penalty is assessed for the lowest performing tier. Another comment suggested that in a budget neutrality system, however, it was impossible to provide an upward bump-up in the payment adjustment for all groups caring for high-risk beneficiaries, because there would be fewer funds to distribute to high performing groups.

Response: We thank commenters for their support and, for the reasons noted above, are finalizing our proposal to provide an upward payment adjustment for groups electing quality-tiering that are high performers and care for high-risk beneficiaries.

i. Proposed Informal Review and Inquiry Process

Section 1848(p)(10) of the Act provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The establishment of the value-based payment modifier;
- The evaluation of the quality of care composite, including the establishment of appropriate measure of the quality of care;
- The evaluation of costs composite, including establishment of appropriate measures of costs;
- The dates of implementation of the value-based payment modifier;
- The specification of the initial performance period and any other performance period;
- The application of the value-based payment modifier; and
- The determination of costs.

Despite the preclusion of administrative and judicial review, we believe it is useful for groups of physicians to understand how their payment under the PFS could be changed by the value-based payment modifier. We also believe that an informal mechanism is needed for groups of physicians to review and to identify any possible errors prior to application of the value-based payment modifier.

Therefore, we intend to disseminate Physician Feedback reports containing calendar year 2013 data in the fall of 2014 to groups of physicians subject to these policies; these reports would be the basis of the value-based payment modifier in 2015. We proposed that these reports would contain, among other things, the quality and cost measures and measure performance and benchmarks used to score the composites, and quality of care and cost composite scores, and the value-based payment modifier amount (77 FR 45012).

After the dissemination of the Physician Feedback reports in the fall of 2014, we proposed that physicians would be able to email or call a technical help desk to inquire about their report and the calculation of the value-based payment modifier. We envisioned this process to help educate and inform physicians about the value-based payment modifier, especially for those groups of physicians that have elected that their value-based payment modifier be calculated using a quality-tiering approach.

In anticipation of the reports that we would produce in 2014, in the fall of 2013 we plan to produce and disseminate Physician Feedback reports at the TIN level to all groups of physicians with 25 or more eligible professionals based on 2012 data. These reports will include a ''first look'' at the methodologies we proposed in this rule for the value-based payment modifier. We view these reports as a way to help educate groups of physicians about how the value-based payment modifier could affect their payment under the PFS.

Comment: We received comments in support of making feedback available to participating physician groups and the opportunity to discuss this feedback with CMS. One commenter noted that the dissemination of physician feedback reports should be the first step in a large scale educational campaign on the implementation of the value-based modifier. Further, in their view, the success of the program depends on physician practices believing in the data and acting on it to improve their performance. Some commenters recommended that data be shared with all satisfactory PQRS reporters. One commenter asked that CMS share or post sample data so that physician groups could model what the value-based modifier might mean for them financially as they decide whether or not to participate. Another commenter requested that patient-specific information should be available to assist practices in verifying the data. In contrast, another commenter offered the view that while these reports could be relevant to primary care physicians or large multi-specialty practices, they might be less so to single specialty practices such as podiatrists.

A number of commenters noted the importance of making feedback reports available in a timely manner, and expressed concerns about the usefulness of data that are not current. For example, commenters reported that untimely data are not actionable and assessing payments on such data offer little incentive for change. One commenter suggested that data need to be timely or penalties should otherwise be waived.

We also received comments expressing support for the availability of technical assistance, for example, through a technical help desk as well as an appeals or review process. One commenter suggested that CMS establish corrective action plans or some means to assist poorer performers before applying a payment adjustment. One commenter disagreed with the ''limited distribution of physician feedback reports prior to implementation of the value based modifier'' and suggested we provide feedback reports to all physicians in advance of payment adjustments.'' In addition, some commenters urged CMS to consider adopting a Corrective Action Plan, or similar program, for outliers/poor performers prior to applying the value-based payment modifier.

Response: We thank commenters for their support. We will provide physician feedback reports during the fall of 2014 for all groups of physicians affected by the value-based payment modifier in 2015 and, as discussed below, we will make a help desk available to address questions related to the reports. We also are planning on many enhancements and features suggested by the commenters so that the feedback reports provide meaningful and actionable information to physicians to improve the quality of care they furnish to Medicare beneficiaries.

(4) Physician Feedback Program

Section 1848(n) of the Act requires us to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare FFS beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare FFS beneficiaries. In September 2011, we produced and disseminated confidential feedback reports to physician groups that participated in the PQRS Group Practice Reporting Option (GPRO) in 2010, and in March 2012 we produced and disseminated reports to physicians practicing in the following states: Iowa, Kansas, Missouri, and Nebraska.

In the CY 2013 PFS proposed rule, we discussed that, in the fall of 2012, we plan to disseminate Physician Feedback reports to physicians in nine states (California, Iowa, Illinois, Kansas,

Michigan, Minnesota, Missouri, Nebraska, and Wisconsin) based on 2011 data. These reports will contain the PQRS measures that physicians in these states submitted via any of the PQRS reporting methods, as well as information on 28 administrative claims measures included in the 2010 reports. We also will produce and disseminate Physician Feedback reports to the groups of physicians that reported measures through the PQRS GPRO web interface in 2011. We adjusted and improved the content and organization of the Physician Feedback reports that we plan to produce later this year based on the comments we received from the Program Year 2010 report recipients. We plan to increase our outreach efforts to encourage physicians to view their reports, to begin to understand the methodologies we have adopted in this final rule for the value-based payment modifier and that are included in the 2011 reports, and to provide suggestions on how we can make these reports more meaningful and actionable in the future.

In the fall of 2013, we plan to produce and disseminate Physician Feedback reports at the TIN level to all groups of physicians with 25 or more eligible professionals. These reports will include a ''first look'' at the methodologies that we have adopted in this final rule for the value-based payment modifier.

In addition, section 1848(n) of the Act requires that we use the episode-based costs in the Physician Feedback reports beginning in 2013 for the reports based on 2012 data. As discussed above in relation to the value-based payment modifier, we plan to include episode-based cost measures for several episode types in future Physician Feedback reports. In addition, we plan to consider adjusting the format and organization of the reports, to the extent practicable, to address the best practices outlined in the American Medical Association's Guidelines for Reporting Physician Data. We believe that this dissemination plan satisfies our obligations under the section 1848(p)(4)(B)(ii)(II) of the Act to provide information to physicians and groups of physicians about the quality of care furnished to Medicare FFS beneficiaries.

In the fall of 2014, we plan to disseminate Physician Feedback reports based on 2013 data that show the amount of the value-based payment modifier and the basis for its determination. We plan to provide these reports to all groups of physicians (at the TIN level) with 25 or more eligible professionals even though groups of physicians with 25 to 99 eligible professionals will not be subject to the value-based payment modifier in 2015. We are examining whether we can provide reports to groups of physicians with fewer than 25 eligible professionals and individual level reports as well. These reports will contain, among other things, performance on the quality and cost measures used to score the composites and the value-based payment modifier amount. As discussed above, we anticipate providing an opportunity for review and correction as outlined in our value-based payment modifier proposals above.

We received many comments on our future plans for the Physician Feedback reports. A summary of the comments and our responses to those comments are provided below.

Comment: We received many suggestions from commenters on ways to improve the content, format, and distribution of the Physician Feedback reports (also termed the ''Quality and Resource Use Reports'' (QRURs)), with a focus on making the content more actionable for quality improvement.

Response: We appreciate all of the suggestions on how to improve the Physician Feedback reports. We are working with the American Medical Association, state medical societies, specialty societies, and other stakeholders to address these issues in future feedback reports.

Comment: A commenter stated that it was unclear whether the physician feedback reports will replace the PQRS reports that are released when incentive payments are distributed and would support the integration of the two reports.

Response: We are looking at ways to streamline the reports supporting the PQRS and the physician value-based payment modifier programs in order to create one unified format for quality assessment.

Comment: Commenters appreciated CMS' planned physician outreach activities to garner physician reaction to the information contained in the Physician Feedback reports and elicit physician input on ways to increase their utility in future years. Additionally, they suggested that CMS should:

- Work with national and state medical specialty societies to ensure that physicians understand these reports.
- Work with medical specialty societies to improve the Physician Feedback reports.
- Further increase physician awareness of and education for the value-based payment modifier and Physician Feedback Program.
- Provide a mechanism for interpretation of feedback reports and meaningful dialogue between physicians, specialty society staff, and CMS.

Response: We appreciate the commenters' support of our outreach activities and are already undertaking the activities recommended by commenters.

Comment: Several commenters stated that many practices did not receive reports for individual physicians within their practice or they received reports for physicians who are no longer in the practice due to inaccuracies. In addition, the commenters stated that some practices had a difficult time obtaining the reports. The commenters recommended that CMS should work to ensure that it is not difficult for physicians to obtain these reports—particularly if the information on the report is tied to penalties.

Response: We are already aware of the concerns raised by these commenters. Accordingly, we have adjusted our procedures for disseminating the 2011 physician feedback reports later in 2012, in order to minimize the difficulties physicians may have in obtaining their reports and to ensure reports go to their intended recipients.

Comment: A commenter expressed concern about possible unintended consequences that physician feedback reports may have for clinical practice. The commenter stated a belief that aspects of the program will lead physicians to avoid sicker, more complicated patients and expressed concern about the potential of the program to move physician attention toward program compliance and away from evaluating and addressing the concerns of patients during visits. The commenter states that this has the potential to reduce quality of care and patient satisfaction.

Response: We do not agree that the Physician Feedback reports will have negative consequences on clinical practice. We believe that the Physician Feedback reports provide useful information to physicians about the quality of care furnished to Medicare beneficiaries and should be used by physicians to determine the areas where they need to make improvements in their clinical practice. Moreover, the cost measures in the Physician Feedback reports are risk adjusted so that we are controlling for preexisting health conditions and other patient factors when making comparisons in the reports.

Comment: A number of commenters were concerned that the Physician Feedback reports would not be provided

in time to inform physicians about their 2015 utilization, which is the basis for the 2017 payment adjustment period.

Response: As we stated above, in the fall of 2013, we plan to produce and disseminate Physician Feedback reports at the TIN level to all groups of physicians with 25 or more eligible professionals These reports will provide a ''first look'' at the methodologies that will be used to develop the value-based payment modifier. We view these reports as a way to help educate physicians about how the value-based payment modifier could affect their payment under the PFS. Even though we are applying the value-based payment modifier to groups of physicians of 100 or more eligible professionals, we believe it is important to provide the Physician Feedback reports to a wider audience in anticipation of making proposals in future rulemaking on applying the value-based payment modifier to all physicians and groups of physicians starting January 1, 2017.

Comment: Several commenters stated that CMS should make the Physician Feedback reports available to all physicians in 2014.

Response: We will take the commenters' recommendation under consideration as we develop the policy for disseminating the 2014 Physician Feedback reports. However, we believe it is important to prioritize our efforts on groups of physicians that would be subject to the value-based payment modifier in the near future first.

Comment: A number of commenters stated that CMS should provide a mechanism for physicians to request the list of patients for which cost and quality measures are attributed in their Physician Feedback reports.

Response: We agree that it would be useful for physicians to have a list of the patients who were attributed in the calculation of their cost and quality measures and are working to include this information as part of future Physician Feedback reports, recognizing that we seek to ensure that the data provided is used for quality improvement purposes and is consistent with privacy regulations.

Comment: A commenter recommended that future Physician Feedback reports focus on the cost of the care provided by the physician receiving the report instead of the total cost of all care received by the beneficiary. The commenter indicated that this would be both more informative and more actionable for individual physicians than the current per capita cost measures.

Response: As we stated earlier, one of the principles governing the implementation of the value-based payment modifier is a ''focus on shared accountability.'' Under this principle, we believe that the value-based payment modifier can facilitate shared accountability by assessing performance at the practice group level and by focusing on the total costs of care, not just the costs of care furnished by an individual physician. Physicians reporting measures at the group level are encouraged to seek innovative ways to furnish high-quality, patient-centered, and efficient care to the Medicare FFS beneficiaries they treat.

L. Medicare Coverage of Hepatitis B Vaccine

1. Modification of High Risk Groups Eligible for Medicare Part B Coverage of Hepatitis B Vaccine

a. Background and Statutory Authority—Medicare Part B Coverage of Hepatitis B Vaccine

Section 1861(s)(10)(B) of the Act authorizes Medicare Part B coverage of hepatitis B vaccine and its administration if furnished to an individual who is at high or intermediate risk of contracting hepatitis B. High and intermediate risk groups are defined in regulations at § 410.63.

On December 23, 2011, the United States Centers for Disease Control and Prevention (CDC) published a Morbidity and Mortality Weekly Report (MMWR), which included an article entitled ''Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP).'' The article stated that ''In the United States, since 1996, a total of 29 outbreaks of HBV [Hepatitis B virus] infection in one or multiple long-term care (LTC) facilities, including nursing homes and assisted-living facilities, were reported to CDC; of these, 25 involved adults with diabetes receiving assisted blood glucose monitoring. These outbreaks prompted the Hepatitis Vaccines Work Group of the Advisory Committee on Immunization Practices (ACIP) to evaluate the risk for HBV infection among all adults with diagnosed diabetes.''

''HBV is highly infectious and environmentally stable; HBV can be transmitted by medical equipment that is contaminated with blood that is not visible to the unaided eye. Percutaneous exposures to HBV occur as a result of assisted monitoring of blood glucose and other procedures involving instruments or parenteral treatments shared between persons. Lapses in infection control during assisted blood glucose monitoring that have led to HBV transmission include multipatient use of finger stick devices designed for single-patient use and inadequate disinfection and cleaning of blood glucose monitors between patients. Breaches have been documented in various settings, including LTC facilities, hospitals, community health centers, ambulatory surgical centers, private offices, homes, and health fairs.'' Additionally, in analyses of persons without hepatitis B-related risk behaviors (that is, injection-drug use, male sex with a male, and sex with multiple partners), persons aged 23 through 59 years with diabetes had 2.1 times the odds of developing acute hepatitis B as those without diabetes; and the odds for hepatitis B infection were 1.5 times as likely for persons aged 60 and older. (MMWR, December 23, 2011).

Based on the Hepatitis Vaccines Work Group findings, ACIP recommended that:

- Hepatitis B vaccination should be administered to unvaccinated adults with diabetes mellitus who are aged 19 through 59 years.
- Hepatitis B vaccination may be administered at the discretion of the treating clinician to unvaccinated adults with diabetes mellitus who are aged 60 years and older.

b. Implementation

Based on the ACIP recommendations, we proposed to modify § 410.63(a)(1), High Risk Groups, by adding new paragraph ''(viii) Persons diagnosed with diabetes mellitus.'' Since HBV can be transmitted by medical equipment (that is, finger stick devices and blood glucose monitors) that is contaminated with blood that is not visible to the unaided eye, we believe that persons diagnosed with diabetes mellitus should be added to the high risk group. Since lapses in infection control have been reported in both community and facility settings, the increased risk of contracting HBV is not limited to the facility setting. We believe that expanding coverage of Hepatitis B vaccinations and administration to those diagnosed with diabetes mellitus is supported by the findings and evidence reviewed by the Hepatitis Vaccines Work Group and the ACIP recommendations. Hepatitis B vaccination is a preventive measure that needs to occur before exposure. It is difficult to predict which diabetics will eventually be exposed in the circumstances that we discussed above. Therefore, we proposed to expand coverage for hepatitis B vaccine and its

administration to all individuals diagnosed with diabetes mellitus, not just those individuals with diabetes that are receiving glucose monitoring in facilities, for example, in nursing homes.

c. Summary of Public Comments

We received 15 public comments that supported the proposed rule to expand coverage of hepatitis B vaccination and its administration to individuals diagnosed with diabetes mellitus. We did not receive any public comments that opposed our proposed expansion. In addition to their support of our proposal, below is a summary of additional comments received and our responses.

Comment: One commenter suggested that coverage should be limited to individuals with diabetes when the treating physician recommends to the individual that he or she receive a hepatitis B vaccination, rather than having the vaccination be mandatory for all individuals diagnosed with diabetes mellitus.

Response: We believe that our proposal provides the physician with flexibility to determine whether provision of hepatitis B vaccination to a patient is appropriate based on the individual patient's risk factors. Nothing in the proposed rule or this final rule mandates vaccination for individuals diagnosed with diabetes mellitus. Accordingly, we are not making the suggested changes in this final rule.

Comment: Some commenters requested that we provide coverage under Medicare Part B for all ACIP-recommended immunizations, the herpes zoster vaccine, and hepatitis C virus screening, as Medicare preventive benefits.

Response: These comments are outside the scope of this rulemaking, as our proposed rule specifically addressed Medicare coverage of Hepatitis B vaccine and its administration under a specific statute, § 1861(s)(10)(B) of the Act. The commenters' requested expansions would not be based on this statute.

Based on the overwhelming support of the public comments received, we are implementing this rule as proposed.

M. Updating Existing Standards for E-Prescribing Under Medicare Part D and Lifting the LTC Exemption

1. Background

a. Legislative History

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended title XVIII of the Act to establish a voluntary prescription drug benefit program at section 1860D–4(e) of the Act. Among other things, these provisions required the adoption of Part D e-prescribing standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect. The Medicare Part—D e-prescribing Program adopts standards that allow Eligible Professionals (EP) to participate in the eRx Incentive Payment program and Other CMS programs that require the reporting of electronic prescribing transactions.

For a further discussion of the statutory basis for this final rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256).

b. Regulatory History

(1) Foundation and Final Standards

(a) Adopting and Updating

CMS utilized several rounds of rulemaking to adopt standards for the Part D e-prescribing program. Its first rule, which was published on November 7, 2005 (70 FR 67568), adopted three standards that were collectively referred to as the ''foundation'' standards. One of these standards, the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 5, Release 0 (Version 5.0), May 12, 2004 (excluding the Prescription Fill Status Notification Transaction and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill), hereafter referred to as the NCPDP SCRIPT 5.0, is the subject of several of the changes effectuated by this and prior final rules. We issued a subsequent rule on April 7, 2008 (73 FR 18918) that adopted additional standards which are referred to as ''final'' standards. One of these standards, Version 1.0 of the NCPDP Formulary and Benefit standard, Implementation Guide, Version 1, Release 0, hereafter referred to as the NCPDP Formulary and Benefit 1.0) is also the subject of another of the changes effectuated by this final rule. Please see the ''Initial Standards Versus Final Standards'' discussion at 70 FR 67568 in the November 7, 2005 rule for a more detailed discussion about ''foundation'' and ''final'' standards.

(b) Exemption From the NCPDP SCRIPT Standard in Long Term Care Settings (LTC)

While prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are generally required to comply with any applicable Part D e-prescribing standards that are in effect at the time of their transmission, the early versions of the NCPDP SCRIPT standard did not support the complexities of the prescribing process for patients in long term care facilities where the prescribing process involves not only a prescriber and a pharmacy, but also a facility and its staff. As such, we exempted such entities from use of the NCPDP SCRIPT standard. That exemption, currently found at § 423.160(a)(3)(iv), provides an exemption for entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser.

For a more detailed discussion, see the November 7, 2005 final rule (70 FR 67583).

(2) Updating e-Prescribing Standards

Transaction standards are periodically updated to take new knowledge, technology and other considerations into account. As CMS adopted specific versions of the standards when it adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced over time to ensure that the standards did not hold back progress in the industry. CMS discussed these processes in its November 7, 2005 final rule (70 FR 67579).

The discussion noted that the rulemaking process will generally be used to retire, replace or adopt a new e-prescribing standard, but it also provided for a simplified ''updating

process'' when a standard could be updated with a newer ''backward-compatible'' version of the adopted standard. In instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification, it noted that notice and comment rulemaking could be waived, in which case the use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version's incorporation by reference in the **Federal Register**. We utilized this streamlined updating process when we published an interim final rule with comment on June 23, 2006 (71 FR 36020). That rule recognized NCPDP SCRIPT 8.1 as a backward compatible update to the NCPDP SCRIPT 5.0, thereby allowing for use of either of the two versions in the Part D program. Then, on April 7, 2008, CMS used notice and comment rulemaking (73 FR 18918) to finalize the identification of the NCPDP SCRIPT 8.1 as a backward compatible update of the NCPDP SCRIPT 5.0, and, effective April 1, 2009, retire NCPDP SCRIPT 5.0 and adopt NCPDP SCRIPT 8.1 as the official Part D e-prescribing standard. Finally, on July 1, 2010, CMS utilized the streamlined process to recognize NCPDP SCRIPT 10.6 as a backward compatible update of NCPDP SCRIPT 8.1 in an interim final rule (75 FR 38026).

In contrast to the extensive updating that was done to the NCPDP SCRIPT standard in the Part D e-prescribing program, the original NCPDP Formulary and Benefit 1.0 is still in place as the official Part D e-prescribing standard.

2. Proposals for Calendar Year 2013

a. Proposed Finalization of NCPDP SCRIPT 10.6 as a Backward Compatible Version of NCPDP SCRIPT 8.1, Retirement of NCPDP SCRIPT 8.1 and Adoption of NCPDP SCRIPT 10.6 as the Official Part D E-Prescribing Standard

As described in the CY 2013 Physician Fee Schedule proposed rule (77 FR 45022–45023) we proposed to finalize our recognition of NCPDP SCRIPT 10.6 as a backward compatible version of the official Part D e-prescribing standard NCPDP SCRIPT 8.1, effective from the effective date of the final rule through October 31, 2013, but, in response to the comments that were received to the interim final rule with comment, we also proposed to retire NCPDP SCRIPT 8.1 effective October 31, 2013, and we proposed to adopt NCPDP SCRIPT 10.6 as the official Part D e-prescribing standard effective November 1, 2013. For further discussion on our NCPDP SCRIPT updating proposals please see CY 2013 Physician Fee Schedule proposed rule (77 FR 45022 through 45025).

As such, we proposed to revise § 423.160(b)(2)(ii) so as to limit its application to transactions on or before October 31, 2013 and add a new § 423.160(b)(2)(iii) to require that, as of November 1, 2013, providers and dispensers would use NCPDP SCRIPT 10.6 for the following electronic transactions that convey prescription or prescription related information:

- Get message transaction.
- Status response transaction.
- Error response transaction.
- New prescription transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill prescription request transaction.
- Refill prescription response transaction.
- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction
- Fill status notification.

Furthermore, we proposed to amend § 423.160(b)(1) by adding a new 423.160(b)(1)(iii) to amend the information about which subsequent requirements in the section are applicable to which timeframes and amend § 423.160(b)(1)(ii) to limit its application to transactions on or before October 31, 2013.

The following is a summary of the comments we received regarding the finalization of NCPDP SCRIPT 10.6 as a backward compatible version of NCPDP SCRIPT 8.1, the proposed retirement of NCPDP SCRIPT 8.1, and the proposed adoption of NCPDP SCRIPT 10.6 as the official Part D E-Prescribing standard. We received comments on all three proposals.

Comment: All commenters agreed with our proposals to finalize NCPDP SCRIPT 10.6 as a backward compatible version of NCPDP SCRIPT 8.1 and to retire NCPDP SCRIPT 8.1. They also agreed that CMS should move forward with the adoption of NCPDP SCRIPT 10.6 as the official Part D e-prescribing standard.

Response: We appreciate the favorable feedback that we received on this proposal and are in agreement with the commenters who responded.

Comment: Most commenters agreed on our timeline to retire NCPDP SCRIPT Version 8.1 on October 31, 2013 and adopt NCPDP SCRIPT Version 10.6 as the official Part D e-prescribing standard on November 1, 2013.

Response: We appreciate the feedback we received on the proposed timeline to retire NCPDP SCRIPT 8.1 on October 31, 2013 and finalize the adoption of NCPDP SCRIPT 10.6 on November 1, 2013 as the official Part D e-prescribing standard. We are in agreement with those commenters that responded to finalize NCPDP SCRIPT 10.6 as proposed.

Comment: One commenter suggested that CMS finalize the adoption of the NCPDP SCRIPT Version 10.6 Part D e-prescribing standard effective January 1, 2014, which would coincide with the Office of the National Coordinator for Health IT (ONC) requirement for use of NCPDP SCRIPT 10.6 for certification of electronic health record (EHR) technology. The commenter did not, however, note any harm that would result if we were to stick with the proposed effective date of November 1, 2013.

Response: We appreciate the comment, but we do not believe that there is a compelling reason to change the proposed (November 1, 2013) effective date. As proposed, Part D e-prescribers will be free to use either version 8.1 or version 10.6 through October 31, 2013, after which time they will need to use version 10.6 when e-prescribing Part D covered drugs for Part D eligible individuals. As such, ONC's 2011 Edition EHR certification criteria (which permit the certification of EHR technology to versions 8.1 or 10.6 and subsequently enable an eligible professional (EP)/eligible hospital (EH) to use either standard through the calendar year (CY)/fiscal year (FY) 2013 meaningful use reporting period) and 2014 Edition EHR certification criteria (which requires EHR technology to be certified to only version 10.6 and subsequently enables EPs/EHs to use EHR technology certified to such standard when they start their CY/FY 2014 meaningful use reporting) will never require use of a version of NCPDP SCRIPT that is not also an option under the Part D e-prescribing standards. Furthermore, NCPDP SCRIPT 10.6 is backwards compatible with version 8.1, so version 10.6 EHR users will always be able to communicate with version 8.1 users, and vice versa.

In light of the overwhelmingly positive comments that we received in response to our proposals to finalize the NCPDP SCRIPT 10.6 as a Backward Compatible Version of NCPDP SCRIPT 8.1 as of the effective date of this final rule, and retire NCPDP SCRIPT 8.1 and adopt NCPDP SCRIPT 10.6 as the official Part D e-Prescribing Standard

effective November 1, 2013, we are finalizing our proposals. To effectuate this, we revised § 423.160(b)(1)(ii) to limit its applicability to transactions taking place between April 1, 2009 and October 31, 2013, added a new § 423.160(b)(1)(iii) to cover transactions on or after November 1, 2013, and added a new § 423.160(b)(2)(iii) to cover the communication of a prescription or prescription-related information between prescribers and dispensers on or after November 1, 2013.

b. Proposed Recognition of NCPDP Formulary and Benefit Standard 3.0 as a Backward Compatible Version of the NCPDP Formulary and Benefit Standard 1.0, Proposed Retirement of NCPDP Formulary and Benefit Standard 1.0 and Proposed Adoption of NCPDP Formulary and Benefit Standard 3.0

Formulary and Benefits standards provide a uniform means for pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via point-of-care (POC) systems. These include:

- General formulary data (for example, therapeutic classes and subclasses);
- Formulary status of individual drugs (that is, which drugs are covered);
- Preferred alternatives (including any coverage restrictions, such as quantity limits and need for prior authorization); and
- Copayment (the copayments for one drug option versus another).

The NCPDP Formulary and Benefits Standard 1.0 enables the prescriber to consider this information during the prescribing process, and make the most appropriate drug choice without extensive back-and-forth administrative activities with the pharmacy or the health plan.

As discussed above, the November 7, 2005 final rule (70 FR 67579) established the process of updating an official Part D e-prescribing standard with the recognition of ''backward-compatible'' versions of the official standard in instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification. In these instances, notice and comment rulemaking could be waived, and use of either the new or old version of the adopted standard would be considered compliant with the adopted standard upon the effective date of the newer version's incorporation by reference in the **Federal Register**. This backward compatible version updating process allows for the standards' updating/maintenance to correct technical errors, eliminate technical inconsistencies, and add optional functions that provide optional enhancements to the specified e-prescribing transaction standard. Since the adoption of the NCPDP Formulary and Benefits 1.0 standard in the Part D e-prescribing program, NCPDP has updated its Formulary and Benefits standard. Changes were based upon industry feedback and business needs and ranged in complexity from creating whole new fields or lists within the standard to simply changing a particular field designation from mandatory to optional. Each time a change is made to a standard it is given a new version number. The current version of the Formulary and Benefits standard is Version 3.0.

One of the major improvements between Version 1.0 and 3.0 involved the addition of Text message support for ''Coverage and Copay Information,'' the addition of the ''Text Message Type (A46–1S)'' field and the addition of ''Optional Prior Authorization Lists.'' Theses list were added for use in conveying prior authorization requirements.

Other improvements included conversion of certain elements from optional to mandatory. Version 3.0 also provides for ''Formulary Status List Headers,'' which are fields that allow the sender to specify a default formulary status for non-listed drugs. Subsequent versions also allowed for the omission of ''Formulary Status Detail'' records when the non-listed formulary policies are used exclusively to convey the status of a drug on a formulary.

Changes to a standard may also involve removing fields that are not widely used in industry. The removed fields are often replaced by new fields that better serve the business needs of the industry. For example, the following items have been removed through the various updates that led up to Version 3.0: ''Classification List'' and references to it (such as Drug Classification Information), ''Coverage Information Detail—Medical Necessity (MN),'' ''Coverage Information Detail–Resource Link–Summary Level (RS),'' and the Classification ID in the Cross Reference Detail.

In place of these deleted fields, the following fields were added or amended to ultimately result in Version 3.0: The ''Formulary Status existing value 2'' field was changed to ''On Formulary/Non-Preferred,'' and ''The file load also enables payers to specify a single coverage-related text message for each drug'' field was changed to ''A payer may send multiple quantity limits, step medications, text messages and resource links for the same drug.''

We reviewed Version 3.0, and based on our findings, we have determined that NCPDP Formulary and Benefits 3.0 maintains full functionality of the official adopted Part D e-prescribing standard NCPDP Formulary and Benefits 1.0, and would permit the successful communication of the applicable transaction with entities that continue to use Version 1.0.

While we would usually use the ''backward compatible'' waiver of notice and comment procedures that are described above to recognize Version 3.0 as a backward compatible version of the officially adopted Version 1.0, this would have to be done in an interim final rule with comment. As we cannot combine proposals and elements of a final rule in one rule, we elected this one time to formally propose recognizing a subsequent standard as a backward compatible version of an adopted standard through full notice and comment rulemaking to avoid having to publish two rules contemporaneously. We therefore proposed to recognize the use of either Version 1.0 or 3.0 as compliant with the adopted Version 1.0 effective 60 days after the publication of a final rule.

As noted above, according to the November 7, 2005 final rule (70 FR 67580), entities that voluntarily adopt later versions of standards that are recognized as backward compatible versions of the official Part D e-prescribing standard must still accommodate the earlier official Part D e-prescribing standard without modification. Therefore, as we used full notice and comment in place of the backward compatible methodology in this one instance, we also proposed to require users of 3.0 to support users who are still using Version 1.0 until such time as Version 1.0 is officially retired as a Part D e-prescribing standard and Version 3.0 is adopted as the official Part D e-prescribing standard.

To effectuate these proposals, we proposed to revise § 423.160(b)(5) by placing the existing material in a new subsection (b)(5)(i), and creating a second new subsection (b)(5)(ii) to reflect the use of Version 3.0. as a backward compatible version of the official Part D e-prescribing standard, effective 60 days after the publication of the final rule through October 31, 2013. We further proposed revising § 423.160(b)(5) by adding a new section § 423.160(b)(5)(iii) to cover Formulary and Benefit transactions on or after November 1, 2013 We also needed to add an end date of January 15, 2013 to § 423.160(b)(5)(i). We solicited comments on our proposals, the timing

for these proposals, and when we ought to retire Version 1.0 as the official Part D e-prescribing standard, and adopt the NCPDP Formulary and Benefit Version 3.0. as the official Part D e-prescribing standard.

The following is a summary of the comments we received regarding our proposal to recognize NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of the NCPDP Formulary and Benefit Standard 1.0, the proposed retirement of NCPDP Formulary and Benefit Standard 1.0 and the proposed adoption of NCPDP Formulary and Benefit Standard 3.0.

Comment: Commenters generally supported our proposals for effective dates for the use of NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of the adopted NCPDP Formulary and Benefit 1.0 (60 days after the publication of the final rule), and the retirement of Version 1.0 as an official Part D e-prescribing standard as of November 1, 2013. However, one commenter suggested a Version 1.0 sunset date of July 1, 2014 to coordinate the Part D e-prescribing standards with the date upon which NCPDP will cease to support Version 1.0 .

Response: We appreciate the overwhelming support from the commenters who agreed witt us in recognizing Version 3.0 as a backward compatible version of Version 1.0 and the retirement of Version 1.0 and the adoption of Version 3.0 as the official Part D e-prescribing standard effective November 1, 2013.We also appreciate the suggestion to alter the proposed retirement date for Version 1.0 to coincide with the date upon which NCPDP will cease to support that version of the standard. While maintaining Version 1.0 as a Part D e-prescribing standard would delay the industry's fully benefiting from the improvements found in Version 3.0, as Version 3.0 is a backward compatible version of Version 1.0, we would not anticipate significant added burden on the industry if we were to allow the continued use of Version 1.0 until it is no longer supported by NCPDP. As we aim to ensure that our regulations impose the minimum burden possible on the industry, we therefore believe that it would be appropriate to not finalize the adoption of Version 3.0 at this time. Although the commententer have shown support for our proposal we believe that there is ample time to finalize NCPDP Formulary and Benefits Version 3.0 at a later date in future rulemaking. We believe that allowing the use of Version 3.0 as a backward compatible verion of Version 1.0 would create some confusion because of the extended timeframe to adopt Version 3.0 and the retirement of Version 1.0 as proposed by the commenters.

As a result of the comments, It is our intention to keep NCPDP Formulary and Benefits Version 1.0 as the official standard for the Medicare Part D eprescribing program and hold off on finalizing Verison 3.0 until future rulemaking.

c. Proposed Elimination of the Exemption for Non-Prescribing Providers (Long Term Care)

In our November 16, 2007 proposed rule (72 FR 64902–64906), we discussed the inability of NCPDP SCRIPT versions 5.0 and 8.1 to support the workflows and legal responsibilities in the long-term care setting, that is, entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser (''three-way prescribing communications'' between facility, physician, and pharmacy). As such, such entities were provided with an exemption from the requirement to use the NCPDP SCRIPT standard in transmitting such prescriptions or prescription-related information. On July 1, 2010 we published an IFC (75 FR 38029) in which we conveyed that we would consider removing the LTC exemption when there was an NCPDP SCRIPT standard that could address the unique needs of long-term care settings. We noted that NCPDP SCRIPT Version 10.6 was available, and that we believed that it addressed the concerns of the LTC industry regarding their ability to successfully support their workflows when e-prescribing. We solicited comments on the impact and timing of adopting version 10.6 as the official Part D e-prescribing standard and the removal of the long-term care facility exemption from the NCPDP SCIPT standard. For further background discussion on our proposal to lift the LTC exemption please refer to the proposed rule (77 FR 45024–45025).

We proposed to eliminate the current exemption at § 423.160(a)(3)(iv) upon adoption of NCPDP SCRIPT 10.6 as the official Part D e-prescribing standard, which, as described above, was proposed to take place on November 1, 2013.

We solicited comments on lifting the Long Term Care exemption, effective November 1, 2013 in conjunction with the effective date of NCPDP SCRIPT 10.6. We also solicited comments regarding the impact of these proposed effective dates on industry and other interested stakeholders, and whether an earlier or later effective date should be adopted.

The following is summary of the comments we received regarding the proposal.

Comment: The commenters agreed with our proposal to lift the current exemption for entities transmitting prescriptions or prescription-related information in the LTL setting. The commenters, however, did not agree with our proposed timeline for the lifting the current exemption. They suggested that CMS push the effective date until November 1, 2014 instead of the proposed November 1, 2013 proposal.

They stated that while they are supportive of moving to NCPDP SCRIPT 10.6 and encourage LTC providers to move toward a single standard, they fully expect that those entities currently using HL7 or propriety messaging will need additional time to make the transition. They also recommend an extended transition period to ensure that both vendors and providers are ready for the new requirements.

Response: Upon review, we believe the commenters have made valid arguments in regards to moving the effective to November 1, 2014. We realize that many in the LTC community may need extra time to transition their IT systems to accommodate and support the current Part D e-prescribing standards. Based on industry comments we will lift the LTC exemption based on November 1, 2014 date as suggested by the commenters to give them more time to make the transition to a single standard for e-prescribing. Therefore, we will amend § 423.160(a)(3)(iv) to insert November 1, 2014 as the expiration of the exemption. We would note, however, that if a member of the LTC industry and their trading partner are ready to use this standard to prescribe electronically before the exemption is lifted on November 1, 2014, they are certainly free to use the standard, but they will not be required to do so under the Part D e-prescribing program.

Comment: One commenter called on CMS to encourage state Boards of Pharmacy to reexamine the medication management process in the LTPAC settings and develop and allow more effective and efficient mechanisms for e-prescribing in LTPAC. The commenter stated that if the e-prescribing system could be suitably, sufficiently and appropriately modified, such that the various state Boards of Pharmacy were to consider a physicians' order from a facility as a valid prescription, the

conditions would be in place for electronic medication management and e-prescribing to be more widely adopted in LTPAC settings. They also asked CMS to facilitate, encourage and work with regulators, industry and other stakeholders to resolve these issues.

Response: We have prescribed legislative authority under the MMA to adopt Part D e-prescribing standards. The MMA outlines out the process through which we can adopt Part D e-prescribing standards to facilitate e-prescribing. We do not have the authority to facilitate, encourage, or work with the various state Boards of Pharmacy to change how they define the transaction from the LTC facility to the dispensing pharmacy. As a result of these comments, we are eliminating the exemption at § 423.160(a)(3)(iv) effective November 1, 2014.

IV. Additional Provisions

A. Waiver of Deductible for Surgical Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test and Colorectal Cancer Screening Test Definition—Technical Correction

Section 4104(c) of the Affordable Care Act amended section 1833(b) of the Act to waive the Part B deductible for colorectal cancer screening tests that become diagnostic in the course of the procedure or visit. Specifically, section 1833(b) of the Act waives the deductible for ''colorectal screening tests regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test.'' We note that in the proposed rule, we referred in this discussion to section 1833(b)(1) of the Act; however, the relevant amendment was a new sentence added at the end of section 1833(b). We have corrected the reference in this final rule with comment period. To implement this statutory provision, we proposed in the PFS proposed rule for CY 2011 that ''all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema be considered to be furnished in connection with, as a result of, and in the same clinical encounter as the screening test.'' After receiving public comment, this proposal was finalized in the CY 2011 final rule with comment period (75 FR 73431) and the policy was implemented, effective January 1, 2011. However, we neglected to amend our regulations to reflect this policy.

When a screening test becomes a diagnostic service, we instruct the practitioner to bill the procedure that is actually furnished and to append the PT modifier to the diagnostic procedure code that is reported. By use of this modifier, the practitioner signals that the procedure meets the criteria for the deductible to be waived.

In the CY 2013 PFS proposed rule, we proposed to amend our regulations at § 410.160, Part B annual deductible, to include colorectal screening tests that become diagnostic services in the list of services for which the deductible does not apply. Specifically, we proposed to add a new § 410.160(b)(8) to read, ''Beginning January 1, 2011, a surgical service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.''

The following is summary of the comments we received regarding the proposal to amend our regulations to the policy we adopted for CY 2011 to implement the statutory amendment that waives the Part B deductible for a colorectal cancer screening test that becomes diagnostic.

Comment: We received two comments on this proposal. One commenter was appreciative and supportive of the proposal. The other commenter stated that we had ''violated the intent of the Affordable Care Act'' and not implemented this provision consistent with the statute at section 1833(b) of the Act. The commenter stated that by using ''surgical service'' in the proposed regulation when the statute referred to ''other procedure,'' we were inappropriately applying the deductible to pathology and anesthesia services when they are furnished in connection with a colorectal screening test that becomes a diagnostic procedure. The commenter also expressed concern with our covering procedures ''on the same date'' when the Act covers procedures ''in the same clinical encounter.''

Response: We thank the commenter who supported our proposal. We note that we did not propose to modify the policy we adopted as final in the CY 2011 PFS final rule with comment period, and which we have been applying in accordance with section 1833(b) of the statute since January 1, 2011. Rather, we proposed to codify our current policy in our regulations. Our current policy, as stated in the CY 2011 PFS final rule with comment period, is to waive the deductible for all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema (because these services are considered to be ''furnished in connection with, as a result of, and in the same clinical encounter as the screening test.'') We received and responded to comments similar to the second one noted above in the course of rulemaking for CY 2011. However, because the commenter questioned the language we used in the proposed text of the regulation, we discuss the issue in this final rule. After evaluating the comment regarding whether the deductible is appropriately applied to payments for anesthesia and biopsy services, we conclude that it is. We believe that the intent of section 1833(b) of the statute, as amended by section 4104(c) of the Affordable Care Act, is to waive the deductible for tests that are scheduled and begin as colorectal screening tests, but that become diagnostic in the course of the treatment, so that even though the test is no longer considered and billed as a screening test, the deductible is nonetheless waived as it would have been if the test had remained a screening test. Thus, we believe Congress intended to insure that we apply the deductible for these ''screening turned diagnostic'' tests consistently with the way it is applied to colorectal screening tests. When a colorectal screening test is furnished, the payment for moderate sedation is included in the payment for the procedure, and there would be no associated pathology service. The deductible is waived for these tests under section 1833(b) of the Act. As a result, the deductible would be waived for the typical sedation furnished in connection with a colorectal screening test (since it is included within the code); and there would be no need to waive any deductible for a pathology service. The proposed regulation applies the same policy to colorectal screening tests that become diagnostic. To the extent that moderate sedation is included in a procedure that is billed with the PT modifier, the beneficiary pays no deductible. When a beneficiary receives anesthesia other than moderate sedation with a colorectal screening test, a separate charge is incurred to which the deductible applies. The proposed regulation would specify that same policy for screening tests that become diagnostic.

We also believe that the language of the Act is consistent with applying the deductible to pathology services. By the use of the term a ''colorectal screening test regardless of the code that is billed,'' the statute waives the deductible for procedures that, in and of themselves, begin as colorectal screening tests. As noted above,

pathology services would not be part of a colorectal screening test.

In regard to the commenter's concern about using ''same day,'' instead of ''same clinical encounter,'' this too is the policy we established through notice and comment rulemaking for CY 2011. We believe it would be exceedingly rare for a beneficiary to have additional procedures on the same date as a screening colorectal cancer test or a ''screening turned diagnostic'' colorectal procedure that are not in the same clinical encounter. Therefore, we believe ''same day'' is the practical equivalent of ''same clinical encounter.'' To the extent there is a difference between these two terms, the language we proposed would provide broader rather than more limited waiver of the deductible as the commenter asserted. Given the practical equivalence between the language in the statute and in the proposed regulation, and the fact that our claims processing system can easily distinguish ''same day'' but not ''same clinical encounter,'' we will not modify our policy or the proposed regulation language as the commenter suggests.

Based upon the comments we received, and further review of the policy we established to implement the statute, we are finalizing the proposed amendment to the regulation as initially proposed. Specifically, we will amend the regulation at § 410.160, Part B annual deductible, to include colorectal screening tests that become diagnostic services in the list of services for which the Part B deductible does not apply and will add a new § 410.160(b)(8), which will read, ''Beginning January 1, 2011, a surgical service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.''

Section 103 of the BIPA amended section 1861(pp)(1)(C) of the Act to permit coverage of screening colonoscopies for individuals not at high risk for colorectal cancer who meet certain requirements. To conform our regulations to section 1861(pp)(1)(C) of the Act, we proposed to modify § 410.37(a)(1)(iii) of our regulations to define ''Screening colonoscopies'' by removing the phrase ''In the case of an individual at high risk for colorectal cancer'' from this paragraph.

We also proposed to delete paragraph (g)(1) from this section since Medicare no longer receives claims for dates of service between January 1, 1998 and June 30, 2001, making this paragraph obsolete. We also proposed to redesignate paragraphs (g)(2) through (g)(4) and make technical changes to newly redesignated paragraph (g)(1) by replacing the reference to paragraph (g)(4) with a reference to newly redesignated paragraph (g)(3).

Comment: We received no comments addressing the proposed modifications to § 410.37.

Response: We are finalizing the proposed regulation as initially proposed for § 410.37. Specifically, Section 103 of the BIPA amended section 1861(pp)(1)(C) of the Act to permit coverage of screening colonoscopies for individuals not at high risk for colorectal cancer who meet certain requirements. To conform our regulations to section 1861(pp)(1)(C) of the Act, we will modify § 410.37(a)(1)(iii) to define ''Screening colonoscopies'' by removing the phrase ''In the case of an individual at high risk for colorectal cancer'' from this paragraph.

Finally, we will delete paragraph (g)(1) from this section since Medicare no longer receives claims for dates of service between January 1, 1998 and June 30, 2001, making this paragraph obsolete, will redesignate paragraphs (g)(2) through (g)(4) and make technical changes to newly redesignated paragraph (g)(1) by replacing the reference to paragraph (g)(4) with a reference to newly redesignated paragraph (g)(3).

B. Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- Dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h)).

The definition of DHS at § 411.351 excludes services that are reimbursed by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services).

EPO and other dialysis-related drugs furnished by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration) are currently being paid under the ESRD PPS (effective January 1, 2011) promulgated in the final rule published on August 12, 2010 in the **Federal Register** (75 FR 49030). Drugs for which there are no injectable equivalents or other forms of administration will be payable under the ESRD PPS beginning January 1, 2014.

The Code List was last updated in Addendum J of the CY 2012 PFS final rule with comment period.

b. Response to Comments

We received no public comments relating to the Code List that became effective January 1, 2012.

c. Revisions Effective for 2013

The updated, comprehensive Code List effective January 1, 2013, appears on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/*

PhysicianSelfReferral/List_of_Codes.html.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status.

Tables 127 and 128 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2013. Tables 127 and 128 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis–related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

In Table 127, we specify additions that reflect new CPT and HCPCS codes that become effective January 1, 2013, or that became effective since our last update, including those additions that reflect changes in Medicare coverage policy or payment status. Table 128 reflects the deletions necessary to conform the Code List to the most recent publications of the CPT and HCPCS, and to changes in Medicare coverage policy and payment status.

We will consider comments regarding the codes listed in Tables 127 and 128. Comments will be considered if we receive them by the date specified in the "**DATES**" section of this final rule with comment period. We will not consider any comment that advocates a substantive change to any of the DHS defined in § 411.351.

TABLE 127—ADDITIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1] HCPCS CODES

CLINICAL LABORATORY SERVICES
86152 Cell enumeration & id
86153 Cell enumeration phys interp
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH–LANGUAGE PATHOLOGY SERVICES
{No additions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
78012 Thyroid uptake measurement
78013 Thyroid imaging w/blood flow
78014 Thyroid imaging w/blood flow
78071 Parathyrd planar w/wo subtrj
78072 Parathyrd planar w/spect&ct
RADIATION THERAPY SERVICES AND SUPPLIES
32701 Thorax stereo rad targetw/tx
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
G0106 Colon CA screen;barium enema
G0120 Colon ca scrn; barium enema
G0118 Glaucoma scrn hgh risk direc
Q2034 Agriflu vaccine
90672 Flu vaccine 4 valent nasal

[1] CPT codes and descriptions only are copyright 2012 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 128—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1] HCPCS CODES

0030T Antiprothrombin antibody
0279T Ctc test
0280T Ctc test w/i&r
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No deletions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
78006 Thyroid imaging with uptake
78007 Thyroid image mult uptakes
78010 Thyroid imaging
78011 Thyroid imaging with flow
RADIATION THERAPY SERVICES AND SUPPLIES
{No deletions}
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
{No deletions}

[1] CPT codes and descriptions only are copyright 2012 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the CY 2013 PFS proposed rule, we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). No PRA-related comments were received.

A. ICRs Regarding Durable Medical Equipment Scope and Conditions (§ 410.38(g))

As a condition of payment for certain covered items of DME, § 410.38(g) specifies that a physician must have documented and communicated to the DME supplier that the physician or physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary no more than 6 months before the order is written.

In the proposed rule, we proposed that when the face-to-face encounter is performed by a physician, the submission of the pertinent portion(s) of the beneficiary's medical record (portions containing sufficient information to document that the face-to-face encounter meets our requirements) would be considered sufficient and valid documentation of the face-to-face encounter when submitted to the supplier and made available to CMS or its agents upon request. While we believe that many of the practitioners addressed in this final rule with comment period are already conducting a needs assessment and evaluating or treating the beneficiary for conditions relevant to the covered item of DME, this final rule with comment period may require some changes in their procedures to ensure that their documentation fulfills Medicare's regulatory requirements. Suppliers should already be receiving written orders and documentation to support the appropriateness of certain items of DME.

To promote the authenticity and comprehensiveness of the written order and as part of our efforts to reduce the risk of waste, fraud, and abuse, as a condition of payment, a written order must include the following: (1) The beneficiaries' name; (2) the item of DME ordered; (3) the signature of the prescribing practitioner; (4) the prescribing practitioner NPI; and (5) the date of the order.

To determine costs, we utilized the Bureau of Labor Statistics mean hourly rates for the professional, analyzed for the year that the original data was received. The hourly rate for a physician, including fringe benefits and overhead is estimated at $118 per hour. The hourly rate, including fringe benefits and overhead, for a NP, PA, or CNS is estimated at $55 per hour. The hourly rate for administrative assistant, including fringe benefits and overhead, is estimated at $23 per hour.

Physicians are now required to document the face-to-face encounter if it was performed by a PA, NP, or CNS. To allow payment for this documentation, a G code is established for this service. Since the effective date for this regulation is July 1, 2013, only 6 months of year 1 are included in calendar year 2013. Likewise, it was assumed that about 500,000 of these documentation services would be billed in year 1. We estimate the time for a physician to review each one of these encounters that results in an order is 10 minutes. Therefore, we estimate that the physician documentation burden to review and document when a PA, NP or CNS performed the face-to-face encounter in year 1 would be nearly 83,333 hours and a total of 483,333 hours over 5 years. The associated cost in year 1 is nearly $9.8 million and over 5 years has associated costs of nearly $57.03 million based on the growth rate of the Medicare population. The increase is slightly more than five-fold because the number of Medicare beneficiaries would increase over time. The average annual burden over 5-years for 580,000 claims (2,900,000/5) is 96,667 hours at a cost of $11,406,667.

TABLE 129—PHYSICIAN TIME TO DOCUMENT OCCURRENCE OF A FACE-TO-FACE ENCOUNTER

	Year 1	5 Years
Number of claims affected	500,000	2,900,000.
Time for physician review of each claim	10 min	10 min.
Total Time	83,333 hours	483,333 hours.
Estimated Total Cost (Hours times $118)	$9,833,333	$57,033,333.

We assume it will take 3 minutes for a PA, NP, or CNS to prepare the medical record for the review of the face-to-face encounter. For the 500,000 orders used in the previous estimate, this creates a total of 25,000 hours at a cost of about $1.4 million in year 1 and nearly 145,000 hours over 5 years at a cost of nearly $8 million based on the growth rate of the Medicare population. Though consistent with previous estimates, we believe that using a PA, NP, or CNS hourly rate creates a high burden impact estimate since most of these tasks would more than likely be completed by administrative personnel. We invited but received no public comments on our estimates related to the appropriateness of these estimates. The average annual burden over 5-years for 580,000 claims (2,900,000/5) is 29,000 hours at a cost of $1,595,000.

TABLE 130—PHYSICIAN ASSISTANT, NURSE PRACTITIONER OR CLINICAL NURSE SPECIALIST TIME

	Year 1	5 Years
Number of claims affected	500,000	2,900,000.
Time for PAs, NPs, or CNSs to gather and provide each claim	3 min	3 min.
Total Time	25,000 hours	145,000 hours.
Estimated Total Cost (Hours times $55)	$1,375,000	$7,975,000.

This final rule with comment period creates only a minimal change in the normal course of business activities in regards to recordkeeping. Although we believe the documentation of a needs assessment, evaluation, and/or treatment of a beneficiary for a condition relevant to an item of DME is a common practice, it is possible that

some practitioners may not be documenting the results of all encounters so there may be additional impact for some practitioners.

This regulation requires that the supplier have access to the documentation of the face-to-face encounter (required when CMS conducts an audit), CMS already accounts for the audit burden associated with the exchange of documentation for claims subject to prepayment review (approved under OCN 0938–0969). As a business practice we recognize that some suppliers may receive the documentation of the face-to-face for all applicable claims, voluntarily.

We believe that the requirements that are set out in this final rule with comment period meet the utility and clarity standards. We invited but received no public comments on this assumption and on ways to minimize the burden on affected parties. The recordkeeping requirement in § 410.38(g)(5) and the requirement to maintain and make the supplier's order/additional documentation available to CMS upon request is subject to the PRA, but we believe that these requirements are usual and customary business practices as defined in 5 CFR 1320.3(b)(2) and, therefore, the associated burden is exempt from the PRA.

B. ICRs Regarding the Physician Quality Reporting System (§ 414.90)

We are making several program revisions to the Physician Quality Reporting System for reporting periods that occur in 2013 and 2014, and, therefore, we are making several revisions to § 414.90. All of the requirements and burden estimates are currently approved by OMB under OCN 0938–1059, and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

First, we are revising § 414.90(e)—Use of Consensus-based Quality Measures. We are redesignating § 414.90(e) as § 414.90(f) and then revising newly designated § 414.90(f) to broadly define our use of consensus-based quality measures. The current regulation at § 414.90(e) (now redesignated as § 414.90(f)) states that we will publish a final list of measures every year. However, we finalized measures for 2013 and beyond this year. While § 414.90(e) (now redesignated as § 414.90(f)) contains information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions.

Second, we are revising § 414.90(b)—Definitions under the Physician Quality Reporting System. Specifically, we are revising the definition of ''group practice'' to include groups of 2–24 eligible professionals in the definition. We are revising the definition of ''qualified registry'' to indicate CMS' authority to disqualify registries. We are also eliminating the definition of ''qualified electronic health record product'' to more specifically address the EHR-based reporting mechanisms available under PQRS as ''direct electronic health record (EHR) product'' and ''electronic health record (EHR) data submission vendor.'' We are also adding the definition of ''administrative claims,'' which is a newly-established reporting mechanism available under PQRS for the purpose of reporting quality measures for the 2015 and 2016 PQRS payment adjustments. In addition, we are adding the definition of ''group practice reporting option (GPRO) web-interface.'' While the GPRO web-interface was available as a reporting mechanism in CY 2012, we had not previously included a definition for the GPRO web-interface. While § 414.90(b) contains information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule would not revise any of the information collection requirements or burden estimates that are associated with § 414.90(b).

Third, we are revising § 414.90(g) (formerly designated as 414.90(f))—Requirements for the Incentive Payments. In this final rule, we are redesignating 414.90(f) as 414.90(g) and making changes to newly designated § 414.90(g) to indicate the applicable incentive amounts and requirements for the 2013 and 2014 PQRS incentives. While § 414.90(e) (newly designated in this final rule as § 414.90(f)) contains information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions.

Fourth, we are adding § 414.90(e)—Requirements for the Payment Adjustments. We are adding § 414.90(e) to indicate the applicable adjustment amounts and requirements for the 2015 and 2016 PQRS payment adjustments. While § 414.90(e) contains information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions. The impact of this revision to the current information collection requirements or burden estimates that are associated with those provisions are described here:

The preamble of this final rule with comment period discusses the background of the PQRS, provides information about the measures and reporting mechanisms that will be available to eligible professionals and group practices who choose to participate in the 2013 and 2014 PQRS, and provides the criteria for satisfactory reporting in CYs 2013 and 2014 (for the 2013 and 2014 PQRS incentives and the 2015 and 2016 PQRS payment adjustments).

a. Participation in the 2013 and 2014 PQRS

According to the 2010 Reporting Experience Report, a total of $391,635,495 in PQRS incentives was paid by CMS for the 2010 program year, which encompassed 168,843 individual eligible professionals. In 2010, eligible professionals earned a 2.0 percent incentive (that is, a bonus payment equal to 2.0 percent of the total allowed part B charges for covered professional services under the PFS furnished by the eligible professional in the reporting period) for satisfactory reporting under PQRS. For 2013 and 2014, eligible professionals can earn a 0.5 percent incentive for satisfactory reporting, a reduction of 1.5 percent from 2010. Therefore, based on 2010, we would expect that approximately $97 million (approximately ¼ of $391,635,495) in incentive payments would be distributed to eligible professionals who satisfactorily report. However, we estimate that, due to the implementation of payment adjustments beginning in 2015, participation in PQRS would rise to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014 respectively.

The average incentive distributed to each eligible professional in 2010 was $2,157. Taking into account the 1.5 percent incentive reduction from 2.0 percent in 2010 to 0.5 percent in 2013 and 2014, we estimate that the average amount per eligible professional earning an incentive in 2013 and 2014 would be $539. Therefore, we estimated that we would distribute approximately $162 million ($539 × 300,000 eligible professionals) and $216 million ($539 × 400,000 eligible professionals) in incentive payments in 2013 and 2014, respectively. We believe these incentive payments will help offset the cost to

eligible professionals participating in PQRS for the applicable year. Please note that, beginning 2015, incentive payments for satisfactory reporting in PQRS will cease and payment adjustments for not satisfactorily reporting will commence.

We noted that the total burden associated with participating in PQRS is the time and effort associated with indicating intent to participate in PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assumed the following:

- The requirements for reporting for the PQRS 2013 and 2014 incentives and payment adjustments for 2015 and beyond would be established as proposed in this 2013 Medicare PFS final rule with comment period.
- For an eligible professional using the claims, registry, or EHR-based reporting mechanisms and group practices using the registry or EHR-based reporting mechanisms, that the eligible professional or group practice would report on 3 measures.
- With respect to labor costs, we believe that a billing clerk would handle the administrative duties associated with participating, while a computer analyst would handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

b. Burden Estimate on Participation in 2013 and 2014—New Individual Eligible Professionals: Preparation

For an eligible professional who wishes to participate in PQRS as an individual using the traditional reporting mechanisms, the eligible professional need not indicate his/her intent to participate. Instead, the eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review the PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in PQRS would be approximately $80 ($16/hour × 5 hours).

c. Burden Estimate on Participation in 2013 and 2014 via the Claims Reporting Mechanism—Individual Eligible Professionals

(1) The Traditional Claims-based Reporting Mechanism

In 2010, approximately 200,000 of the roughly 245,000 eligible professionals (or 84 percent) of eligible professionals used the claims-based reporting mechanism. We believe that although the number of eligible professionals or group practices using the claims-based reporting mechanism will increase in 2013 and 2014, we anticipated that the percentage of eligible professionals or group practices using the claims-based reporting mechanism will decrease slightly as eligible professionals and group practices transition towards using the EHR-based reporting mechanism. Therefore, we estimated that the percentage of PQRS participants using the claims-based reporting mechanism will decrease as we anticipate that more eligible professionals would use the registry and EHR-based reporting mechanisms. For these reasons, we estimated that approximately 320,000 eligible professionals would participate in PQRS using the traditional claims-based reporting mechanism by 2014.

With respect to an eligible professional who participated in PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submitted for payment. PQRS will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN 0938–0999). Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims would range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 3 measures would range from 0.75 minutes to 36 minutes. Using an average labor cost of $40/hour, we estimated that the time cost of reporting for an eligible professional via claims would range from $0.50 (0.75 minutes × $40/hour) to $24.00 (36 minutes × $40/hour) per reported case. With respect to how many cases an eligible professional would report when using the claims-based reporting mechanism, we established that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional reports would vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent, we found that the median number of reporting cases for each measure was 9. Since we reduced the reporting threshold to 50 percent, we estimated that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimated that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from ($0.50/per reported case × 6 reported cases) $3.00 to ($24.00/reported case × 6 reported cases) $144.

(2) The Administrative Claims Reporting Mechanism

We note that, for the 2015 PQRS payment adjustments, we are finalizing an administrative claims reporting option for eligible professionals and group practices. The burden associated with reporting using the administrative claims reporting option is the time and effort associated with using this option. To submit quality measures data for PQRS using the administrative claims reporting option, an eligible professional or group practice would need to (1) register as an administrative claims reporter for the applicable payment adjustment and (2) report quality measures data. With respect to registration, we believe it would take approximately 2 hours to register to participate in PQRS as an administrative claims reporter. Therefore, we estimated that the cost of undergoing the administrative claims selection process would be ($16/hour × 2 hours) $32.

With respect to reporting, we noted that any burden associated with reporting would be negligible, as an eligible professional or group practice would not be required to attach reporting G-codes on the claims they submitted. Rather, CMS would bear the burden of calculating the measures rates from claims data submitted by the eligible professional or group practice. We note that there would be no additional burden on the eligible professional or group practice to submit these claims, as the eligible professional or group practice would have already submitted these claims for reimbursement purposes.

d. Burden Estimate on Participation in the CYs 2013 and 2014 PQRS via the Registry-Based or EHR-Based Reporting Mechanism

In 2010, approximately 40,000 of the roughly 245,000 eligible professionals (or 16 percent) of eligible professionals used the registry-based reporting mechanism. We believe the number of eligible professionals and group practices using the registry based reporting mechanism would remain the same, as we believe the decision for an eligible professional or group practice to purchase a registry would not likely be solely to report PQRS quality measures data to CMS. Rather, we believe that eligible professionals use registries for functions other than PQRS and therefore would obtain a registry solely for PQRS reporting by CY 2014.

In 2010, only 14 of the roughly 245,000 eligible professionals (or <1 percent) of eligible professionals used the EHR-based reporting mechanism. We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism would increase as eligible professionals become more familiar with EHR products. In particular, we believe eligible professionals and group practices would transition from using the claims-based to the EHR-based reporting mechanisms. We estimated that approximately 40,000 eligible professionals (4 percent), whether participating as an individual or part of a group practice, would use the EHR-based reporting mechanism in CY 2014.

With respect to an eligible professional or group practice who participated in PQRS via a qualified registry, direct EHR product, or EHR data submission vendor product, we believe there would be little to no burden associated for an eligible professional to report PQRS quality measures data to CMS, because the selected reporting mechanism would submit the quality measures data for the eligible professional. While we noted that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, or EHR data submission vendor, we believe that an eligible professional or group practice would not purchase a qualified registry, direct EHR product, or EHR data submission vendor product solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of purchasing a qualified registry, direct EHR, or EHR data submission vendor product in our burden estimates.

e. Burden Estimate on Participation in the CYs 2013 and 2014 PQRS—Group Practices

Unlike eligible professionals who choose to report individually, we noted that we proposed that eligible professionals choosing to participate as part of a group practice under the GPRO would need to indicate their intent to participate in PQRS as a group practice. The total burden for group practices who submit PQRS quality measures data via the GPRO web-interface would be the time and effort associated with submitting this data. To submit quality measures data for PQRS, a group practice would need to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in PQRS as a GPRO, we believe it would take approximately 6 hours—including 2 hours to decide to participate in PQRS as a GPRO; 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in PQRS GPRO for the applicable year. Therefore, we estimated that the cost of undergoing the GPRO selection process would be ($16/hour × 6 hours) $96.

With respect to reporting PQRS quality measures using the GPRO web-interface, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completing the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimated the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimated that the report cost for a group practice to submit PQRS quality measures data for an applicable year would be ($40/hour × 79 hours) $3,160.

f. Maintenance of Certification Program Incentive

Eligible professionals who wish to qualify for an additional 0.5 percent Maintenance of Certification Program incentive would need to ''more frequently'' than is required to qualify for or maintain board certification status participate in a qualified Maintenance of Certification Program for the year in which the eligible professionals seek to qualify for this additional incentive and successfully complete a qualified Maintenance of Certification Program practice assessment for the applicable year. Although we understand that there is a cost associated with participating in a Maintenance of Certification Board, we believe that most of the eligible professionals attempting to earn this additional incentive would already be enrolled in a Maintenance of Certification Board for reasons other than earning the additional Maintenance of Certification Program incentive. Therefore, the burden to earn this additional incentive would depend on what a certification board establishes as ''more frequently'' and the time needed to complete the practice assessment component. We expect that the amount of time needed to complete a qualified Maintenance of Certification Program practice assessment would be spread out over time since a quality improvement component is often required. With respect to the practice assessment component, according to an informal poll conducted by ABMS in 2012, the time an individual spent to complete the practice assessment component of the Maintenance of Certification ranged from 8–12 hours.

g. Burden Estimate on Vendor Participation in the 2013 and 2014

Aside from the burden of eligible professionals and group practices participating in PQRS, we believe that registry and EHR vendor products incur costs associated with participating in PQRS.

Based on the number of registries that have self-nominated to become a qualified PQRS registry in prior program years, we estimated that approximately 50 additional registries would self-nominate to be considered a qualified registry for PQRS. With respect to qualified registries, the total burden for qualified registries who submitted PQRS quality measures data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed PQRS program years, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process, we estimated that it would take a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wished to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report PQRS quality measures data. Therefore, we estimated that it would cost a registry approximately ($16.00/hour × 10 hours) $160 to become qualified to submit PQRS quality

measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, the burden associated with reporting is the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective of participating in PQRS. Therefore, we believe there is little to no additional burden associated with reporting PQRS quality measures data. Whether there is any additional reporting burden would vary with each registry, depending on the registry's level of knowledge with submitting quality measures data for PQRS.

With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit PQRS quality measures data would be the time and effort associated with submitting this data. To submit quality measures data for PQRS, a direct EHR product or EHR data submission vendor would need to report quality measures data on behalf of its eligible professionals. Please note that since we are not continuing to require direct EHR products and EHR data submission vendors to become qualified to submit PQRS quality measures data, there is no burden associated with a qualification process for direct EHR products and EHR data submission vendor products. With respect to reporting quality measures data, we believe the burden associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional would need to submit to CMS will depend on the vendor's familiarity with PQRS and the vendor's system and programming capabilities. Since we believe that an EHR vendor would be submitting data for reasons other than reporting under PQRS, we believe there would be no additional burden for an EHR vendor to submit quality measures data for PQRS reporting.

g. Summary of Burden Estimates on Participation in the 2013 and 2014 PQRS-Eligible Professionals and Vendors

TABLE 131—ESTIMATED COSTS FOR REPORTING PQRS QUALITY MEASURES DATA FOR ELIGIBLE PROFESSIONALS

	Estimated hours	Estimated cases	Number of measures	Hourly rate	Total cost
Individual Eligible Professional (EP): Preparation	5.0	1	N/A	$16	$80.
Individual EP: Claims	0.2	6	3	$40	$144.
Individual EP: Administrative Claims	2	1	N/A	$16	$32.
Individual EP: Registry	N/A	1	N/A	N/A	Minimal.
Individual EP: HER	N/A	1	N/A	N/A	Minimal.
Group Practice: Self-Nomination	6.0	1	N/A	$16	$96.
Group Practice: Reporting	79	1	N/A	$40	$3,160.

TABLE 132—ESTIMATED COSTS TO VENDORS TO PARTICIPATE IN PQRS

	Estimated hours	Hourly rate	Total cost
Registry: Self-Nomination	10	$160	$160
EHR: Programming	0	0	0

We invited but received no public comments on our estimates related to the impact of the collection of information requirements related to PQRS. However, we believe that the estimated changes from the requirements and burden estimates currently approved by OMB under OCN 0938–1059 are due to a combination of all revisions being made at § 414.90(b), newly designated § 414.90(f), and newly created§ 414.90(e), rather than just one outstanding provision. Therefore, please note that we have combined all impacts of the collection of information requirements related to PQRS in this section, in lieu of separating these impacts as it was proposed. Otherwise, our burden estimates remain unchanged.

C. ICRs Regarding Physician Quality Reporting System—Requirements for the Payment Adjustments (§ 414.90)

While § 414.90 contains information collection requirements regarding the PQRS payment adjustments, this rule will not revise any of the information collection requirements or burden estimates that are associated with those provisions, except for the provisions that would allow the administrative claims reporting option. Otherwise, all of the requirements and burden estimates are currently approved by OMB under OCN 0938–1083 and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Specifically, although we are finalizing the criteria to report 1 measure or measures group for the 2015 PQRS payment adjustment, we do not expect eligible professional and group practices to stop reporting when they have met this threshold. Rather, since the reporting period for the 2013 PQRS incentive and 2015 PQRS payment adjustment coincide, we expect that all eligible professionals and group practices who use the traditional PQRS reporting mechanisms—claims, registry, EHR, and GPRO web interface—will attempt to report PQRS quality measures to meet the criteria for the 2013 PQRS Incentive. Therefore, the burden estimates for the 2013 PQRS incentive apply to the 2015 PQRS payment adjustment.

With respect to the 2016 PQRS payment adjustment, we did not finalize the criteria to report 1 measure or measures group. Therefore, at this time, eligible professionals and group practices using the traditional PQRS reporting mechanisms—claims, registry, EHR, and GPRO web interface must meet the criteria for the 2014 PQRS incentive for the 2016 PQRS payment adjustment. Therefore, the burden estimates for the 2014 PQRS incentive apply to the 2016 PQRS payment adjustment.

(2) The Administrative Claims Reporting Mechanism

We note that, for the 2015 PQRS payment adjustment, we are finalizing an administrative claims reporting option for eligible professionals and group practices. The burden associated with reporting using the administrative claims reporting option is the time and effort associated with using this option. To submit quality measures data for PQRS using the administrative claims reporting option, an eligible professional or group practice would need to (1) elect to use the administrative claims-based reporting mechanism for the applicable payment adjustment and (2) be analyzed under the administrative claims-based reporting mechanism. With respect to election, we believe it would take approximately 2 hours to register to participate in PQRS as an administrative claims reporter. Therefore, we estimated that the cost of undergoing the administrative claims selection process would be ($16/hour × 2 hours) $32.

With respect to reporting, we noted that any burden associated with reporting would be negligible, as an eligible professional or group practice would not be required to attach reporting G-codes on the claims they submitted. Rather, CMS would calculate the administrative claims measures rates from claims submitted by group practices and eligible professionals. We note that there would be no additional burden on the eligible professional or group practice to submit these claims, as the eligible professional or group practice would have already submitted these claims for reimbursement purposes.

D. Summary of Annual Burden Estimates for Codified Requirements

The requirements for the eRx Incentive Program for 2012–2014 were established in the CY 2012 Medicare PFS final rule. Although we made proposals related to the eRx Incentive Program in the CY 2013 Medicare PFS, these proposals have no additional burden or impact on the public. Therefore, this rule does not revise the requirements or burden estimates approved by OMB under OCN 0938–1059. We invited but received no public comment on our proposed impact analysis and are therefore finalizing the analysis for the collection of information requirements associated with the Electronic Prescribing (eRx) Incentive Program.

TABLE 133—SUMMARY OF ANNUAL BURDEN ESTIMATES

Regulation section(s)	OCN	Respondents	Responses	Burden per response (hr)	Total burden (hr)
§ 410.38(g) re: Physician	0938-New	580,000	580,000	10 min	96,667
§ 410.38(g) re: PA, NP, or CNS.				3 min	29,000
§ 414.90	0938–1059	400,000	400,000 (400,000 responses × 3 measures).	0.5 (31.5 minutes—the median).	200,000

E. Additional Information Collection Requirements

While this final rule with comment period will impose collection of information requirements that are set out in the regulatory text (see above), this rule also sets out information collection requirements that are set out only in the preamble. Following is a discussion of the preamble-specific information collections, all of which have already received OMB approval.

1. Part B Drug Payment

The discussion of average sales price (ASP) issues in section III.B.1 of this final rule with comment period rule does not contain any new information collection requirements with respect to payment for Medicare Part B drugs and biologicals under the ASP methodology. Drug manufacturers are required to submit ASP data to us on a quarterly basis. The ASP reporting requirements are set forth in section 1927(b) of the Act. The burden associated with this requirement is the time and effort required by manufacturers of Medicare Part B drugs and biologicals to calculate, record, and submit the required data to CMS. All of the requirements and burden estimates are currently approved by OMB under OCN 0938–0921, and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

2. CAHPS Survey for the Physician Quality Reporting System and Physician Compare

As explained previously, the burden estimates related to PQRS are under OCN 0938–1083. However, we note that, to meet the criteria for the 2013 and 2014 PQRS incentives, we are requiring that group practices using the GPRO web interface complete a CAHPS survey. This would require the collection of information to obtain the patient experience data that will be included in the quality information reported by eligible professionals. The data collected in the survey will be scored and reported via Physician Compare on the cms.gov Web site. The information collection—a survey—will be targeted to Fee-for-service Medicare beneficiaries who have received care in the prior 12 months from the physician group practices participating in Physician Quality Reporting. The survey will be administered in English and Spanish, and beneficiaries may have assistance to complete the survey or designate a proxy respond on their behalf.

Administering the CAHPS survey is different from the estimates provided from reporting measures, as beneficiaries must actively participate in the reporting of data by completing these surveys. According to estimates we have performed with respect to administering this survey, we anticipate that it will take approximately 39.53 hours to administer the CAHPS survey. We estimate that the cost per response will be $7,673.50. We understand the estimated cost is high. However, as we indicate in Section G in this final rule, CMS will assume the expense of administering the CAHPS survey. A summary of the burden estimates for administering the CAHPS survey is provided below:

	Time per response	Hour per response	Annual hour burden	Cost per response	Annual cost burden
Reporting	20.24	0.337	39,530	$7.6735	$900,100
Record Keeping	0	0	0	0	0
Third Party Disclosure	0	0	0	0	0
Total	*20.24	0.337	39,530	$7.6735	$900,100

* Minutes.

F. Submission of PRA-Related Comments

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–1590–FC]; Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

VI. 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 drug coding system comprised of Level I (CPT) codes and Level II (HCPCS National Codes) that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. Level I (CPT) codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures. The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both Level I and Level II codes, is similarly updated annually on a CY basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the PFS. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on these codes and the RVUs assigned to them in advance of publication of the final rule that implements the PFS. Yet, it is imperative that these coding changes be accounted for and recognized timely under the PFS for payment because services represented by these codes will be provided to Medicare beneficiaries by physicians during the CY in which they become effective. Moreover, regulations implementing HIPAA (42 CFR parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the PFS. We assign interim RVUs to any new codes based on a review of the AMA RUC recommendations for valuing these services. We also assign interim RVUs to certain codes for which we did not receive specific AMA RUC recommendations, but that are components of new combined codes. We set interim RVUs for the component codes in order to conform them to the value of the combined code. Finally, we assign interim RVUs to certain codes for which we received AMA RUC recommendations for only one component (work or PE) but not both. By reviewing these AMA RUC recommendations for the new codes, we are able to assign RVUs to services based on input from the medical community and to establish payment for them, on an interim basis, that corresponds to the relative resources associated with furnishing the services. We are also able to determine, on an interim final basis, whether the codes will be subject other payment policies. If we did not assign RVUs to new codes on an interim basis, the alternative would be to either not pay for these services during the initial CY or have each Medicare contractor establish a payment rate for these new codes. We believe both of these alternatives are contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to our establishing payment for these codes on an interim basis. Therefore, we believe it would be contrary to the public interest to delay establishment of fee schedule payment amounts for these codes.

For the reasons previously outlined in this section, we find good cause to waive the notice of proposed rulemaking for the interim RVUs for selected procedure codes identified in Addendum C and to establish RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

Section II.C. of this final rule with comment period discusses the identification and review of potentially misvalued codes by the AMA RUC, as well as our review and decisions regarding the AMA RUC recommendations. Similar to the AMA RUC recommendations for new and revised codes previously discussed, due to the timing of the AMA RUC recommendations for the potentially misvalued codes, it was impracticable for CMS to solicit public comment regarding specific proposals for revision prior to this final rule with comment period. We believe it is in the public interest to implement the revised RVUs for the codes that were identified as misvalued, and that have been reviewed and re-evaluated by the AMA RUC, on an interim final basis for CY 2013. The revisions of RVUs for these codes will establish a more appropriate payment that better corresponds to the relative resources associated with furnishing these services. A delay in implementing revised values for these misvalued codes would not only perpetuate the known misvaluation for these services, it would also perpetuate a distortion in the payment for other services under the PFS. Implementing the changes now allows for a more equitable distribution of payments across all PFS services. We believe a delay in implementation of these revisions would be contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to the AMA RUC's recommendation to CMS. For the

reasons previously described, we find good cause to waive notice and comment procedures with respect to the misvalued codes and to revise RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

We ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d)), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 553(d)(3); 5 U.S.C. 808(2)).

VII. 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 considered all comments we received by the date and time specified in the ''DATES'' section of this preamble, and, when we proceeded with a subsequent document, we responded to the comments in the preamble to that document.

VIII. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period is necessary in order to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA), the Affordable Care Act, and other statutory changes. This final rule with comment period also is necessary to make changes to Part B drug payment policy and other related Part B related policies.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2012), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed below in this section, that the PFS provisions included in this proposed rule will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year (for details see the SBA's Web site at *www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities that the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

For purposes of the RFA, physicians, NPPs, and suppliers including IDTFs are considered small businesses if they generate revenues of $10 million or less based on SBA size standards. Approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS.

Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis for the remaining provisions and addresses comments received on these issues.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately $139 million. This final rule with comment period would have no consequential spending effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule with comment period; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule with comment period, we proposed to implement a variety of changes to our regulations, payments, or payment

policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement statutory provisions. We provided information for each of the policy changes in the relevant sections of this final rule with comment period. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule with comment period. The relevant sections of this final rule with comment period contain a description of significant alternatives if applicable.

C. Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and Malpractice RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve BN.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2012 with final payment rates for CY 2013 using CY 2011 Medicare utilization as the basis for the comparison. To the extent that there are year-to-year changes in the volume and mix of services furnished by physicians, the actual impact on total Medicare revenues would be different from those shown in Tables 134 (CY 2013 PFS Final Rule with Comment Period Estimated Impact on Total Allowed Charges by Specialty) and 135 (CY 2013 PFS Final Rule with Comment Period Estimated Impact on Total Allowed Charges by Specialty by Selected Policy). The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average and would depend on the mix of services the physician furnishes. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 85 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Tables 134 and 135 show the payment impact on PFS services. We note that these impacts do not include the effect of the January 2013 conversion factor changes under current law. The annual update to the PFS conversion factor is calculated based on a statutory formula that measures actual versus allowed or ''target'' expenditures, and applies a sustainable growth rate (SGR) calculation intended to control growth in aggregate Medicare expenditures for physicians' services. This update methodology is typically referred to as the ''SGR'' methodology, although the SGR is only one component of the formula. Medicare PFS payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. By law, we are required to apply these updates in accordance with section 1848(d) and (f) of the Act, and any negative updates can only be averted by an Act of the Congress. While the Congress has provided temporary relief from negative updates for every year since 2003, a long-term solution is critical. We are committed to working with the Congress to permanently reform the SGR methodology for Medicare PFS updates. We provide our most recent estimate of the SGR and physician update for CY 2013 in section III.N. of this final rule with comment period.

The following is an explanation of the information represented in Table 134:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2011 utilization and CY 2012 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work and Malpractice (MP) RVU Changes):* This column shows the estimated CY 2013 impact on total allowed charges of the changes in the work and malpractice RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2013 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Combined Impact):* This column shows the estimated CY 2013 combined impact on total allowed charges of all the changes in the previous columns.

TABLE 134—CY 2013 PFS FINAL RULE WITH COMMENT PERIOD ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

(A) Specialty	(B) Allowed charges (mil)	(C) Impact of work and MP RVU changes %	(D) Impact of PE RVU changes %	(E) Combined impact %
TOTAL	$ 86,588	0	0	0
01–ALLERGY/IMMUNOLOGY	200	0	3	3
02–ANESTHESIOLOGY **	1,923	0	1	1
03–CARDIAC SURGERY	369	0	−1	−1
04–CARDIOLOGY	6,733	−1	−2	−2
05–COLON AND RECTAL SURGERY	153	0	2	2
06–CRITICAL CARE	263	0	1	1
07–DERMATOLOGY	3,024	0	0	0
08–EMERGENCY MEDICINE	2,839	0	0	0
09–ENDOCRINOLOGY	437	0	1	1
10–FAMILY PRACTICE	5,943	2	4	7

TABLE 134—CY 2013 PFS FINAL RULE WITH COMMENT PERIOD ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *—Continued

(A) Specialty	(B) Allowed charges (mil)	(C) Impact of work and MP RVU changes %	(D) Impact of PE RVU changes %	(E) Combined impact %
11–GASTROENTEROLOGY	1,896	0	0	0
12–GENERAL PRACTICE	587	0	1	1
13–GENERAL SURGERY	2,283	0	1	0
14–GERIATRICS	220	1	3	5
15–HAND SURGERY	135	0	1	1
16–HEMATOLOGY/ONCOLOGY	1,909	0	2	2
17–INFECTIOUS DISEASE	629	0	1	1
18–INTERNAL MEDICINE	11,163	2	3	4
19–INTERVENTIONAL PAIN MGMT	539	0	1	1
20–INTERVENTIONAL RADIOLOGY	204	0	−2	−3
21–MULTISPECIALTY CLINIC/OTHER PHY	81	0	0	−1
22–NEPHROLOGY	2,080	0	0	0
23–NEUROLOGY	1,604	−2	−5	−7
24–NEUROSURGERY	687	0	0	0
25–NUCLEAR MEDICINE	49	0	−2	−3
27–OBSTETRICS/GYNECOLOGY	704	0	0	0
28–OPHTHALMOLOGY	5,645	−3	0	−3
29–ORTHOPEDIC SURGERY	3,643	0	0	0
30–OTOLARNGOLOGY	1,076	0	2	2
31–PATHOLOGY	1,210	0	−6	−6
32–PEDIATRICS	65	1	3	3
33–PHYSICAL MEDICINE	999	−1	−3	−4
34–PLASTIC SURGERY	356	−1	1	1
35–PSYCHIATRY	1,170	−1	3	2
36–PULMONARY DISEASE	1,703	0	1	1
37–RADIATION ONCOLOGY	1,988	0	−7	−7
38–RADIOLOGY	4,818	0	−3	−3
39–RHEUMATOLOGY	548	0	0	0
40–THORACIC SURGERY	343	0	−1	−1
41–UROLOGY	1,918	0	−1	−1
42–VASCULAR SURGERY	888	0	−2	−2
43–AUDIOLOGIST	57	0	−4	−4
44–CHIROPRACTOR	746	0	1	1
45–CLINICAL PSYCHOLOGIST	575	1	−3	−2
46–CLINICAL SOCIAL WORKER	406	1	−3	−2
47–DIAGNOSTIC TESTING FACILITY	888	0	−7	−7
48–INDEPENDENT LABORATORY	1,073	0	−14	−14
49–NURSE ANES/ANES ASST**	1,104	0	1	1
50–NURSE PRACTITIONER	1,623	1	3	4
51–OPTOMETRY	1,061	−1	1	1
52–ORAL/MAXILLOFACIAL SURGERY	45	0	1	1
53–PHYSICAL/OCCUPATIONAL THERAPY	2,636	0	4	4
54–PHYSICIAN ASSISTANT	1,229	1	2	3
55–PODIATRY	1,925	0	2	2
56–PORTABLE X–RAY SUPPLIER	106	0	5	5
57–RADIATION THERAPY CENTERS	72	0	−9	−9
98–OTHER	19	0	1	1

* Table 83 shows only the proposed payment policy impact on PFS services. We note that these impacts do not include the effects of the negative January 2013 conversion factor change under current law.

** These figures have been revised to correct errors in the calculations presented in the CY 2013 PFS proposed rule.

Table 135 shows the estimated impact of selected policies in this final rule with comment period on total allowed charges, by specialty. The following is an explanation of the information represented in Table 135:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2011 utilization and CY 2012 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column (C) (Impact of End of PPIS Transition):* This column shows the estimated CY 2013 impact on total allowed charges of the changes in the RVUs due to the final year of the PPIS transition.
- *Column D (Impact of New and Revised Codes, Updated Claims Data, MPPR on the TC of ophthalmology and cardiovascular diagnostic tests, and Other Factors):* This column shows the

estimated CY 2013 impact on total allowed charges of the changes in the RVUs, due to new and revised codes, proposed multiple procedure payment reduction for the TC of cardiovascular and ophthalmology diagnostic tests furnished on the same day (section III.B.4. of this final rule with comment period), and other final policies that resulted in minimal redistribution of payments under the PFS, the use of CY 2011 claims data to model payment rates, and other factors.

• *Column E (Impact of Updated Equipment Interest Rate Assumption):* This column shows the estimated CY 2013 impact on total allowed charges of the changes in the RVUs resulting from our update to the equipment interest rate assumption as discussed in section III.A.2.f. of this final rule with comment period.

• *Column F (Impact of Discharge Transitional Care Management Services):* This column shows the estimated CY 2013 combined impact on total allowed charges of the changes in the RVUs resulting from our policy to recognize new CPT codes that pay for post-discharge transitional care management services in the 30 days following an inpatient hospital, outpatient observation or partial hospitalization, skilled nursing facility (SNF), or community mental health center (CMHC) discharge as discussed in section III.H.1. of this final rule with comment period.

• *Column G (Impact of Input and Price Changes for Certain Radiation Therapy Procedures):* This column shows the estimated CY 2013 combined impact on total allowed charges of the changes in the RVUs resulting from our policy to adjust inputs on certain radiation therapy procedures.

• *Column H (Cumulative Impact):* This column shows the estimated CY 2013 combined impact on total allowed charges of all changes from the policies in this final rule with comment period in the previous columns.

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TABLE 135: CY 2013 PFS Final Rule with Comment Period Estimated Impact on Total Allowed Charges by Specialty by Selected Policy*

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of End of PPIS Transition	(D) New and Revised Codes, MPPR, New Utilization and Other Factors	(E) Updated Equipment Interest Rate Assumption	(F) Transitional Care Management	(G) Input Changes for Certain Radiation Therapy Procedures	(H) Total (Cumulative Impact)
TOTAL	$ 86,588	0%	0%	0%	0%	0%	0%
01-ALLERGY/ IMMUNOLOGY	$ 200	0%	1%	2%	0%	0%	3%
02-ANESTHESIOLOGY **	$ 1,923	1%	-1%	0%	0%	0%	1%
03-CARDIAC SURGERY	$ 369	-1%	0%	0%	0%	0%	-1%
04-CARDIOLOGY	$ 6,733	-2%	0%	0%	-1%	0%	-2%
05-COLON AND RECTAL SURGERY	$ 153	1%	0%	0%	0%	0%	2%
06-CRITICAL CARE	$ 263	0%	0%	0%	0%	0%	1%
07-DERMATOLOGY	$ 3,024	0%	0%	1%	-1%	0%	0%
08-EMERGENCY MEDICINE	$ 2,839	0%	0%	0%	0%	0%	0%
09-ENDOCRINOLOGY	$ 437	1%	1%	0%	-1%	0%	1%
10-FAMILY PRACTICE	$ 5,943	1%	1%	0%	4%	0%	7%
11-GASTROENTEROLOGY	$ 1,896	0%	0%	0%	0%	0%	0%
12-GENERAL PRACTICE	$ 587	1%	0%	0%	-1%	0%	1%
13-GENERAL SURGERY	$ 2,283	1%	0%	0%	0%	0%	0%
14-GERIATRICS	$ 220	1%	1%	0%	2%	0%	5%
15-HAND SURGERY	$ 135	1%	0%	0%	-1%	0%	1%
16-HEMATOLOGY/ ONCOLOGY	$ 1,909	-1%	3%	1%	-1%	0%	2%
17-INFECTIOUS DISEASE	$ 629	1%	1%	0%	0%	0%	1%
18-INTERNAL MEDICINE	$ 11,163	1%	1%	0%	3%	0%	4%
19-INTERVENTIONAL PAIN MGMT	$ 539	1%	0%	0%	-1%	0%	1%
20-INTERVENTIONAL RADIOLOGY	$ 204	-2%	0%	0%	0%	0%	-3%
21-MULTISPECIALTY CLINIC/OTHER PHY	$ 81	0%	0%	0%	-1%	0%	-1%
22-NEPHROLOGY	$ 2,080	0%	0%	0%	0%	0%	0%
23-NEUROLOGY	$ 1,604	1%	-8%	0%	0%	0%	-7%
24-NEUROSURGERY	$ 687	0%	0%	0%	0%	0%	0%
25-NUCLEAR MEDICINE	$ 49	-2%	0%	-1%	0%	0%	-3%
27-OBSTETRICS/ GYNECOLOGY	$ 704	0%	0%	0%	-1%	0%	0%

28-OPHTHALMOLOGY	$ 5,645	2%	-4%	0%	0%	0%	-3%
29-ORTHOPEDIC SURGERY	$ 3,643	1%	0%	0%	0%	0%	0%
30-OTOLARNGOLOGY	$ 1,076	1%	1%	1%	-1%	0%	2%
31-PATHOLOGY	$ 1,210	-1%	-5%	0%	0%	0%	-6%
32-PEDIATRICS	$ 65	1%	0%	0%	3%	0%	3%
33-PHYSICAL MEDICINE	$ 999	1%	-5%	0%	-1%	0%	-4%
34-PLASTIC SURGERY	$ 356	1%	0%	0%	0%	0%	1%
35-PSYCHIATRY	$ 1,170	0%	2%	0%	-1%	0%	2%
36-PULMONARY DISEASE	$ 1,703	0%	1%	0%	-1%	0%	1%
37-RADIATION ONCOLOGY	$ 1,988	-4%	2%	-3%	-1%	-1%	-7%
38-RADIOLOGY	$ 4,818	-2%	0%	-1%	0%	0%	-3%
39-RHEUMATOLOGY	$ 548	0%	1%	0%	-1%	0%	0%
40-THORACIC SURGERY	$ 343	-1%	0%	0%	0%	0%	-1%
41-UROLOGY	$ 1,918	-2%	1%	0%	-1%	0%	-1%
42-VASCULAR SURGERY	$ 888	-1%	-1%	0%	0%	0%	-2%
43-AUDIOLOGIST	$ 57	-3%	0%	0%	0%	0%	-4%
44-CHIROPRACTOR	$ 746	1%	0%	0%	0%	0%	1%
45-CLINICAL PSYCHOLOGIST	$ 575	-2%	1%	0%	0%	0%	-2%
46-CLINICAL SOCIAL WORKER	$ 406	-2%	0%	0%	0%	0%	-2%
47-DIAGNOSTIC TESTING FACILITY	$ 888	-5%	0%	-2%	-1%	0%	-7%
48-INDEPENDENT LABORATORY	$ 1,073	-2%	-12%	1%	-1%	0%	-14%
49-NURSE ANES / ANES ASST **	$ 1,104	2%	-1%	0%	0%	0%	1%
50-NURSE PRACTITIONER	$ 1,623	1%	1%	0%	2%	0%	4%
51-OPTOMETRY	$ 1,061	2%	-1%	0%	0%	0%	1%
52-ORAL/MAXILLOFACIAL SURGERY	$ 45	1%	0%	1%	-1%	0%	1%
53-PHYSICAL/OCCUPATIONAL THERAPY	$ 2,636	2%	2%	0%	0%	0%	4%
54-PHYSICIAN ASSISTANT	$ 1,229	1%	0%	0%	2%	0%	3%
55-PODIATRY	$ 1,925	2%	0%	1%	-1%	0%	2%
56-POR X-RAY SUPPLIER	$ 106	1%	4%	1%	-1%	0%	5%
57-RADIATION THERAPY CENTERS	$ 72	-5%	4%	-5%	-1%	-1%	-9%
98-OTHER	$ 19	1%	0%	0%	0%	0%	1%

*Table 135 shows only the proposed payment policy impact on PFS services. We note that these impacts do not include the effects of the negative January 2013 conversion factor change under current law.

** These figures have been revised to correct errors in the calculations presented in the CY 2013 PFS proposed rule.

2. CY 2013 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to several factors. First, as discussed in section III.A.2. of this final rule with comment period, we are currently implementing the final year of the 4-year transition to new PE RVUs using the PPIS data that were adopted in the CY 2010 PFS final rule with comment period. This impact appears in column C of Table 135. The impacts of the final year of the transition are generally consistent with the impacts that would be expected based on the impacts displayed in the CY 2012 final rule with comment period. The second factor is the post-discharge transitional care management policy, under which we will pay for care coordination in the 30 days following an inpatient hospital, outpatient hospital observation services or partial hospitalization, SNF, or CMHC discharge from the treating physician in the hospital to the beneficiary's primary physician in the community. We estimate that CPT codes 99495 and 99496 for TCM will redistribute approximately $0.6 billion in allowed charges to primary care specialties under the physician fee schedule (estimated using the CY 2012 CF), with approximately 20 percent of that representing redistributed beneficiary coinsurance. The redistributive effect of this policy appears on column F of Table 135.

Column E in Table 135 also reflects updates to the proposed interest rate assumption used in the medical equipment calculation in the PE RVU methodology. Other final rule policies, including the multiple procedure payment reduction policy for the technical component of diagnostic cardiovascular and ophthalmological procedures, as well as new values for new and revised codes are included in Column D. Column G in Table 135 isolates the impact of revisions to equipment inputs and prices for certain radiation therapy services. Table 135 shows the same information as provided in Table 134, but rather than isolating the policy impact on physician work, PE, and malpractice separately, Table 135 shows the impact of varied final policies on total RVUs.

b. Combined Impact

Column E of Table 134 and column H of Table 135 display the estimated CY 2013 combined impact on total allowed charges by specialty of all the RVU and MPPR changes. These impacts range from an increase of 7 percent for family practice to a decrease of 14 percent for independent laboratory. We have received numerous new codes with new values and revised codes with new values for CY 2013 as a result of our ongoing misvalued codes initiative. Many of the new and revised codes that we valued on an interim basis for CY 2013 originated with the potentially misvalued codes initiative. Reductions for pathology, neurology, and independent laboratories are a result of the potentially misvalued code initiative. In the case of independent laboratories, we note that independent laboratories receive the majority of the Medicare revenue from the Clinical Lab Fee Schedule, which is unaffected by the potentially misvalued code initiative. Again, these impacts are estimated prior to the application of the negative CY 2013 Conversion Factor (CF) update applicable under the current statute.

Table 136 (Impact of Final Rule with Comment Period on CY 2013 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the changes discussed previously. We have included CY 2013 payment rates with and without the effect of the CY 2013 negative PFS CF update for comparison purposes. We selected these procedures because they are the most commonly furnished by a broad spectrum of physician specialties. There are separate columns that show the change in the facility rates and the nonfacility rates. For an explanation of facility and nonfacility PE, we refer readers to Addendum A of this final rule with comment period.

TABLE 136: Impact of Final Rule with Comment Period on CY 2013 Payment for Selected Procedures *

CPT/ HCPCS [1]	MOD	Short Descriptor	Facility					Nonfacility				
			CY 2012[2]	CY 2013[3] (pre update)	% Change (pre update)	CY 2013 [4] (post update)	% Change (post update)	CY 2012 [2]	CY 2013[3] (pre update)	% Change (pre update)	CY 2013 [4] (post update)	% Change (post update)
11721		Debride nail 6 or more	$25.19	$24.48	-3%	$18.00	-29%	$43.57	$44.89	3%	$33.00	-24%
17000		Destruct premalg lesion	$56.16	$57.13	2%	$42.00	-25%	$81.01	$83.32	3%	$61.25	-24%
27130		Total hip arthroplasty	$1,445.58	$1,452.08	0%	$1,067.53	-26%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	$1,231.48	$1,240.22	1%	$911.78	-26%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	$1,544.29	$1,550.36	0%	$1,139.79	-26%	NA	NA	NA	NA	NA
33533		Cabg arterial single	$1,950.35	$1,904.37	-2%	$1,400.04	-28%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	$1,112.35	$1,095.35	-2%	$805.28	-28%	NA	NA	NA	NA	NA
43239		Upper gi endoscopy biopsy	$174.61	$174.45	0%	$128.25	-27%	$351.61	$359.45	2%	$264.26	-25%
66821		After cataract laser surgery	$307.70	$324.76	6%	$238.76	-22%	$326.08	$344.15	6%	$253.01	-22%
66984		Cataract surg w/iol 1 stage	$760.74	$666.53	-12%	$490.02	-36%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	$504.10	$519.28	3%	$381.76	-24%	$523.84	$537.64	3%	$395.26	-25%
71010		Chest x-ray 1 view frontal	NA	NA	NA	NA	NA	$23.83	$23.80	0%	$17.50	-27%
71010	26	Chest x-ray 1 view frontal	$8.85	$8.84	0%	$6.50	-27%	$8.85	$8.84	0%	$6.50	-27%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	$112.32	$115.28	3%	$84.75	-25%
77056	26	Mammogram both breasts	$42.55	$42.17	-1%	$31.00	-27%	$42.55	$42.17	-1%	$31.00	-27%
77057		Mammogram screening	NA	NA	NA	NA	NA	$81.35	$82.30	1%	$60.50	-26%
77057	26	Mammogram screening	$34.38	$34.01	-1%	$25.00	-27%	$34.38	$34.01	-1%	$25.00	-27%
77427		Radiation tx management x5	$177.00	$178.19	1%	$131.00	-26%	$177.00	$178.19	1%	$131.00	-26%
88305	26	Tissue exam by pathologist	$36.08	$36.73	2%	$27.00	-25%	$36.08	$36.73	2%	$27.00	-25%
90935		Hemodialysis one evaluation	$72.84	$71.07	-2%	$52.25	-28%	NA	NA	NA	NA	NA
92012		Eye exam establish patient	$51.40	$53.05	3%	$39.00	-24%	$82.71	$87.40	6%	$64.25	-22%
92014		Eye exam&tx estab pt 1/>vst	$78.29	$80.26	3%	$59.00	-25%	$119.81	$126.16	5%	$92.75	-23%
93000		Electrocardiogram complete	NA	NA	NA	NA	NA	$19.06	$18.36	-4%	$13.50	-29%
93010		Electrocardiogram report	$8.51	$8.16	-4%	$6.00	-29%	$8.51	$8.16	-4%	$6.00	-29%
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	$88.50	$79.58	-10%	$58.50	-34%

93307	26	Tte w/o doppler complete	$45.95	$44.21	-4%	32.5	-29%	$45.95	$44.21	-4%	$32.50	-29%
93458	26	L hrt artery/ventricle angio	$315.87	$315.24	0%	$231.76	-27%	$315.87	$315.24	0%	$231.76	-27%
98941		Chiropract manj 3-4 regions	$30.63	$30.27	-1%	$22.25	-27%	$36.08	$36.39	1%	$26.75	-26%
99203		Office/outpatient visit new	$74.88	$74.81	0%	$55.00	-27%	$105.18	$107.80	2%	$79.25	-25%
99213		Office/outpatient visit est	$49.69	$49.65	0%	$36.50	-27%	$70.46	$72.43	3%	$53.25	-24%
99214		Office/outpatient visit est	$76.24	$76.51	0%	$56.25	-26%	$104.16	$106.44	2%	$78.25	-25%
99222		Initial hospital care	$133.09	$134.33	1%	$98.75	-26%	NA	NA	NA	NA	NA
99223		Initial hospital care	$195.38	$197.58	1%	$145.25	-26%	NA	NA	NA	NA	NA
99231		Subsequent hospital care	$38.12	$38.09	0%	$28.00	-27%	NA	NA	NA	NA	NA
99232		Subsequent hospital care	$69.78	$70.05	0%	$51.50	-26%	NA	NA	NA	NA	NA
99233		Subsequent hospital care	$100.07	$101.00	1%	$74.25	-26%	NA	NA	NA	NA	NA
99236		Observ/hosp same date	$212.05	$212.20	0%	$156.00	-26%	NA	NA	NA	NA	NA
99239		Hospital discharge day	$103.13	$104.40	1%	$76.75	-26%	NA	NA	NA	NA	NA
99283		Emergency dept visit	$60.25	$59.85	-1%	$44.00	-27%	NA	NA	NA	NA	NA
99284		Emergency dept visit	$114.71	$114.26	0%	$84.00	-27%	NA	NA	NA	NA	NA
99291		Critical care first hour	$217.16	$217.64	0%	$160.01	-26%	$267.20	$271.71	2%	$199.76	-25%
99292		Critical care addl 30 min	$108.92	$109.50	1%	$80.50	-26%	$119.47	$120.72	1%	$88.75	-26%
99348		Home visit est patient	NA	NA	NA	NA	NA	$ 82.03	$ 82.30	0%	$60.50	-26%
99350		Home visit est patient	NA	NA	NA	NA	NA	$ 171.21	$ 173.43	1%	$127.50	-26%
G0008		Immunization admin	NA	NA	NA	NA	NA	$ 24.17	$ 25.85	7%	$19.00	-21%

1 CPT codes and descriptions are copyright 2012American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

2 Payments based on the 2012 conversion factor of 34.0376

3 Payments based on the 2012 conversion factor of 34.0376, adjusted to 34.0066 to include the budget neutrality adjustment.

4 Payments based on the 2013 conversion factor of 25.0008, which includes the budget neutrality adjustment.

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D. Effect of Proposed Changes to Medicare Telehealth Services Under the PFS

As discussed in section III.E.3 of this final rule with comment period, we are finalizing our proposal to add several new codes to the list of Medicare telehealth services. While we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the additions.

E. Effect of Proposed Definition of Certified Registered Nurse Anesthetists' (CRNA) Services

As discussed in section III.K.1. of this final rule with comment period, we clarified that ''anesthesia and related care'', with respect to the statutory benefit category for CRNAs under Section 1861(bb)(2) of the Social Security Act, means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the service is furnished.

Our final rule clarification recognizes local variation in state scope of practice, which does not diverge significantly from current practice. Therefore, we estimate no significant budgetary impact from this proposed change.

F. Effects of Proposed Change to Ordering Requirements for Portable X-Ray Services Under the PFS

As discussed in section III.K.2. of this final rule with comment period, we are finalizing our proposal to revise our current regulation that limits ordering of portable x-ray services to only a doctor of medicine or a doctor of osteopathy to allow other physicians and nonphysician practitioners (acting within the scope of state law and their Medicare benefit) to order portable x-ray services. We estimated no significant impact on PFS expenditures from the additions.

G. Geographic Practice Cost Indices (GPCIs)

As discussed in section III.E. of this final rule with comment period, we are required to review and revise the GPCIs at least every 3 years and phase in the adjustment over 2 years (if there has not been an adjustment in the past year). For CY 2013, we did not propose any revisions related to the data or methodologies used to calculate the GPCIs. However, since the 1.0 work GPCI floor provided in section 1848 (e)(1)(E) of the Act is set to expire prior to the implementation of the CY 2013 PFS, the CY 2013 physician work GPCIs and summarized geographic adjustment factors (GAFs) published in addendums D and E of this CY 2013 PFS final rule with comment period do not reflect the 1.0 work GPCI floor for CY 2013. As required by section 1848 (e)(1)(G) and section1848 (e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are applicable in CY 2013.

H. Other Provisions of the Final Regulation

1. Ambulance Fee Schedule-

As discussed in section III.A. of this final rule with comment period, section 306 of the TPTCCA and section 3007 of the MCTRJCA required the extension of certain add-on payments for ground ambulance services, and the extension of certain rural area designations for purposes of air ambulance payment, through CY 2012. As further discussed in section III.A. of this final rule with comment period, this legislation is self-implementing, and we proposed to amend the regulation text at § 414.610 only to conform the regulations to these self-implementing statutory requirements. As a result, we did not make any policy proposals associated with these legislative provisions and there is no associated regulatory impact.

2. Part B Drug Payment: ASP Issues

As discussed in section III of this final rule with comment period, we proposed to update the AMP-based price substitution policy that would allow Medicare to pay based off lower market prices for those drugs and biologicals that consistently exceed the applicable threshold percentage. Our impact analysis is unchanged from last year (76 FR 73462): based on estimates published in various OIG reports cited in the CY 2012 PFS final rule with comment period (76 FR 73290–1), we believe that this proposal will generate minor savings for the Medicare program and its beneficiaries since any substituted prices would be for amounts less than the calculated 106 percent of the ASP.

Our policy clarification regarding Pharmacy Billing for Part B Drugs Administered Incident to a Physician's Services, which is discussed in section III of this final rule with comment period states that only physicians and not pharmacies (or DME suppliers) are allowed to bill Medicare under Part B for drugs administered to beneficiaries in physicians' offices. We do not believe that this clarification will significantly impact the quantity or payment amount for Part B drugs that are administered through implanted DME and or the procedures used to refill such pumps because it is a clarification of current policy.

3. Medicare Program; Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery

a. Overall Impact

The majority of changes regarding the impact between the proposed and the final result from the change in timeframe, from 90 days before the written order or 30 days after to six months before the written order. Moreover, the effective date for this regulation is July 1, 2013; therefore, only 6 months of year 1 (calendar year 2013) are included in this analysis. . We estimated the overall economic impact of this provision on the health care sector to be a cost of $30.2 million in the first year approximately half of which would be in CY 2013. The 5 year impact is $172.3 million. This overall impact is composed of additional administrative paperwork costs to private sector providers; a slight increase in Medicare spending, consisting of additional costs and some offsetting savings; and additional opportunity and out-of-pocket costs to Medicare beneficiaries. We believe there are likely to be other benefits and cost savings that result from the DME face-to-face requirement; however, many of those benefits cannot be quantified. For instance, we expect to see savings in the form of reduced fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (note that not all improper payments are fraudulent). Our detailed cost and benefit analysis is explained below. We specifically solicited comments on the potential increased costs and benefits associated with this provision.

The following is a summary of the comments we received regarding the potential increased costs and benefits associated with this provision.

Comment: Several commenters stated that if the belief is that fraud is on the physician/non-physician provider side, then having a strong rationale for the DME equipment in their encounter note should provide the paper trail to determine the medical need for the DME and establish the trail of the request and justification for each piece of DME. No additional paperwork would need to be transmitted and no interpretation of the encounter note (by non-clinician DME suppliers) would need to be done. The process could create a clear auditing trail for investigators.

Response: CMS appreciates these comments; however, CMS must implement the regulation based on the statutory requirement, which is to require a physician to document the occurrence of a face-to-face encounter for covered items of DME. Through the implementation of the statutory requirements and based on comments, CMS tried to balance the need to protect the trust fund and limit burden through many ways including the list of covered items and the documentation requirements.

Comment: Commenters appreciated CMS's efforts to reduce waste, fraud and abuse. Commenters stated that CMS should apply the new encounter and documentation requirements initially to a smaller number of HCPCS codes and first evaluate the impact of the requirements on beneficiary access to DME and costs to providers before expanding the list in the future.

Response: CMS believes that this is an important requirement aimed at reducing waste, fraud and abuse. CMS utilized a criterion driven approach to select these items and did not receive sufficiently detailed alternative criteria to those proposed to be implementable. CMS will monitor the effects of this requirement on reducing waste, fraud and abuse and monitor beneficiary access to care.

TABLE 137—OVERALL ECONOMIC IMPACT TO HEALTH SECTOR

[In millions]

	Year 1	5 years
Private Sector (Paperwork Cost)	$11.2	$ 64.8
Net Medicare impact of additional visits and G code billings	5	30
Beneficiaries	14.4	77.5
Total Economic Impact to Health Sector	30.6	172.3

Note: CY 2013 only includes the first 6 months of Year 1.

The definition of small entity in the RFA includes non-profit organizations. Most suppliers and providers are small entities as that term is used in the RFA. Likewise, the vast majority of physician and NP practices are considered small businesses according to the Small Business Administration's size standards with total revenues of $10 million or less in any 1 year. While the economic costs and benefits of this rule are substantial in the aggregate, the economic impacts on individual entities will be relatively small. We estimate that 90 to 95 percent of DME suppliers and practitioners who order DME are small entities under the RFA definition. Physicians and other professionals would receive extra payments for some of the costs imposed, and other costs (for example, for additional practitioner visits) would be reimbursed by Medicare under regular payment rules. The rationale behind requiring a face-to-face encounter is to reduce inappropriate claims from those DME suppliers who have been abusing or defrauding the program. The impact on these suppliers could be significant; however, since we believe that the purpose of the statute and this regulation is to reduce abusive and fraudulent DME sales, we do not view the burden placed on those providers and suppliers in the form of lost revenues as a condition that we must mitigate. We believe that the effect on legitimate suppliers and practitioners would be minimal.

Anticipated Effects

b. Costs

(1) Private Sector Paperwork Costs

We believe that most practitioners are already seeing the beneficiary no more than 6 months prior to the written order. However, this regulation potentially requires increased documentation.

Although we have no quantitative data for a specific dollar figure for the additional DME that may now be authorized in accordance with § 410.38(g), nor can we determine if there would be cost avoidance and a reduction of unnecessary DME, we acknowledge the potential for this provision to surpass the economically significant threshold. We do not believe that this final rule with comment period would significantly affect the number of legitimate written orders for DME. However, we would expect a decline in fraudulent, wasteful and abusive orders, thereby causing a decrease in the amount paid for DME overall.

The covered items of DME as outlined in III.C, including the list of specified covered items, contains items that meet at least one of the following four criteria: (1) Items that currently require a written order prior to delivery per instructions in our Program Integrity Manual; (2) items that cost more than $1,000; (3) items that we, based on our experience and recommendations from the DME MACs, believe are particularly susceptible to fraud, waste, and abuse; (4) items determined by CMS as vulnerable to fraud, waste and abuse based on reports of the HHS Office of Inspector General, the Government Accountability Office or other oversight entities. CMS will not include items on the covered list of items that are cited in statute explicitly as not having a face-to-face encounter requirement. A summary of comments regarding the criteria is available in III.C.

We also have estimated the number of different covered Medicare items subject to this final rule with comment period at approximately 155 HCPCS codes for items of DME. As new products enter the market this number could increase, which could increase the impact. In addition, we propose a G-code to pay physicians for documenting the encounter conducted by a PA, a NP, or a CNS.

We anticipated there would be an impact as a result of additional office visits for the face-to-face encounter and the additional time spent by physicians to document the face-to-face encounters with a beneficiary when it is furnished by a PA, a NP, or a CNS.

In our estimate of overall cost we included the estimates from section III, of this final rule with comment period (Collection of Information Requirements section). These are estimated at $11.2 million in year 1 and $ 64.8 million over 5 years. These are driven by the physician documenting face-to-face encounters with a beneficiary when it is furnished by a PA, a NP, or a CNS, including the time to communicate the practitioners' findings to physicians so they can complete the necessary documentation.

TABLE 138—PRIVATE SECTOR PAPERWORK COSTS

[In millions]

	Year 1	5 years
Physician time to document occurrence of a face-to-face encounter cost	$9.8	$57
PA, NP, or CNS costs	1.4	7.8
Total Cost	11.2	64.8

Note: CY 2013 only includes the first 6 months of Year 1.

(2) Medicare Costs

Medicare would incur additional costs associated with this final rule with comment period related to additional face-to-face encounters in the form of office visits, and additional payment for time spent documenting the face-to-face encounter if furnished by the PA, NP or CNS and not by the physician directly. Subsequently, a G-Code is being created to allow Medicare payment to physicians for documenting the face-to-face encounters that are furnished by a PA, NP, and CNS, and is included in this final rule with comment period.

From a programmatic standpoint we believe that there would be 375,000 additional office visits billed and 500,000 G code claims for the documentation in year 1. It is difficult to determine how many PAs, NPs or CNSs wrote orders for covered items of DME and while we lack exact empirical data, in order to provide an estimate, we assumed that 5 percent of the orders for covered items of DME were written by a PA, NP or CNS. For the purpose of this estimate, we assumed that each order requires a separate face-to-face encounter, recognizing fully that the estimate might be inflated.

While we believe that currently the majority of practitioners evaluate beneficiaries before ordering DME, some may not, and therefore, a certain number of beneficiaries would be required to have a new visit in order to fulfill the face-to-face encounter requirement. Actuarial estimates indicated approximately 2.5 percent of those obtaining covered items of DME in a given year did not see a practitioner in the 6 months preceding the order. This percentage changed due to the modified timeframe from the proposed rule. We estimated that 250,000 beneficiaries would not see their practitioners in the 6 months prior to the written order. We assumed that 1.5 visits per year per affected beneficiary would be required to cover the DME services that currently fail to meet the face-to-face requirement. The range would be about one to three; possibly less than one if many beneficiaries choose not to meet the requirement or reschedule services. DME claims for beneficiaries who failed to meet the physician contact requirements averaged 3 line items per beneficiary. However, about 40 percent of these line items occur on the same date and so probably refer to the same event and could be authorized during a single visit. Some additional coordination is probable for DME purchases within a narrow time frame. To estimate the impact of the additional office visits, we assumed 375,000 additional office visits (1.5 visits * 250,000 beneficiaries). We also assumed that the average cost for these office visits is around $65, which is consistent with a mid-level office visit under the PFS. This represents the total amount that the practitioners would receive, either from Medicare or the beneficiary, who is responsible for the 20 percent coinsurance.

Physicians are now required to document the face-to-face encounter if it was furnished by a PA, NP, or CNS. In order to allow payment for this documentation, a G code is established for this service. There are approximately 10 million DME users and it we assumed that roughly 5 percent of face-to-face encounters are actually furnished by these other practitioner types, thereby requiring documentation of the encounter. Therefore, we assumed that about 500,000 of these documentation services would be billed. As discussed in section III.M.3 of this final rule with comment period, we are establishing work and malpractice RVUs for HCPCS codes for G0454 by crosswalking to the work and malpractice RVUs for CPT code 99211 (Level 1 office or other outpatient visit, established patient). With regard to practice expense RVUs, we are not including any direct practice expense inputs for clinical labor, disposable medical supplies, or equipment in the direct PE input database for this code; practice expense RVUs will reflect resources for overhead costs only. The work, malpractice, and practice expense RVUs for HCPCS code G0454 are reflected in Addendum B of this CY 2013 PFS final rule with comment period *www.cms.gov/physicianfeesched/*. A complete list of the interim final times assigned to HCPCS code G0454 is available on the CMS Web site at *www.cms.gov/physicianfeesched/*. This represents the total amount that the physician would receive, either from Medicare or the beneficiary, who is responsible for the 20 percent coinsurance.

Therefore the estimated gross cost is estimated to be $10 million in CY 2013 and $115 million over 5 years; note that there are also savings to Medicare that must be netted against the cost of additional practitioner office visits, which are described later in the Benefits section. There is a high degree of uncertainty surrounding this estimate because it was difficult to predict how physicians and beneficiaries would respond to the new requirement.

This provision would assist in providing better documentation which may help to lower the error rate and thus reduce improper payments, including those stemming from waste, fraud and abuse. Since there is a large amount of potential variation in the amount of time that a face-to-face encounter may take for an item of DME, as a proxy our estimate is based on the amount of time needed for a mid-level visit to evaluate a beneficiary (E&M code 99213). The time allotted for this visit to furnish the face-to-face evaluation under a 99213 is 15 minutes. We solicited comments as to the appropriateness of E&M Code 99213 as a proxy measure of time required for a face-to-face encounter but did not receive any public comments.

Based on actual data, projecting these historical patterns in light of the draft regulation was not straight-forward. Some line items may be bundled (perhaps because they were used together). Beneficiaries may also change their behavior in response to the regulation. For example, beneficiaries who would be required to visit a physician in order for Medicare to pay for a new piece of equipment may substitute this visit for a later visit that would have been for a routine service. In this situation, the overall number of visits would not increase. Moreover, some beneficiaries may choose not to pursue the DME item at that time. On

the other hand, the final rule with comment period points out that some of the encounters reported on the practitioner claim now may not support the need for the item of DME. We assume that beneficiaries would decide not to schedule 10 percent of the additional visits required as a result of not needing the DME item and that some would substitute a required service for a later planned visit.

TABLE 139—MEDICARE 5-YEAR COSTS FOR ADDITIONAL FACE-TO-FACE VISITS AND G CODE BILLINGS

2013	2014	2015	2016	2017
$10	$25	$25	$25	$30

Note: These costs represent 80 percent of the allowed charges for the additional visits and the new G codes.

The requirement for a face-to-face encounter with a beneficiary in a certain time period as a condition of payment for DME is a new statutory requirement. It is not subject to the physician fee schedule budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. However, by regulation, we are making an additional payment through a new G-code for physician work documenting the face-to-face encounters that are performed by a PA, NP, and CNS. This additional regulatory spending is subject to the physician fee schedule budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act.

(c) Beneficiary Cost Impact

From a programmatic standpoint, approximately 2.5 percent of those obtaining covered items of DME in that year did not see a practitioner in the 6 months preceding the order. We estimated that 250,000 beneficiaries would not see their practitioners in the 6 months prior to the written order for the covered item. As mentioned above, we assumed that 1.5 visits per year per affected beneficiary would be required to cover the DME services that currently fail to meet the face-to-face requirement. The range would be about one to three; possibly less than one if many beneficiaries chose not to meet the requirement or reschedule services. DME claims for beneficiaries who failed to meet the physician contact requirements averaged 3 line items per beneficiary. However, about 40 percent of these line items occur on the same date and so probably refer to the same event and could be authorized during a single visit. Some additional coordination is probable for DME purchases within a narrow time frame. There are effects on travel time and cost for these beneficiaries. We estimate that there will be an additional 375,000 office visits as a number of beneficiaries would not have seen their practitioner in the six months prior to the written order for the covered item. If it takes a beneficiary 1.25 hours to go to a practitioner, the total estimate is approximately 468,750 hours of time for this final rule with comment period. We assumed that an average trip requires one hour and 15 minutes (1.25 hours) (45 minutes of round trip travel time and 30 minutes in the doctor's office—half for waiting and half for time with the staff). As a proxy we use $20 to estimate the cost per hour including loss of leisure time and travel cost for a beneficiary to see a practitioner. This is consistent with previous estimates of beneficiary leisure time as proposed in the May 4, 2011 proposed rule entitled ''Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Medicare & Medicaid Participating Providers and Suppliers'' (76 FR 25469). This creates an economic cost of nearly $9,375,000 in year 1 and $52.5 million over 5 years. There will be additional out of pocket expenses at the 20 percent Medicare Part B coinsurance. We estimated this cost to be $5 million in year 1 and $25 million over 5 years.

TABLE 140—BENEFICIARY COST IMPACT RESULTING FROM ADDITIONAL FACE-TO-FACE VISITS TO OBTAIN DME SERVICES

BENEFICIARY COST: OUT OF POCKET EXPENSE

[In millions]

2013	2014	2015	2016	2017
$5	$5	$5	$5	$5

	Year 1	5 Years
Total beneficiaries visits impacted	375,000	2,100,000.
Time per beneficiary	1.25 hours	1.25 hours.
Total Time	468,750	2,625,000.
Beneficiary Time Cost ($20)	$9.4 million	$52,500,000.
Out of Pocket Expense	$5 million	$25,000,000.
Estimated Total Beneficiary Cost Impact	$ 14.4 million	$ 77.5 million.

Note: These costs represent 20 percent of the allowed charges for the additional visits and the new G codes.

b. Benefits

There would be quantifiable benefits from an expected reduction in Medicare DME services provided. In addition, we anticipated additional, qualitative benefits from a decrease in waste, fraud, and abuse, which would decrease the number of services. Further, requiring that there be a face-to-face evaluation of the beneficiary helps ensure appropriate orders are based on the individual's medical condition, which increases the quality of care that the beneficiary receives. It is difficult to measure how much waste, fraud, and abuse will be prevented as a result of this final rule with comment period since it is impossible to determine what would have happened in the absence of the final rule with comment period. This provision is expected to improve physician's documentation of DME, and therefore, will help reduce improper payments and move the agency towards its strategic goal to reduce the Medicare fee-for-service error rate for DME items, which has a higher error rate than other Medicare services. Fraud is an improper payment, but not all improper payments are fraud.

Therefore, creating a measure of how much this final rule with comment period would save in terms of a reduction in waste, fraud and abuse is not possible. With that stated, in 2009 Medicare paid $1.7 billion for DME items covered by this proposed rule, and we estimated that $1.9 billion would be paid for covered items in 2012, and $9.9 billion over 5 years. Preventing waste, fraud and abuse by changing behavior that results in just a small percentage reduction in inappropriate or unnecessary ordering of DME services will generate Medicare savings. This is an area where savings

can be found through increased oversight We believe that the cost of the visits will be offset by the savings produced by this provision.

We project Medicare savings from reduced DME services; these savings partially offset the costs of additional physician office visits and documentation payments described earlier in the impact analysis. The year-to-year Medicare savings from reduced DME services is as follows:

TABLE 141—YEAR-TO-YEAR MEDICARE SAVINGS FROM REDUCED DME SERVICES

[In millions]

	2013	2014	2015	2016	2017
DME savings	−$5	−$20	−$20	−$20	−$20

Based on an analysis of 2007 DME claims, approximately 1 percent of total DME spending was for those beneficiaries who had little contact with their physician during the year. The gross savings to Medicare has been reduced from the estimated savings in the proposed rule due to the change in timeframe from 90 days to 6 months. We believe that some beneficiaries who would not order a DME service because they did not have face-to-face visit within 90 days prior to the written order, would likely have a face-to-face visit within the 6-month timeframe. For this subset of spending we assumed that there would be a 20 percent reduction in spending due to the face-to- face requirement. We found similar reductions in DME expenditures among managed care enrollees compared to fee-for service (FFS) beneficiaries in the Medical Expenditure Panel Survey. This assumption is fairly speculative but we think it is modest compared to the estimates of improper payments across Medicare services including DME. The savings would occur because some beneficiaries would not choose to go to the physician to authorize the DME item, some physicians would not order the items that would otherwise have been provided in the absence of the regulation, and some suppliers would not be able to achieve a payment that might have occurred through an unnecessary sale or outright fraud.

The overall net impact to Medicare of the DME face-to-face encounter policy is $5 million in the first year and $30 million over the first 5 years.

This regulation produced an extra benefit that is difficult to quantify, but is an extremely positive one in terms of greater practitioner involvement. By increasing practitioner interactions with beneficiaries before ordering DME, beneficiaries would receive more appropriate DME and benefit from higher quality care. Beneficiaries would also benefit from reduced out-of-pocket costs by not having to pay for unnecessary DME. This accomplished the objective of achieving greater practitioner accountability noted in the provisions of and the amendments made by section 6407 and other sections of the Affordable Care Act.

Alternatives Considered

In this final rule with comment period, we considered a variety of options and sought comments on these options in other sections of this final rule with comment period. We expected public comment on how to limit the burden associated with the supplier being notified that a face-to-face encounter has occurred. We proposed several options for the physician documentation of a face-to-face encounter furnished by that physician. We believe just submitting the medical record for the applicable date of service would create the least cost while still producing the desired benefits. We had also proposed different options for how the physician must document the face-to-face encounter if performed by a NP, PA, or CNS. In this final rule with comment period we establish that physicians must document a face-to-face encounter furnished by a PA, NP or CNS by signing or cosigning the pertinent portion of the medical record thereby documenting that the beneficiary was evaluated or treated for a condition relevant to an item of DME on that date of service.

Finally, there are other possible periods of time that could be set as the window within which face-to-face encounters must occur. We believe the 6 month timeframe for the face-to-face to occur helps to best limit burden.

4. Non-Random Prepayment Review

We estimated no significant budgetary impact. We believe that the overall costs for most providers and suppliers would remain the same unless they are subject to non-random prepayment complex medical review for an extended period of time.

5. Ambulance Coverage-Physician Certification Statement

We estimated no significant budgetary impact.

6. Physician Compare Web Site

Section IV.N.2. of this final rule with comment period addresses the background of the Physician Compare Web site. As described in section IV.N.2. of this final rule with comment period, we are developing aspects of the Physician Compare Web site using a phased approach. In the first phase, which was completed in 2011, we posted the names of those eligible professionals who satisfactorily participated in the 2009 Physician Quality Reporting System. The second phase of the plan, which was completed in 2012, included posting the names of eligible professionals who were successful electronic prescribers under the 2009 eRx Incentive Program, as well as eligible professionals (EPs) who participated in the EHR Incentive Program. The next phase of the plan included posting of performance information with respect to the 2012 Physician Quality Reporting System GPRO measures which is targeted to be completed in 2013.

We are finalizing proposals to include performance information for the 2013 Physician Quality Reporting System GPRO web interface measures data, and targeted posting this data in 2014, in addition to 2013 patient experience data for group practices participating in the 2013 Physician Quality Reporting System GPRO. As reporting of physician performance rates and patient experience data on the Physician Compare Web site would be performed directly by us using the data that we collect under the 2012 Physician Quality Reporting System GPRO and other data collection methods, we did not anticipate any notable impact on eligible professionals with respect to the posting of information on the Physician Compare Web site.

We invited but received no public comment on the Regulatory Impact Analysis related to Physician Compare and are therefore finalizing this analysis.

7. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

According to the 2010 Reporting Experience Report, a total of $391,635,495 in Physician Quality Reporting System (PQRS) incentives was paid by CMS for the 2010 program year, which encompassed 168,843 individual eligible professionals. In 2010, eligible professionals earned a 2.0 percent incentive (that is, a bonus payment equal to 2.0 percent of the total allowed part B charges for covered professional services under the PFS furnished by the eligible professional during the reporting period) for satisfactory reporting under the PQRS. For 2013 and 2014, eligible professionals can earn a 0.5 percent incentive for satisfactory reporting, a reduction of 1.5 percent from 2010. Therefore, based on 2010, which is the latest year in which PQRS has full participation data, we would expect that approximately $97 million (approximately ¼ of $391,635,495) in incentive payments would be distributed to eligible professionals who satisfactorily report. However, we expect that due to the implementation of payment adjustments beginning in 2015, participation in the PQRS would rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively.

The average incentive distributed to each eligible professional in 2010 was $2,157. Taking into account the 1.5 percent incentive reduction from 2.0 percent in 2010 to 0.5 percent in 2013 and 2014, we estimated that the average amount per eligible professional earning an incentive in 2013 and 2014 would be $539. Therefore, we estimate that the PQRS would distribute approximately $162 million ($539 × 300,000 eligible professionals) and $216 million ($539 × 400,000 eligible professionals) in incentive payments in 2013 and 2014, respectively. We believe these incentive payments will help offset the cost to eligible professionals for participating in the PQRS for the applicable year. Please note that, beginning 2015, incentive payments for satisfactory reporting in the PQRS will cease and payment adjustments for not satisfactorily reporting will commence.

We note that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assumed the following:

- The requirements for reporting for the PQRS 2013 and 2014 incentives and payment adjustments for 2015 and beyond would be established as proposed in this 2013 Medicare PFS final rule with comment period.
- For an eligible professional or group practice using the claims, registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice would report on 3 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

For an eligible professional who wished to participate in the PQRS as an individual, the eligible professional need not indicate his/her intent to participate, if using the traditional reporting mechanisms. The eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in the PQRS are based on the traditional reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review the PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in the PQRS would be approximately $80 ($16/hour × 5 hours).

Traditional Claims-Based Reporting Mechanism. With respect to an eligible professional who participates in the PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS collects QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN: 0938–0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continued to estimate that the time needed to perform all the steps necessary to report each measure via claims would range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 3 measures would range from 0.75 minutes to 36 minutes. Using an average labor cost of $40/hour, we estimated that time cost of reporting for an eligible professional via claims would range from $0.50 (0.75 minutes × $40/hour) to $24.00 (36 minutes × $40/hour) per reported case. With respect to how many cases an eligible professional would report when using the claims-based reporting mechanism, we established that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional would report would vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent, we found that the median number of reporting cases for each measure was 9. Since we reduced the reporting threshold to 50 percent, we estimated that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimated that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from ($0.50/per reported case × 6 reported cases) $3.00 to ($24.00/reported case × 6 reported cases) $144.

Administrative Claims-Based Reporting Mechanism. We note that, for the 2015 PQRS payment adjustments, we are finalizing an administrative claims reporting option for eligible professionals and group practices. The burden associated with reporting using the administrative claims reporting option is the time and effort associated with using this option. To submit quality measures data for PQRS using the administrative claims reporting option, an eligible professional or group practice would need to (1) register as an administrative claims reporter for the applicable payment adjustment and (2) report quality measures data. With respect to registration, we believe it would take approximately 2 hours to register for and to participate in PQRS as an administrative claims reporter. Therefore, we estimated that the cost of undergoing the GPRO selection process would be ($16/hour × 2 hours) $32. With respect to reporting, we noted that any burden associated with reporting would be negligible, as an eligible professional or group practice would not be required to attach reporting G-codes on the claims they submitted.

Rather, CMS would bear the burden with respect to calculating the measure rates for claims. We noted that there would be no additional burden on the eligible professional or group practice to submit these claims, as the eligible professional or group practice would have already submitted these claims for reimbursement purposes.

Registry-Based and EHR-Based Reporting Mechanisms. With respect to an eligible professional or group practice who participates in the PQRS via a qualified registry, direct EHR product, or EHR data submission vendor product, we believe there would be little to no burden associated for an eligible professional to report PQRS quality measures data to CMS, because the selected reporting mechanism submits the quality measures data for the eligible professional. While we note that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, or EHR data submission vendor, we believe that an eligible professional or group practice would not purchase a qualified registry, direct EHR product, or EHR data submission vendor product solely for the purpose of reporting PQRS quality measures. Therefore, we did not include the cost of purchasing a qualified registry, direct EHR, or EHR data submission vendor product in our burden estimates.

The Group Practice Reporting Option. Unlike eligible professionals who choose to report individually, we noted that eligible professionals choosing to participate as part of a group practice under the GPRO must indicate their intent to participate in the PQRS as a group practice. The total burden for group practices who submitted PQRS quality measures data via the proposed GPRO web-interface would be the time and effort associated with submitting this data. To submit quality measures data for the PQRS, a group practice would need to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in the PQRS as a group practice, we believe it would take approximately 6 hours—including 2 hours to decide whether to participate in the PQRS GPRO as a group practice, 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in the PQRS GPRO for the applicable year. Therefore, we estimated that the cost of undergoing the GPRO selection process would be ($16/hour × 6 hours) $96. With respect to reporting, the total reporting burden was the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimated the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimated that the report cost for a group practice to submit PQRS quality measures data for the final reporting options in an applicable year would be ($40/hour × 79 hours) $3,160.

Maintenance of Certification Program Incentive. Eligible professionals who wish to quality for an additional 0.5 percent Maintenance of Certification Program incentive must ''more frequently'' than is required to qualify for or maintain board certification status participate in a qualified Maintenance of Certification Program for 2013 and/or 2014 and successfully complete a qualified Maintenance of Certification Program practice assessment for the applicable year. Although we understand that there is a cost associated with participating in a Maintenance of Certification Board, we believe that most of the eligible professionals attempting to earn this additional incentive would already be enrolled in a Maintenance of Certification Board for reasons other than earning the additional Maintenance of Certification Program incentive. Therefore, the burden to earn this additional incentive would depend on what a certification board establishes as ''more frequently'' and the time needed to complete the practice assessment component. We expect that the amount of time needed to complete a qualified Maintenance of Certification Program practice assessment would be spread out over time since a quality improvement component is often required. With respect to the practice assessment component, according to an informal poll conducted by ABMS in 2012, the time an individual spent to complete the practice assessment component of the Maintenance of Certification ranged from 8–12 hours.

Registry and EHR Vendors. Aside from the burden of eligible professionals and group practices participating in the PQRS, we believe that registry, direct EHR, and EHR data submission vendor products incur costs associated with participating in the PQRS.

Registry Vendors. With respect to qualified registries, the total burden for qualified registries who submit PQRS quality measures data would be the time and effort associated with submitting this data. To submit quality measures data for the program years we are finalizing for PQRS, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process, we estimated that it will take a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report PQRS quality measures data. Therefore, we estimated that it would cost a registry approximately ($16.00/hour × 10 hours) $160 to become qualified to submit PQRS quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, we believe the burden associated with reporting was the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective of participating in the PQRS. Therefore, we believe there would be little to no additional burden associated with reporting PQRS quality measures data. Whether there is any additional reporting burden will vary with each registry, depending on the registry's level of savvy with submitting quality measures data for the PQRS.

EHR Vendors. With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit PQRS quality measures data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed program years under the PQRS, a direct EHR product or EHR data submission vendor would need to report quality measures data on behalf of its eligible professionals. Please note that we are not continuing to require direct EHR products and EHR data submission vendors to become qualified to submit PQRS quality measures data. With respect to reporting quality measures data, we believe the burden associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional must submit to CMS would depend on the vendor's familiarity with

the PQRS and the vendor's system and programming capabilities. We believe it would take a vendor approximately 40 hours (for experienced vendors) to 200 hours (for first-time vendor participants) to submit PQRS quality measures data. Therefore, we estimated that it would cost an EHR vendor ($40/hour × 40 hours) $1,600 to $8,000 to submit PQRS quality measures data for its eligible professionals.

TABLE 142—ESTIMATED COSTS FOR REPORTING PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES DATA FOR ELIGIBLE PROFESSIONALS

	Estimated hours	Estimated cases	Number of Measures	Hourly rate	Total cost
Individual Eligible Professional (EP): Preparation	5.0	1	N/A	$16	$80
Individual EP: Claims	0.2	6	3	40	144
Individual EP: Administrative Claims	2	1	N/A	16	32
Individual EP: Registry	N/A	1	N/A	N/A	(*)
Individual EP: EHR	N/A	1	N/A	N/A	(*)
Group Practice: Self-Nomination	6.0	1	N/A	16	96
Group Practice: Reporting	79	1	N/A	40	3,160

* Minimal.

TABLE 143—ESTIMATED COSTS TO VENDORS TO PARTICIPATE IN THE PHYSICIAN QUALITY REPORTING SYSTEM

	Estimated hours	Hourly rate	Total cost
Registry: Self-Nomination	10	$40	$400
EHR: Programming	40–200	40	1,600–1,800

We invited but received no public comment on the Regulatory Impact Analysis related to PQRS and are therefore finalizing this analysis.

8. Electronic Prescribing (eRx) Incentive Program

Please note that the requirements for becoming a successful electronic prescriber for the 2013 incentive and 2014 payment adjustment were established in the CY 2012 MPFS final rule with comment period. The final provisions contained in this CY 2013 MPFS final rule with comment period would make additional changes to the requirements for the 2013 incentive and 2014 payment adjustment for group practices. Specifically, CMS is finalizing a new criterion for being a successful electronic prescriber for the 2013 incentive and 2014 payment adjustments for group practices of 2–24 eligible professionals given that CMS is modifying the definition of group practice. However, we note that any additional impact as a result of this additional requirement would be minimal, as it is our understanding the eligible professionals who would use this new reporting option are already participating in the eRx Incentive Program as individual eligible professionals.

For the reasons stated, the final changes would have no additional impact other than the impact of the 2013 and 2014 payment adjustments described in the CY 2012 MPFS final rule with comment period. We invited but received no public comment on the Regulatory Impact Analysis related to the eRx Incentive Program and are therefore finalizing this analysis.

9. Medicare Shared Savings Program

Please note that the requirements for participating in the Medicare Shared Saving Program and the impacts of these requirements were established in the final rule for the Medicare Shared Savings Program that appeared in the **Federal Register** on November 2, 2011 (76 FR 67962). The requirements for the Medicare Shared Savings Program set forth in the CY 2013 MPFS final rule with comment period imposed requirements that eligible professionals in group practices within accountable care organizations would need to satisfy for purposes of the PQRS payment adjustment under the Medicare Shared Savings Program as the proposals related to the ACOs for the PQRS payment adjustment mirror the requirements that were established for earning the PQRS incentives.

We invited but received no public comment on the Regulatory Impact Analysis related to the Medicare Shared Savings Program and are therefore finalizing this analysis.

10. Medicare EHR Incentive Program

Please note that the requirements for reporting clinical quality measures (CQMs) to achieve meaningful use under the EHR Incentive Program were established in a standalone final rule published on July 28, 2010 (75 FR 44544) and September 4, 2012 (77 FR 53968). The requirements contained in this CY 2013 MPFS final rule with comment period merely propose methods to report CQMs for purposes of achieving meaningful use under the EHR Incentive Program. Therefore, the impacts of the extension of the use of attestation and the PQRS-Medicare EHR Incentive Pilot to report CQMs were absorbed in the impacts discussion published in the EHR Incentive Program final rules published on July 28, 2010 and September 4, 2012.

We invited but received no public comment on the Regulatory Impact Analysis related to The Medicare EHR Incentive Program and are therefore finalizing this analysis.

11. Chiropractic Services Demonstration

As discussed in section III of this final rule with comment period, we continue the recoupment of the $50 million in expenditures from this demonstration in order to satisfy the BN requirement in section 651(f)(1)(B) of the MMA. We initiated this recoupment in CY 2010 and this will be the fourth year. As discussed in the CY 2010 PFS final rule with comment period, we finalized a policy to recoup $10 million each year through adjustments to the PFS for all chiropractors in CY s 2010 through 2014. To implement this required BN adjustment, we are recouping $10 million in CY 2013 by reducing the payment amount under the PFS for the chiropractic CPT codes (that is, CPT codes 98940, 98941, and 98942) by approximately 2 percent.

12. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

The Physician Value-Based Payment Modifier and the Physician Feedback Program final policies discussed in section IV.I. of this final rule with comment period would not impact CY 2013 physician payments under the PFS. However, we expect that our proposals to use the PQRS quality measures in the Physician Feedback reports and in the value-based payment modifier to be implemented in CY 2015 may result in increased participation in the PQRS in CY 2013. We anticipate that as we approach implementation of the value-based payment modifier, physicians would increasingly participate in the PQRS to determine and understand how the value-based payment modifier could affect their payments.

13. Medicare Coverage of Hepatitis B Vaccine: Modification of High Risk Groups Eligible for Medicare Part B Coverage of Hepatitis B Vaccine

As discussed in section III of this final rule with comment period, section 1861(s)(10)(B) of the Act authorizes Medicare coverage of hepatitis B vaccine and its administration if furnished to an individual who is at high or intermediate risk of contracting hepatitis B, as determined by the Secretary under regulations. Our current regulations are established at 42 CFR 410.63. We proposed to modify § 410.63(a)(1) by adding persons diagnosed with diabetes mellitus to the high risk group. While it is estimated that approximately 23 percent of non-institutionalized Medicare beneficiaries are diagnosed with diabetes mellitus, it is unclear how many of these beneficiaries would obtain these services. Therefore, the estimated impact of adding persons diagnosed with diabetes mellitus to the high risk group eligible for coverage of hepatitis B vaccine and its administration is unknown for CY 2013.

14. Existing Standards for E-Prescribing Under Medicare Part D and Identification and Lifting the LTC Exemption

The e-prescribing standard updates that are adopted in this final rule with comment period impose no new requirements as the burden of using the updated standards is anticipated to be the same as using the old standards. We believe that prescribers and dispensers that are now e-prescribing largely invested in the hardware, software, and connectivity necessary to e-prescribe. We do not anticipate that the retirement of NCPDP SCRIPT 8.1 in favor of NCPDP SCRIPT 10.6 will result in significant costs. Nor do we believe that the eventual retirement of the NCPDP Formulary and Benefit 1.0 and the adoption of the updates for NCPDP Formulary and Benefits 3.0 as the official Part D standard will result in significant costs.

The removal of the LTC exception to the NCPDP SCRIPT standard would impose a small burden on the LTC industry. LTC entities who use and developed proprietary solutions may need to invest in software programming updates if they had not already incorporated the Part D e-prescribing standards in their solutions. It is reasonable to assume that a small number of proprietary solutions would have to be modified to enable adherence to the adopted e-prescribing standards. Other costs may be incurred through staff training on the use of the e-prescribing standards and the use of any e-prescribing solution adopted by a LTC facility. Additional training cost may involve prescribers and dispensers learning the new workflows that an electronic prescription may or may not require.

I. Alternatives Considered

This final rule with comment period contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provided descriptions of the statutory provisions that are addressed, identified those policies when discretion has been exercised, presented rationale for our final policies and, where relevant, alternatives that were considered.

J. Impact on Beneficiaries

There are a number of changes in this final rule with comment period that would have an effect on beneficiaries. In general, we believe that many of the changes adopted in this final rule with comment period, including the refinements of the PQRS with its focus on measuring, submitting, and analyzing quality data; establishing the value-based payment modifier to adjust physician payment beginning in CY 2015; creating a separate payment for post-discharge transitional care management services in the 30 days after a beneficiary has been discharged from an inpatient hospital admission, from outpatient observation services and partial hospitalization program, from a SNF, or from a CMHC; improved accuracy in payment through revisions to the inputs used to calculate payments under the PFS for certain radiation therapy services; capital interest rate assumptions; multiple procedure payment reduction for ophthalmology and cardiovascular diagnostic tests; revised values for many services identified through the misvalued codes initiative, and revisions to payment for Part B drugs would have a positive impact and improve the quality and value of care furnished to Medicare beneficiaries.

Most of the aforementioned policy changes could result in a change in beneficiary liability as it relates to coinsurance (which is 20 percent of the fee schedule amount if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 136, the CY 2012 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $105.18 which means that in CY 2012 a beneficiary would be responsible for 20 percent of this amount, or $21.04. Based on this final rule with comment period, using the current (CY 2012) CF of 34.0376, the CY 2013 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 136, is $107.80, which means that, in CY 2013, the proposed beneficiary coinsurance for this service would be $21.56. Payment amounts and associated coinsurance would be lower using the current law CY 2013 CF with the negative SGR adjustment.

The transitional care management policy would also have an impact on beneficiary coinsurance for those beneficiaries who have a hospital visit in CY 2013 and require moderate to high complexity decision-making by their community physician in the 30 days post discharge. Prior to the new TCM policy discussed in section III.H. of this final rule with comment period such a recently discharged beneficiary may have had an established patient follow-up visit with their community physician. The CY 2013 national payment amount in the nonfacility setting for CPT code 99215 (Office/outpatient visit, established), the highest level of an established patient office visit, is $142.96, which means that a beneficiary would be responsible for 20 percent of this amount, or $28.59. Under the new transitional care management policy, if a beneficiary received the highest level transitional care management visit, 99496, which has a national payment amount of $231.11, the beneficiary would be responsible for 20 percent of this amount, or $46.22

K. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.*

gov/omb/circulars/a004/a-4.pdf), in Tables 144 and 145 (Accounting Statement), we have prepared an accounting statement showing the estimated expenditures associated with this final rule with comment period. This estimate includes the estimated FY 2012 cash benefit impact associated with certain Affordable Care Act and MCTRJCA provisions, and the CY 2013 incurred benefit impact associated with the estimated CY 2013 PFS conversion factor update based on the Mid-Session Review of the FY 2013 President's Budget baseline.

TABLE 144—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2013 Annualized Monetized Transfers	Estimated decrease in expenditures of $24.8 billion for PFS conversion factor update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2013 Annualized Monetized Transfers	Estimated increase in payment of 162 millions.
From Whom To Whom?	Federal Government to eligible professionals participated in (Physician Quality Reporting System (PQRS)).

TABLE 145—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS IN CY 2013

[$ in millions]

Category	Benefit
Qualitative (unquantified) benefits of fraud, waste, and abuse prevented, and of improved quality of services to patients.	No precise estimate available.
Category	**Cost**
Costs associated with DME face-to-face encounters and written orders prior to delivery.	$30.6 million.*
Qualitative costs of reporting PQRS quality measures data for eligible professionals and for vendors to participate in the PQRS.	No precise estimate available.

* It includes the monetized costs of beneficiary travel time ($9.4 million), out of pocket expenses ($5 million), private sector paperwork costs ($11.2 million), and the increased Medicare payment to the providers associated with the additional visits and G code billings ($5 million).

L. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial ''Regulatory Flexibility Analysis.''

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Incorporation by reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amend 42 CFR chapters IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

■ 2. Section 410.26 is amended by adding new paragraph (b)(8) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

* * * * *

(b) * * *

(8) Claims for drugs payable administered by a physician as defined in section 1861(r) of the Social Security Act to refill an implanted item of DME may only be paid under Part B to the physician as a drug incident to a physician's service under section 1861(s)(2)(A). These drugs are not payable to a pharmacy/supplier as DME under section 1861(s)(6) of the Act.

* * * * *

■ 3. Section 410.32 is amended by—

■ A. Revising paragraphs (b)(2)(iii) introductory text, (d)(2)(i), and (e).

■ B. Redesignating paragraphs (c)(2) and (c)(3) as paragraphs (c)(3) and (c)(4), respectively.
■ C. Adding new paragraph (c)(2).

The revisions and addition read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(2) * * *

(iii) Diagnostic psychological and neuropsychological testing services when—

* * * * *

(c) * * *

(2) These services are ordered by a physician as provided in paragraph (a) or by a nonphysician practitioner as provided in paragraph (a)(2) of this section.

* * * * *

(d) * * *

(2) * * *

(i) *Ordering the service.* The physician or (qualified nonphysican practitioner, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

* * * * *

(e) Diagnostic laboratory tests furnished in hospitals and CAHs. The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

§ 410.37 [Amended.]

■ 4. Amend § 410.37 by—
■ A. Amending paragraph (a)(1)(iii) by removing the phrase ''In the case of an individual at high risk for colorectal cancer,'' and by removing ''screening'' and adding ''Screening'' in its place.
■ B. Removing paragraph (g)(1).
■ C. Redesignating paragraphs (g)(2) through (g)(4) as paragraph (g)(1) through (g)(3), respectively.
■ D. In newly redesignated paragraph (g)(1), removing the reference ''(g)(4)'' and adding in its place the reference ''(g)(3)''.

■ 5. Section 410.38 is amended by revising paragraph (g) to read as follows:

§ 410.38 Durable medical equipment: Scope and conditions.

* * * * *

(g)(1) *Items requiring a written order.* As a condition of payment, Specified Covered Items (as described in paragraph (g)(2) of this section) require a written order that meets the requirements in paragraphs (g)(3) and (4) of this section before delivery of the item.

(2) *Specified covered items.* (i) Specified Covered Items are items of durable medical equipment that CMS has specified in accordance with section 1834(a)(11)(B)(i) of the Act. A list of these items is updated annually in the **Federal Register**.

(ii) The list of Specified Covered Items includes the following:

(A) Any item described by a *Healthcare Common Procedure Coding System (HCPCS)* code for the following types of durable medical equipment:

(*1*) Transcutaneous electrical nerve stimulation (TENS) unit.

(*2*) Rollabout chair.

(*3*) Oxygen and respiratory equipment.

(*4*) Hospital beds and accessories.

(*5*) Traction-cervical.

(B) Any item of durable medical equipment that appears on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule with a price ceiling at or greater than $1,000.

(C) Any other item of durable medical equipment that CMS adds to the list of Specified Covered Items through the notice and comment rulemaking process in order to reduce the risk of fraud, waste, and abuse.

(iii) The list of specific covered items excludes the following:

(A) Any item that is no longer covered by Medicare.

(B) Any HCPCS code that is discontinued.

(3) *Face-to-face encounter requirements.* (i) For orders issued in accordance with paragraphs (g)(1) and (2) of this section, as a condition of payment for the Specified Covered Item, all of the following must occur:

(A) The physician must document and communicate to the DME supplier that the physician or a physician assistant, a nurse practitioner, or a clinical nurse specialist has had a face-to-face encounter with the beneficiary on the date of the written order up to 6 months before the date of the written order.

(B) During the face-to-face encounter the physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist must conduct a needs assessment, evaluate, and/or treat the beneficiary for the medical condition that supports the need for each covered item of DME ordered.

(C) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans or other information as it may be appropriate). Physician must sign or cosign the pertinent portion of the medical record indicating the occurrence of a face-to-face encounter for the beneficiary for the date of the face-to-face encounter when performed by a physician assistant, a nurse practitioner, or a clinical nurse specialist. For purposes of this paragraph (g), a face-to-face encounter does not include DME items and services furnished from an ''incident to'' service.

(ii) For purposes of this paragraph (g), a face-to-face encounter may occur via telehealth in accordance with all of the following:

(A) Section 1834(m) of the Act.

(B)(*1*) Medicare telehealth regulations in § 410.78 and § 414.65 of this chapter; and

(*2*) Subject to the list of payable Medicare telehealth services established by the applicable PFS.

(4) *Written order issuance requirements.* Written orders issued in accordance with paragraphs (g)(1) and (2) of this section must include all of the following:

(i) Beneficiary's name.

(ii) Item of DME ordered.

(iii) Signature of the prescribing practitioner.

(iv) Prescribing practitioner NPI.

(v) The date of the order.

(5) *Supplier's order and documentation requirements.* (i) A supplier must maintain the written order and the supporting documentation provided by the physician, physician assistant, nurse practitioner, or clinical nurse specialist and make them available to CMS upon request for 7 years from the date of service consistent with § 424.516(f) of this chapter.

(ii) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and substantiate that a face-to-face encounter has occurred.

■ 6. Section 410.40 is amended by—
■ A. In paragraph (c)(3)(ii), the word ''fro'' is revised to read ''from.''
■ B. Redesignating paragraph (d)(2) as (d)(2)(i).
■ C. Adding paragraph (d)(2)(ii).

The addition reads as follows:

§ 410.40 Coverage of ambulance services.

* * * * *

(d) * * *

(2) * * *

(ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the signed physician certification statement does not alone demonstrate that the ambulance

transport was medically necessary. All other program criteria must be met in order for payment to be made.

* * * * *

■ 7. Section 410.59 is amended by adding paragraph (a)(4) to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(4) Claims submitted for furnished services contain prescribed information on patient functional limitations.

* * * * *

■ 8. Section 410.60 is amended by adding paragraph (a)(4) to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(4) Claims submitted for furnished services contain prescribed information on patient functional limitations.

* * * * *

■ 9. Section 410.61 is amended by revising paragraph (c) to read as follows:

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

* * * * *

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals that are consistent with the patient function reporting on claims for services.

* * * * *

■ 10. Section 410.62 is amended by adding paragraph (a)(4) to read as follows:

§ 410.62 Outpatient speech-language-pathology services: Conditions and exclusions.

(a) * * *

(4) Claims submitted for furnished services contain prescribed information on patient functional limitations.

* * * * *

■ 11. Section 410.63 is amended by—

■ A. Removing ''and'' from the end of paragraph (a)(1)(vi).

■ B. Removing the period from the end of paragraph (a)(1)(vii) and adding ''; and'' in its place.

■ C. Adding paragraph (a)(1)(viii).

The addition reads as follows:

§ 410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

* * * * *

(a) * * *

(1) * * *

(viii) Persons diagnosed with diabetes mellitus.

* * * * *

■ 12. Section 410.69 is amended in paragraph (b) by adding the definition of ''Anesthesia and related care'' in alphabetical order to read as follows:

§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

* * * * *

(b) * * *

Anesthesia and related care means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished.

* * * * *

■ 13. Section 410.78 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) *General rule.* Medicare Part B pays for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every 3 days by the patient's admitting physician or practitioner), subsequent nursing facility care services (not including the Federally-mandated periodic visits under § 483.40(c) of this chapter and with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention services, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, and behavioral counseling for obesity furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

■ 14. Section 410.105 is amended by—

■ A. Revising paragraph (c)(1)(ii).

■ B. Adding new paragraph (d).

The revision and addition read as follows:

§ 410.105 Requirement for coverage of CORF services.

* * * * *

(c) * * *

(1) * * *

(ii) Prescribes the type, amount, frequency, and duration of the services to be furnished, and indicates the diagnosis and anticipated rehabilitation goals that are consistent with the patient function reporting on the claims for services.

* * * * *

(d) Claims submitted for physical therapy, occupational therapy or speech-language-pathology services, contain prescribed information on patient functional limitations.

■ 15. Section 410.160 is amended by revising paragraph (b)(8) to read as follows:

§ 410.160 Part B annual deductible.

* * * * *

(b) * * *

(8) Beginning January 1, 2011, a surgical service furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal cancer screening test. A surgical service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test means—a surgical service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 16. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 17. Section 414.65 is amended by revising paragraph (a)(1) to read as follows:

§ 414.65 Payment for telehealth services.

(a) * * *

(1) The Medicare payment amount for office or other outpatient visits, subsequent hospital care services (with

the limitation of one telehealth visit every 3 days by the patient's admitting physician or practitioner), subsequent nursing facility care services (with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, and behavioral counseling for obesity furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

(i) *Emergency department or initial inpatient telehealth consultations.* The Medicare payment amount for emergency department or initial inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to initial hospital care provided by a physician or practitioner.

(ii) *Follow-up inpatient telehealth consultations.* The Medicare payment amount for follow-up inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to subsequent hospital care provided by a physician or practitioner.

* * * * *

■ 18. Section 414.90 is amended by—

■ A. In paragraph (b), revising the definitions ''Group practice'' and ''Qualified registry.''

■ B. In paragraph (b), removing the term ''Qualified electronic health record product''.

■ C. In paragraph (b), adding the definitions ''Administrative claims,'' ''Direct electronic health record (EHR) product,'' ''Electronic health record (EHR) data submission vendor product,'' and ''Group practice reporting option (GPRO) web interface'' in alphabetical order.

■ D. Revising paragraphs (c) and (d).

■ E. Redesignating paragraphs (e), (f), (g), (h), (i), and (j) as paragraphs (f), (g), (i), (j), (k), and (l), respectively.

■ F. Adding new paragraphs (e) and (h).

■ G. Revising newly designated paragraphs (f), (g), (i), and (j).

The revisions and additions read as follows:

§ 414.90 Physician Quality Reporting System.

* * * * *

(b) * * *

Administrative claims means a reporting mechanism under which an eligible professional or group practice uses claims to report data on the proposed PQRS quality measures. Under this reporting mechanism, CMS analyzes claims data to determine which measures an eligible professional or group practice reports.

Direct electronic health record (EHR) product means an electronic health record vendor's product and version that submits data on Physician Quality Reporting System measures directly to CMS.

Electronic health record (EHR) data submission vendor product means an entity that receives and transmits data on Physician Quality Reporting System measures from an EHR product to CMS.

* * * * *

Group practice means a physician group practice that is defined by a TIN, with 2 or more individual eligible professionals (or, as identified by NPIs) that has reassigned their billing rights to the TIN.

Group practice reporting option (GPRO) web interface means a web product developed by CMS that is used by group practices that are selected to participate in the group practice reporting option (GPRO) to submit data on Physician Quality Reporting System quality measures.

* * * * *

Qualified registry means a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the Physician Quality Reporting System qualification requirements specified by CMS for that program year. The registry may act as a data submission vendor, which has the requisite legal authority to provide Physician Quality Reporting System data (as specified by CMS) on behalf of an eligible professional to CMS. If CMS finds that a qualified registry submits grossly inaccurate data for reporting periods occurring in a particular year, CMS reserves the right to disqualify a registry for reporting periods occurring in the subsequent year.

* * * * *

(c) *Incentive payments.* For 2007 to 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, an eligible professional (or in the case of a group practice under paragraph (i) of this section, a group practice) may receive an incentive if—

(1) There are any quality measures that have been established under the Physician Quality Reporting System that are applicable to any such services furnished by such professional (or in the case of a group practice under paragraph (i) of this section, such group practice) for such reporting period; and

(2) If the eligible professional (or in the case of a group practice under paragraph (j) of this section, the group practice) satisfactorily submits (as determined under paragraph (g) of this section for the eligible professional and paragraph (i) of this section for the group practice) to the Secretary data on such quality measures in accordance with the Physician Quality Reporting System for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act or, in the case of a group practice under paragraph (i) of this section, to the group practice) from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable quality percent (as specified in paragraph (c)(3) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (i) of this section, by the group practice) during the reporting period.

(3) The applicable quality percent is as follows:

(i) For 2007 and 2008, 1.5 percent.

(ii) For 2009 and 2010, 2.0 percent.

(iii) For 2011, 1.0 percent.

(iv) For 2012, 2013, and 2014, 0.5 percent.

(4) For purposes of this paragraph (c)—

(i) The eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(ii) In the case of the eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(iii) Incentive payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the Physician Quality Reporting System to eligible professionals in the group practice for meeting the criteria for satisfactory reporting for individual eligible professionals. For any program year in which the group practice (as identified by the TIN) is selected to participate in the Physician Quality Reporting System group practice reporting option, the eligible professional cannot individually qualify for a Physician Quality Reporting System incentive payment by meeting the requirements specified in paragraph (g) of this section.

(iv) Incentive payments earned by the eligible professional (or in the case of a group practice under paragraph (i) of this section, by the group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(d) *Additional incentive payment.* Through 2014, if an eligible professional meets the requirements described in paragraph (d)(2) of this section, the applicable percent for such year, as described in paragraphs (c)(3)(iii) and (iv) of this section, must be increased by 0.5 percentage points.

(1) In order to qualify for the additional incentive payment described in paragraph (d) of this section, an eligible professional must meet all of the following requirements:

(i) Satisfactorily submits data on quality measures for purposes of this section for the applicable incentive year.

(ii) Have such data submitted on their behalf through a Maintenance of Certification program (as defined in paragraph (b) of this section) that meets:

(A) The criteria for a registry (as specified by CMS); or

(B) An alternative form and manner determined appropriate by the Secretary.

(iii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

(A) Participates in a maintenance of certification program (as defined in paragraph (b) of this section) for a year; and

(B) Successfully completes a qualified maintenance of certification program practice assessment (as defined in paragraph (b) of this section) for such year.

(2) In order for an eligible professional to receive the additional incentive payment, a Maintenance of Certification Program must submit to the Secretary, on behalf of the eligible professional, information—

(i) In a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of paragraph (d)(1)(iii) of this section, which may be in the form of a structural measure.

(ii) If requested by the Secretary, on the survey of patient experience with care.

(iii) As the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(e) *Payment adjustments.* For 2015 and subsequent years, with respect to covered professional services furnished by an eligible professional, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under section 1848(m)(3)(A) of the Act), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes for determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection.

(1) The applicable percent is as follows:

(i) For 2015, 98.5 percent; and

(ii) For 2016 and each subsequent year, 98 percent.

(2) [Reserved.]

(f) *Use of consensus-based quality measures.* For measures selected for inclusion in the Physician Quality Reporting System quality measure set, CMS will use consensus-based quality measures that meet one of the following criteria:

(1) Be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act.

(2) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(3) For each quality measure adopted by the Secretary under this paragraph, the Secretary ensures that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of quality measures applicable to services they furnish.

(g) *Requirements for the incentive payments.* In order to qualify to earn a Physician Quality Reporting System incentive payment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, (or in the case of a group practice under paragraph (i) of this section, by the group practice) must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups identified by CMS during a reporting period specified in paragraph (g)(1) of this section and using one of the reporting mechanisms specified in paragraph (g)(2) or (g)(3) of this section.

(1) *Reporting periods.* For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 of such program year.

(ii) A 6-month period from July 1 through December 31 of such program year.

(A) For 2011, such 6-month reporting period is not available for EHR-based reporting of individual Physician Quality Reporting System quality measures.

(B) For 2012 and subsequent program years, such 6-month reporting period from July 1 through December 31 of such program year is only available for registry-based reporting of Physician Quality Reporting System measures groups by eligible professionals.

(2) *Reporting mechanisms for individual eligible professionals.* An individual eligible professional who wishes to participate in the Physician Quality Reporting System must report information on Physician Quality Reporting System quality measures identified by CMS in one of the following manners:

(i) *Claims.* Reporting Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on individual Physician Quality Reporting System measures or measures groups.

(B) [Reserved]

(ii) *Registry.* Reporting Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to a qualified registry (as specified in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* Reporting Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* Reporting Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) Although an eligible professional may attempt to qualify for the Physician Quality Reporting System incentive payment by reporting on both individual Physician Quality Reporting System quality measures and measures groups, using more than one reporting mechanism (as specified in paragraph (g)(2) of this section), or reporting for more than one reporting period, he or she will receive only one Physician Quality Reporting System incentive payment per TIN/NPI combination for a program year.

(3) *Reporting mechanisms for group practices.* A group practice (as defined in paragraph (b) of this section) who wishes to participate in the Physician Quality Reporting System must report information on Physician Quality Reporting System quality measures identified by CMS in one of the following manners:

(i) *Web interface.* For 2013 and subsequent years, reporting Physician Quality Reporting System quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.

(ii) *Registry.* For 2013 and subsequent years, reporting on Physician Quality Reporting System quality measures to a qualified registry (as specified in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* For 2014 and subsequent years, reporting Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* For 2014 and subsequent years, reporting Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) Although a group practice may attempt to qualify for the Physician Quality Reporting System incentive payment by using more than one reporting mechanism (as specified in paragraph (g)(3) of this section), or reporting for more than one reporting period, the group practice will receive only one Physician Quality Reporting System incentive payment for a program year.

(h) *Requirements for the payment adjustments.* In order to satisfy the requirements for the Physician Quality Reporting System payment adjustment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination (or in the case of a group practice under paragraph (i) of this section, by the group practice) must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual Physician Quality Reporting System measures or Physician Quality Reporting System measures groups identified by CMS during a reporting period specified in paragraph (h)(1) of this section and using one of the reporting mechanisms specified in paragraph (h)(2) or (h)(3) of this section.

(1) For purposes of this paragraph (h), the reporting period for the payment adjustment, with respect to a payment adjustment year, is the 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.

(i) For the 2015 and 2016 PQRS payment adjustments only, an alternative 6-month reporting period, from July 1–December 31 that fall 2 years prior to the year in which the payment adjustment is applied, is also available.

(ii) [Reserved]

(2) *Reporting mechanisms for individual eligible professionals.* An individual eligible professional participating in the Physician Quality Reporting System must report information on Physician Quality Reporting System quality measures identified by CMS in one of the following manners:

(i) *Claims.* Reporting Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on individual Physician Quality Reporting System measures or measures groups.

(B) [Reserved]

(ii) *Registry.* Reporting Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to a qualified registry (as specified in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* Reporting Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* Reporting Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) *Administrative claims.* For 2015, reporting data on Physician Quality Reporting System quality measures via administrative claims during the applicable reporting period. Eligible professionals that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Elect to participate in the Physician Quality Reporting System using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the eligible professional has performed services applicable to certain individual Physician Quality Reporting System quality measures.

(3) *Reporting mechanisms for group practices.* A group practice (as defined in paragraph (b) of this section) participating in the Physician Quality Reporting System must report information on Physician Quality Reporting System quality measures identified by CMS in one of the following manners:

(i) *Web interface.* For the 2015 payment adjustment and subsequent payment adjustments, reporting Physician Quality Reporting System quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.

(ii) *Registry.* For the 2015 subsequent adjustment and subsequent payment adjustments, reporting on Physician Quality Reporting System quality measures to a qualified registry (as specified in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* For the 2016 subsequent adjustment and subsequent payment adjustments, reporting Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* For the 2016 subsequent adjustment and subsequent payment adjustments, reporting Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the group practice during the applicable reporting period.

(v) *Administrative claims.* For 2015, reporting data on Physician Quality Reporting System quality measures via administrative claims during the applicable reporting period. Group practices that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Elect to participate in the Physician Quality Reporting System using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the group practice has performed services applicable to certain individual Physician Quality Reporting System quality measures.

(i) *Requirements for group practices.* Under the Physician Quality Reporting System, a group practice (as defined in paragraph (b) of this section) must meet all of the following requirements:

(1) Meet the participation requirements specified by CMS for the Physician Quality Reporting System group practice reporting option.

(2) Report measures in the form and manner specified by CMS.

(3) Meet other requirements for satisfactory reporting specified by CMS.

(4) Meet other requirements for satisfactory reporting specified by CMS.

(5) Meet participation requirements.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a group practice (as identified by the TIN) selected to participate in the Physician Quality Reporting System group practice reporting option for a program year, then for that program year the eligible professional must participate in the Physician Quality Reporting System via the group practice reporting option.

(ii) If, for the program year, the eligible professional participates in the Physician Quality Reporting System as part of a group practice (as identified by the TIN) that is not selected to participate in the Physician Quality Reporting System group practice reporting option for that program year, then the eligible professional may individually participate and qualify for a Physician Quality Reporting System incentive by meeting the requirements specified in paragraph (g) of this section under that TIN.

(j) *Informal review.* Eligible professionals (or in the case of reporting under paragraph (g) of this section, group practices) may seek an informal review of the determination that an eligible professional (or in the case of reporting under paragraph (g) of this section, group practices) did not satisfactorily submit data on quality measures under the Physician Quality Reporting System.

(1) To request an informal review for the PQRS incentives, an eligible professional (or in the case of reporting under paragraph (g) of this section, group practices) must submit a request to CMS via the Web within 90 days of the release of the feedback reports. The request must be submitted in writing or via email and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(i) CMS will provide a written response within 90 days of the receipt of the original request.

(ii) All decisions based on the informal review will be final.

(iii) There will be no further review or appeal.

(2) To request an informal review for the PQRS payment adjustments, an eligible professional or group practices must submit a request to CMS via the Web by February 28 of the year in which the eligible professional is receiving the applicable payment adjustment. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(i) CMS will provide a timely, written response after the receipt of the original request.

(ii) All decisions based on the informal review will be final.

(iii) There will be no further review or appeal.

* * * * *

■ 19. Section 414.92 is amended by—

■ A. Revising paragraphs (c)(2)(ii)(A)(*5*) and (c)(2)(ii)(A)(*6*).

■ B. Adding paragraph (f)(2)(i)(A) and adding and reserving paragraph (f)(2)(i)(B).

■ C. Redesignating paragraph (g) as paragraph (h), and adding new paragraph (g).

The revision and addition reads as follows:

§ 414.92 Electronic Prescribing Incentive Program.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(A) * * *

(*5*) Eligible professionals who achieve meaningful use during the respective 6 or 12-month payment adjustment reporting periods.

(*6*) Eligible professionals who have registered to participate in the EHR Incentive Program and adopted Certified EHR Technology prior to application of the respective payment adjustment.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on the electronic prescribing measure.

(B) [Reserved]

* * * * *

(g) *Informal review.* Eligible professionals (or in the case of reporting under paragraph (e) of this section, group practices) may seek an informal review of the determination that an eligible professional (or in the case of reporting under paragraph (e) of this section, group practices) did not meet the requirements for the 2012 and 2013 incentives or the 2013 and 2014 payment adjustments.

(1) To request an informal review for the 2012 and 2013 incentives, an eligible professional or group practice must submit a request to CMS via email within 90 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(2) To request an informal review for the 2013 and 2014 payment adjustments, an eligible professional or group practices must submit a request to CMS via email by February 28 of the year in which the eligible professional is receiving the applicable payment adjustment. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(3) CMS will provide a written response of CMS' determination.

(i) All decisions based on the informal review will be final.

(ii) There will be no further review or appeal.

* * * * *

■ 20. Section 414.610 is amended by revising paragraphs (c)(1)(ii), (c)(5)(ii), and (h) to read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2012, ambulance services originating in—

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section; and

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 3 percent higher than otherwise is applicable under this section.

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through December 31, 2012, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2012.

■ 21. Section 414.904 is amended by revising paragraphs (d)(3)(ii), (d)(3)(iii), and (d)(3)(iv) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(d) * * *

(3) * * *

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when all of the following criteria are met:

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met.

(B) 103 percent of the average manufacturer price is less than the 106 percent of the average sales price for the quarter in which the substitution would be applied.

(C) Beginning in 2013, the drug and dosage form described by the HCPCS code is not identified by the FDA to be in short supply at the time that ASP calculations are finalized.

(iii) The applicable percentage threshold for average manufacturer price comparisons is 5 percent and is reached when—

(A) The average sales price for the billing code has exceeded the average manufacturer price for the billing code by 5 percent or more in 2 consecutive quarters, or 3 of the previous 4 quarters immediately preceding the quarter to which the price substitution would be applied; and

(B) The average manufacturer price for the billing code is calculated using the same set of National Drug Codes used for the average sales price for the billing code.

(iv) The applicable percentage threshold for widely available market price comparisons is 5 percent.

* * * * *

■ 22. Subpart N is added to Part 414 to read as follows:

Subpart N—Value-Based Payment Modifier Under the Physician Fee Schedule

Sec.
414.1200 Basis and scope.
414.1205 Definitions.
414.1210 Application of the value-based payment modifier.
414.1215 Performance and payment adjustment periods for the value-based payment modifier.
414.1220 Reporting mechanisms for the value-based payment modifier.
414.1225 Alignment of Physician Quality Reporting System (PQRS) quality measures and quality measures for the value-based payment modifier.
414.1230 Additional measures for groups of physicians.
414.1235 Cost measures.
414.1240 Attribution for quality of care and cost measures.
414.1245 Scoring methods for the value-based payment modifier using the quality-tiering approach.
414.1250 Benchmarks for quality of care measures.
414.1255 Benchmarks for cost measures.
414.1260 Composite scores.
414.1265 Reliability of measures.
414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.
414.1275 Value-based payment modifier quality-tiering scoring methodology.
414.1280 Limitation on review.
414.1285 Informal inquiry process.

Subpart N—Value-Based Payment Modifier Under the Physician Fee Schedule

§ 414.1200 Basis and scope.

(a) *Basis.* This subpart implements section 1848(p) of the Act by establishing a payment modifier that provides for differential payment starting in 2015 to a group of physicians under the Medicare physician fee schedule based on the quality of care furnished compared to cost during a performance period.

(b) *Scope.* This subpart sets forth the following:

(1) The application of the value-based payment modifier.

(2) Performance and payment adjustment periods.

(3) Reporting mechanisms for the value-based payment modifier.

(4) Alignment of PQRS quality of care measures with the quality measures for the value-based payment modifier.

(5) Additional measures for groups of physicians.

(6) Cost measures.

(7) Attribution for quality of care and cost measures.

(8) Scoring methods for the value-based payment modifier.

(9) Benchmarks for quality of care measures.

(10) Benchmarks for cost measures.

(11) Composite scores.

(12) Reliability of measures.

(13) Payment adjustments.

(14) Value-based payment modifier quality-tiering scoring methodology.

(15) Limitation of review.

(16) Inquiry process.

§ 414.1205 Definitions.

As used in this subpart, unless otherwise indicated—

Accountable care organization (ACO) has the same meaning given this term under § 425.20 of this chapter.

Critical access hospital has the same meaning given this term under § 400.202 of this chapter.

Electronic health record (EHR) has the same meaning given this term under § 414.92 of this chapter.

Eligible professional has the same meaning given this term under section 1848(k)(3)(B) of the Act.

Federally Qualified Health Center has the same meaning given this term under § 405.2401(b) of this chapter.

Group of physicians means a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN.

Performance period means the calendar year that will be used to assess the quality of care furnished compared to cost.

Performance rate mean the calculated rate for each quality or cost measure such as the percent of times that a particular clinical quality action was reported as being performed, or a particular outcome was attained, for the applicable persons to whom a measure applies as described in the denominator for the measure.

Physician has the same meaning given this term under section 1861(r) of the Act.

Physician Fee Schedule has the same meaning given this term under part 410 of this chapter.

Physician Quality Reporting System means the system established under section 1848(k) of the Act.

Risk score means the beneficiary risk score derived from the CMS Hierarchical Condition Categories (HCC) model.

Taxpayer Identification Number (TIN) has the same meaning given this term under § 425.20 of this chapter.

Value-based payment modifier means the percentage as determined under § 414.1270 by which amounts paid to a physician or group of physicians under the Medicare physician fee schedule established under section 1848 of the Act are adjusted based upon a comparison of the quality of care furnished to cost as determined by this subpart.

§ 414.1210 Application of the value-based payment modifier.

(a) The value-based payment modifier is applicable to physicians:

(1) For CY 2015, in groups with 100 or more eligible professionals based on the performance period described at § 414.1215(a).

(2) [Reserved]

(b) *Exceptions.* (1) Groups of physicians that are participating in the Medicare Shared Savings Program, the testing of the Pioneer ACO model, or other similar Innovation Center or CMS initiatives shall not be subject to any adjustments under the value-based payment modifier for CY 2015 and CY 2016.

(2) [Reserved]

(c) *Group size determination.* Identification of the groups of physicians subject to the value-based payment modifier is based on a query of PECOS on October 15, 2013. Groups of physicians are removed from this October 15 list if, based on a claims analysis, the group of physicians did not have 100 or more eligible professionals that submitted claims during the performance period.

§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

(a) The performance period is calendar year 2013 for value-based payment modifier adjustments made in the calendar year 2015 payment adjustment period.

(b) The performance period is calendar year 2014 for value-based payment modifier adjustments made in the calendar year 2016 payment adjustment period.

§ 414.1220 Reporting mechanisms for the value-based payment modifier.

Groups of physicians subject to the value-based payment modifier may submit data on quality measures as specified under the Physician Quality Reporting System and in § 414.90(g) for which they are eligible and § 414.90(h)(3)(vi) administrative claims.

§ 414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.

All of the quality measures for which groups of physicians are eligible to report under the Physician Quality Reporting System starting in CY 2013 are used to calculate the value-based payment modifier program to the extent the group of physicians submits data on such measures.

§ 414.1230 Additional measures for groups of physicians.

The value-based payment modifier includes the following additional quality measures for all groups of physicians subject to the value-based payment modifier:

(a) A composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes. The rate of potentially preventable hospital admissions for diabetes is a composite measure of uncontrolled diabetes, short term diabetes complications, long term diabetes complications and lower extremity amputation for diabetes.

(b) A composite of rates of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia.

(c) Rates of an all-cause hospital readmissions measure.

§ 414.1235 Cost measures.

Costs for groups of physicians subject to the value-based payment modifier are assessed based on the following 6 cost measures:

(a) Total per capita costs for all attributed beneficiaries; and

(b) Total per capita costs for all attributed beneficiaries with diabetes, coronary artery disease, chronic obstructive pulmonary disease, or heart failure.

(c) Total per capita costs include all fee-for-service payments made under Medicare Part A and Part B.

(1) Payments under Medicare Part A and Part B will be adjusted using CMS' payment standardization methodology to ensure fair comparisons across geographic areas.

(2) The CMS–HCC model (and adjustments for ESRD status) is used to adjust standardized payments for each cost measure; that is—

(i) Total per capita costs; and

(ii) Total per capita costs for beneficiaries with the following conditions: coronary artery disease, COPD, diabetes, and heart failure.

§ 414.1240 Attribution for quality of care and cost measures.

Beneficiaries are attributed to groups of physicians subject to the value-based payment modifier using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter.

§ 414.1245 Scoring methods for the value-based payment modifier using the quality-tiering approach.

For each quality of care and cost measure, a standardized score is calculated for each group of physicians subject to the value-based payment modifier by dividing—

(a) The difference between their performance rate and the benchmark, by

(b) The measure's standard deviation.

§ 414.1250 Benchmarks for quality of care measures.

(a) The benchmark for quality of care measures reported through the PQRS using the claims, registries, EHR, or web interface is the national mean for that measure's performance rate (regardless of the reporting mechanism) during the year prior to the performance period. In calculating the national benchmark, individuals' and groups of physicians' performance rates are weighted by the number of beneficiaries used to calculate the individuals' or group of physician's performance rate.

(b) The benchmark for each quality of care measure reported through the PQRS using the administrative claims option is the national mean for that measure's performance rate during the year prior to the performance period.

§ 414.1255 Benchmarks for cost measures.

The benchmark for each cost measure is the national mean of the performance rates calculated among all groups of physicians for which beneficiaries are attributed to the group of physicians and are subject to the value-based payment modifier. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of beneficiaries used to calculate the group of physician's performance rate.

§ 414.1260 Composite scores.

(a)(1) The standardized score for each quality of care measure is classified into one of the following equally weighted domains to determine the quality composite:

(i) Patient safety.

(ii) Patient experience.

(iii) Care coordination.

(iv) Clinical care.

(v) Population/community health.

(vi) Efficiency.

(2) If a domain includes no measure or does not reach the minimum case size in § 414.1265, the remaining domains are equally weighted to form the quality of care composite.

(b)(1) The standardized score for each cost measure is grouped into two separate and equally weighted domains to determine the cost composite:

(i) Total per capita costs for all attributed beneficiaries (one measures); and

(ii) Total per capita costs for all attributed beneficiaries with specific conditions: Diabetes, coronary artery disease, chronic obstructive pulmonary disease, or heart failure (four measures).

(2) Measures within each domain are equally weighted.

§ 414.1265 Reliability of measures.

To calculate a composite score for a quality or cost measure based on claims, a group of physicians subject to the value-based payment modifier must have 20 or more cases for that measure.

(a) In a performance period, if a group of physicians has fewer than 20 cases for a measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(b) In a performance period, if a reliable quality of care composite or cost composite cannot be calculated, payments shall not be adjusted under the value-based payment modifier.

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

(a) *Downward payment adjustments.* A downward payment adjustment will be applied to a group of physicians subject to the value-based payment modifier if:

(1) Such group does neither self-nominates for the PQRS GPRO and reports at least one measure nor elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h);

(i) Such adjustment will be −1.0 percent.

(ii) [Reserved]

(2) Such group elects that its value-based payment modifier be calculated using a quality-tiering approach, and is determined to have poor performance (low quality and high costs),

(i) Such adjustment will not exceed −1.0 percent as specified in § 414.1275.

(ii) [Reserved]

(b) *No payment adjustments.* There will be no value-based payment modifier adjustment applied to a group of physicians subject to the value-based payment modifier if such group either

(1) Self-nominates for the PQRS GPRO and reports at least one measure; or

(2) Elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h).

(c) *Upward payment adjustments.* If a group of physicians subject to the value-based payment modifier elects that the value-based payment modifier be calculated using a quality-tiering approach, upward payment adjustments are determined based on the projected aggregate amount of downward payment adjustments determined under paragraph (a) of this section and applied as specified in § 414.1275.

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

(a) The value-based payment modifier amount for a group of physicians subject to the value-based payment modifier that elects the quality-tiering approach is based upon a comparison of the composite of quality of care measures and a composite of cost measures.

(b) Quality composite and cost composite are classified into high, average, and low categories based on whether the composites are statistically above, not different from, or below the mean composite scores.

(1) Quality composites that are one or more standard deviations above the mean are classified into the high category. Quality composites that are one or more standard deviations below the mean are classified into the low category.

(2) Cost composites that are one or more standard deviations below the mean are classified into the low category. Cost composites that are one or more standard deviations above the mean are classified into the high category.

(c) The following value-based payment modifier percents apply:

VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR GROUPS OF PHYSICIANS REQUESTING THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost
High quality	[1] +2.0x	[1] +1.0x	+0.0%
Average quality	[1] +1.0x	+0.0%	−0.5%
Low quality	+0.0%	−0.5%	−1.0%

[1] Groups of physicians eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures through the GPRO using the web interface, claims, registries, or EHRs, and average beneficiary risk score in the top 25 percent of all beneficiary risk scores.

(d) Groups of physicians subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and elect the quality-tiering approach, receive a greater upward payment adjustment as follows:

(1) Classified as high quality/low cost receive an upward adjustment of +3x (rather than +2x); and

(2) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +2x (rather than +1x).

§ 414.1280 Limitation on review.

(a) There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of all of the following:

(1) The establishment of the value-based payment modifier.

(2) The evaluation of the quality of care composite, including the establishment of appropriate measure of the quality of care.

(3) The evaluation of costs composite, including establishment of appropriate measures of costs.

(4) The dates of implementation of the value-based payment modifier.

(5) The specification of the initial performance period and any other performance period.

(6) The application of the value-based payment modifier.

(7) The determination of costs.

(b) [Reserved.]

§ 414.1285 Informal inquiry process.

After the dissemination of the annual Physician Feedback reports, a group of physicians may contact CMS to inquire about its report and the calculation of the value-based payment modifier.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 23. The authority citation for part 415 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 415.130 [Amended]

■ 24. In § 415.130(d)(1) and (d)(2), remove the reference to ''December 31, 2011'' and add in its place the reference to ''June 30, 2012.''

PART 421—MEDICARE CONTRACTING

■ 25. The authority citation for part 421 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart F—[Removed and Reserved]

■ 26. Subpart F is removed and reserved.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 27. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 28. Section 423.160 is amended by—

■ A. Revising paragraphs (a)(3)(iv), (b)(1)(i), and (b)(1)(ii).

■ B. Adding paragraphs (b)(1)(iii) and (b)(2)(iii).

The revisions and additions read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(3) * * *

(iv) Until November 1, 2014, entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information. As of November 1, 2014, such entities will be required to use the adopted NCPCP SCRIPT standard(s).

* * * * *

(b) * * *

(1) * * *

(i) Before April 1, 2009 the standards specified in paragraphs (b)(2)(i), (b)(3), (b)(4), (b)(5), and (b)(6) of this section.

(ii) From April 1, 2009 until January 14, 2013, the standards specified in paragraphs (b)(2)(ii), (b)(3)–(b)(4), (b)(5) and (b)(6) of this section.

(iii) From January 15, 2013 until October 31, 2013 the standards specified in paragraphs (b)(2)(ii), (b)(3)–(b)(4), (b)(5) and (b)(6) of this section.

* * * * *

(2) * * *

(iii) The National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 10.6 approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(v) of this section), to provide for the communication of a prescription or related prescription related information between prescribers and dispensers for the following:

(A) Get message transaction.

(B) Status response transaction.
(C) Error response transaction.
(D) New prescription transaction.
(E) Prescription change request transaction.
(F) Prescription change response transaction.
(G) Refill prescription request transaction.
(H) Refill prescription response transaction.
(I) Verification transaction.
(J) Password change transaction.
(K) Cancel prescription request transaction.
(L) Cancel prescription response transaction.
(M) Fill status notification.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 29. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 30. Section 425.308 is amended by revising paragraph (e) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(e) *Results of claims based measures.* Quality measures reported using the GPRO web interface and patient experience of care survey measures will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

■ 31. Section 425.504 is amended by adding paragraph (b) to read as follows:

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System.

* * * * *

(b) *Physician Quality Reporting System payment adjustment.* (1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit one of the measures determined under § 425.500 using the GPRO web interface established by CMS, to satisfactorily report on behalf of their eligible professionals for purposes of the 2015 Physician Quality Reporting System payment adjustment under the Shared Savings Program.

(2)(i) ACO providers/suppliers that are eligible professionals within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the 2015 Physician Quality Reporting System payment adjustment under the Shared Savings Program.

(ii) Under the Shared Savings Program, an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report one of the measures determined under Subpart F of this part during the reporting period for a year, as defined in paragraph (b)(6) of this section, according to the method of submission established by CMS under the Shared Savings Program for purposes of the 2015 Physician Quality Reporting System payment adjustment.

(3) If an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, does not satisfactorily report for purposes of a 2015 Physician Quality Reporting System payment adjustment, each ACO supplier/provider who is an eligible professional, will receive a payment adjustment, as described in paragraph (b)(5) of this section.

(4) ACO participant TINs and individual ACO providers/suppliers who are eligible professionals cannot satisfactorily report for purposes of a 2015 Physician Quality Reporting System payment adjustment outside of the Medicare Shared Savings Program.

(5) For eligible professionals subject to the 2015 Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act.

(i) The applicable percent for 2015 is 98.5 percent.

(ii) The applicable percent for 2016 and subsequent years is 98.0 percent.

(6) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 32. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 33. Section 486.106 is amended by revising the introductory text and paragraphs (a) and (b) to read as follows:

§ 486.106 Condition for coverage: Referral for service and preservation of records.

All portable X-ray services performed for Medicare beneficiaries are ordered by a physician or a nonphysician practitioner as provided in § 410.32(a) of this chapter or by a nonphysician practitioner as provided in § 410.32(a)(2) and records are properly preserved.

(a) *Standard—referral by a physician or nonphysician practitioners.* Portable X-ray examinations are performed only on the order of a physician licensed to practice in the State or by a nonphysician practitioner acting within the scope of State law. Such nonphysician practitioners may be treated the same as physicians treating beneficiaries for the purpose of this paragraph. The supplier's records show that:

(1) The portable X-ray test was ordered by a licensed physician or a nonphysician practitioner acting within the State scope of law; and

(2) Such physician or nonphysician practitioner's written, signed order specifies the reason a portable X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

(b) *Standard—records of examinations performed.* The supplier makes for each patient a record of the date of the portable X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician or nonphysician practitioner, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 34. 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).

■ 35. Section 495.8 is amended by revising paragraph (a)(2)(v) to read as follows:

§ 495.8 Demonstration of meaningful use criteria.

(a) * * *
(2) * * *
(v) *Exception for Medicare EPs for 2012 and 2013—Participation in the*

Physician Quality Reporting System-Medicare EHR Incentive Pilot. To satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, an EP participating in the Physician Quality Reporting System may also participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot through one of the following methods:

(A) Submission of data extracted from the EP's certified EHR technology through a Physician Quality Reporting System qualified EHR data submission vendor; or

(B) Submission of data extracted from the EP's certified EHR technology, which must also be through a Physician Quality Reporting System qualified EHR.

* * * * *

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 24, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 25, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–26900 Filed 11–1–12; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

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Part III

Department of Labor

Office of the Secretary

Delegation of Authority and Assignment of Responsibility to the Director, Office of Labor-Management Standards; Notice

DEPARTMENT OF LABOR

Office of the Secretary

[Secretary's Order 03–2012]

Delegation of Authority and Assignment of Responsibility to the Director, Office of Labor-Management Standards

1. *Purpose.* To delegate authority and assign responsibility to the Director, Office of Labor-Management Standards.

2. *Authorities.* This Order is issued under the authority of 5 U.S.C. 301 (Departmental Regulations); 29 U.S.C. 551 *et seq.* (Establishment of Department; Secretary; Seal); Reorganization Plan No. 6 of 1950 (5 U.S.C. App 1 Reorg. Plan 6 of 1950); and the authorities cited in Section 5 of this Order.

3. *Directives Affected.* Secretary's Order 8–2009 is hereby cancelled.

4. *Background.* On November 8, 2009, the Department of Labor reorganized its organization structure, dissolving the Employment Standards Administration (ESA). ESA had been headed by the Assistant Secretary of Labor for Employment Standards (''Assistant Secretary''). With the dissolution of ESA, its sub-agencies, including the Office of Labor-Management Standards (OLMS) became separate agencies—headed by a Director. Secretary's Order 8–2009 (Section 5) delegated authorities and responsibilities previously held by the Assistant Secretary of ESA to the Director of OLMS. This Order cancels Secretary's Order 8–2009. The Secretary delegated authority and assigned responsibilities to the ARB to review recommended decisions by administrative law judges and issue final agency decisions under the statutes and regulations enumerated in Sections 5(A)(1) and (2) of this Order. *See* Secretary's Order 02–2012.

5. *Delegation of Authority and Assignment of Responsibilities.*

A. *The Director, Office of Labor-Management Standards* is hereby delegated authority and assigned responsibility, except as hereinafter provided, for carrying out the employment standards, labor standards, and labor-management standards policies, programs, and activities of the Department of Labor, including those functions to be performed by the Secretary of Labor under the designated provisions of the following statutes:

(1) The Labor-Management Reporting and Disclosure Act of 1959, as amended, 29 U.S.C. § 401, *et seq.;* with the exception of the authority under 29 U.S.C. 481(h) granted to the Administrative Review Board in Secretary's Order 02–2012. If, in the course of investigations under the Labor-Management Reporting and Disclosure Act, there appear to be indications of organized crime and labor racketeering, the Director of OLMS shall promptly notify the Inspector General, who also has statutory authority to investigate such issues. The Inspector General shall have the power to assume the lead in further investigative activities arising from such case with respect to issues involving organized crime and labor racketeering.

(2) Section 701 (Standards of Conduct for Labor Organizations) of the Civil Service Reform Act of 1978 (5 U.S.C. § 7120), Section 1017 of the Foreign Service Act of 1980 (22 U.S.C. § 4117), and Section 220(a)(1) of the Congressional Accountability Act of 1995 (2 U.S.C. 1351(a)(1)), and the regulations pertaining to such sections at 29 CFR parts 457–459; with the exception of the authority granted to the Administrative Review Board in Secretary's Order 02–2012.

(3) Section 1209 of the Postal Reorganization Act of 1970, 39 U.S.C. § 1209.

(4) The employee protection provisions of the Federal Transit law, as codified at 49 U.S.C. 5333(b), and related provisions.

(5) The employee protection provisions certified under Sections 405(a), (b), (c), and (e) of the Rail Passenger Service Act of 1970, 45 U.S.C. 565(a), (b), (c), and (e).

(6) Executive Order 13496 (Notification of Employee Rights Under Federal Labor Laws) of January 30, 2009.

(7) Section 211(a) of the Labor Management Relations Act, 29 U.S.C. 181(a) (''Compilation of Collective Bargaining Agreements, etc.; Use of Data'').

(8) Such additional Federal acts that from time to time may assign to the Secretary or the Department of Labor duties and responsibilities similar to those listed under subparagraphs (1)–(7) of this paragraph, as directed by the Secretary.

B. *The Solicitor of Labor* is delegated authority and assigned responsibility for providing legal advice and assistance to all officers of the Department relating to the administration of the statutory provisions, regulations, and Executive Orders listed above. The bringing of legal proceedings under those authorities, the representation of the Secretary and/or other officials of the Department of Labor, and the determination of whether such proceedings or representations are appropriate in a given case, are delegated exclusively to the Solicitor.

6. *Reservation of Authority and Responsibility.*

A. The submission of reports and recommendations to the President and the Congress concerning the administration of the statutory provisions and Executive Orders listed above is reserved to the Secretary.

B. Nothing in this Order shall limit or modify the delegation of authority and assignment of responsibility to the Administrative Review Board by Secretary's Order 02–2012.

C. Except as expressly provided in Section 5, nothing in this Order shall limit or modify the provisions of any other Order, including Secretary's Order 4–2006 (Office of Inspector General).

7. *Redelegation of Authority.* Except as otherwise provided by law, all of the authorities delegated in this Order may be redelegated.

8. *Effective Date.* This Order shall become effective immediately.

Dated: October 19, 2012.

Hilda L. Solis,

Secretary of Labor.

[FR Doc. 2012–27803 Filed 11–15–12; 8:45 am]

BILLING CODE 4510–23–P

FEDERAL REGISTER

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Part IV

Department of Labor

Office of the Secretary

Delegation of Authority and Assignment of Responsibility to the Administrative Review Board; Notice

DEPARTMENT OF LABOR

Office of the Secretary

[Secretary's Order 02–2012]

Delegation of Authority and Assignment of Responsibility to the Administrative Review Board

1. *Purpose.* To delegate authority and assign responsibility to the Administrative Review Board, define its composition, and describe its functions.

2. *Authorities.* This Order is issued under the authority of 5 U.S.C. 301 (Departmental Regulations); 29 U.S.C. 551 *et seq.* (Establishment of Department; Secretary; Seal); Reorganization Plan No. 6 1950 (5 U.S.C. App. 1 Reorg. Plan 6 1950); and the authorities cited in Section 5 of this Order.

3. *Background.* The Secretary of Labor (''Secretary'') has the authority and responsibility to decide certain appeals from administrative decisions. The Secretary created the Administrative Review Board (''Board'' or ''ARB'') in Secretary's Order 02–96, which delegated authority and assigned responsibilities to the Board. Secretary's Order 01–2002 delegated this authority and assigned responsibility to the ARB, defined and expanded its composition, clarified ARB procedural authorities, and codified the location of the ARB in the Department's organizational structure. Secretary's Order 01–2010, then, created and designated a Vice-Chair to maintain and operate the Board during a Chair's absence or vacancy. Additionally, S.O. 01–2010 delegated the responsibility for the operational management of the Board and its affairs to the newly created Vice-Chair. This Order would provide updates to the delegation of authority and assignment of responsibilities laid out in the previous orders.

4. *Directives Affected.* Secretary's Order 01–2010 is hereby canceled.

5. *Delegation of Authority and Assignment of Responsibilities.* The Board is hereby delegated authority and assigned responsibility to act for the Secretary of Labor in review or on appeal of the matters listed below, including, but not limited to, the issuance of final agency decisions. The Board shall report to the Secretary of Labor through the Deputy Secretary of Labor.

a. Final decisions of the Administrator of the Wage and Hour Division or an authorized representative of the Administrator, and final decisions of Administrative Law Judges (''ALJs''), under the following:

(1) The Davis-Bacon Act, 40 U.S.C. § 3141 et seq.; any laws now existing or which may be subsequently enacted, providing for prevailing wages determined by the Secretary of Labor in accordance with or pursuant to the Davis-Bacon Act; the Contract Work Hours and Safety Standards Act, 40 U.S.C. § 3701 et seq. (except matters pertaining to safety); the Copeland Act, 40 U.S.C. § 3145; Reorganization Plan No. 14 of 1950; and 29 CFR parts 1, 3, 5, 6, Subpart C and D.

b. Final decisions of the Administrator of the Wage and Hour Division or an authorized representative of the Administrator, and decisions of ALJs, arising under the McNamara-O'Hara Service Contract Act, as amended, 41 U.S.C. § 6701 et seq.; the Contract Work Hours and Safety Standards Act, 40 U.S.C. § 3701 et seq. (except matters pertaining to safety) where the contract is also subject to the McNamara-O'Hara Service Contract Act; and 29 CFR parts 4, 5, 6, Subparts B, D, E.

c. Decisions and recommended decisions by ALJs as provided for or pursuant to the following laws and implementing regulations:

(1) Age Discrimination Act of 1975, 42 U.S.C. § 6103;

(2) Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d–l; 29 CFR Part 31;

(3) Civil Service Reform Act of 1978, 5 U.S.C. § 7120; 29 CFR Part 458, sections 458.70, 458.72, 458.76, 458.81, 458.82, 458.88, 458.90, 459.91, and 458.93;

(4) Clean Air Act, 42 U.S.C. § 7622; 29 CFR Part 24;

(5) Comprehensive Environmental Response, Compensation and Liability Act of 1980, 42 U.S.C. § 9610; 29 CFR Part 24;

(6) Congressional Accountability Act of 1995, 2 U.S.C. 1351(a)(1); 29 CFR Part 458, sections 458.70, 458.72, 458.76, 458.81, 458.82, 458.88, 458.90, 459.91, and 458.93;

(7) Consumer Financial Protection Act of 2010, Section 1057 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, 12 U.S.C. § 5567, Public Law 111–203;

(8) Consumer Product Safety Improvement Act of 2008, 15 U.S.C. § 2087; 29 CFR Part 1983;

(9) Title IX of the Education Amendments of 1972, 20 U.S.C. § 1682; 29 CFR Part 36;

(10) Employee Polygraph Protection Act of 1988, 29 U.S.C. § 2005(a); 29 CFR Part 801, Subpart E;

(11) Energy Reorganization Act of 1974, as amended, 42 U.S.C. § 5851; 29 CFR Part 24;

(12) Equal Access to Justice Act, 5 U.S.C. § 504; 29 CFR Part 16;

(13) Executive Order No. 11246, as amended, 3 CFR part 339 (1964–1965 Comp.); reprinted in 42 U.S.C. 2000e app.; 41 CFR Parts 60–1 and 60–30;

(14) Fair Labor Standards Act of 1938, as amended, 29 U.S.C. 203(m); 29 CFR Part 531, sections 531.4, 531.5;

(15) Fair Labor Standards Act of 1938, as amended, 29 U.S.C. 211(d); 29 CFR Part 530, Subpart E;

(16) Fair Labor Standards Act of 1938, as amended, 29 U.S.C. 214(c) 29 CFR Part 525, section 525.22;

(17) Fair Labor Standards Act of 1938, as amended, 29 U.S.C. 216(e); 29 CFR Part 580;

(18) Fair Labor Standards Act of 1938, as amended by the Affordable Care Act, 29 U.S.C. 218C, Public Law 111–148, section 1558;

(19) Federal Railroad Safety Act, 49 U.S.C. § 20109; 29 CFR Part 1982;

(20) Federal Unemployment Tax Act, 26 U.S.C. 3303(b)(3), 3304(c);

(21) Federal Unemployment Tax Act (addressing agreements under the Trade Act of 1974, as amended), 26 U.S.C. 3302(c)(3); 20 CFR Part 617;

(22) Federal Water Pollution Control Act, 33 U.S.C. 1367; 29 CFR Part 24;

(23) Foreign Service Act of 1980, 22 U.S.C. § 4117; 29 CFR Part 458, sections 458.70, 458.72, 458.76, 458.81, 458.82, 458.88, 458.90, 459.91, 458.92, and 458.93;

(24) Immigration and Nationality Act, as amended, 8 U.S.C. 1182(m); 20 CFR Part 655, Subpart E;

(25) Immigration and Nationality Act, as amended, 8 U.S.C. 1182(m); 20 CFR Part 655, Subpart M;

(26) Immigration and Nationality Act, as amended, 8 U.S.C. 1182(n); 20 CFR Part 655, Subpart I;

(27) Immigration and Nationality Act, as amended, 8 U.S.C. 1184(c)(14), 20 CFR Part 655, Subpart A, 29 CFR Part 503, Subpart C;

(28) Immigration and Nationality Act, as amended, 8 U.S.C. 1188(b)(2), 20 CFR Part 655, Subpart A, 29 CFR Part 503, Subpart C;

(29) Immigration and Nationality Act, as amended, 8 U.S.C. 1288(c) and (d); 20 CFR Part 655, Subpart G;

(30) Immigration and Nationality Act, as amended, 8 U.S.C. 1188(g)(2); 29 CFR Part 501, Subpart C;

(31) Labor-Management Reporting and Disclosure Act of 1959, 29 U.S.C. 481(h); 29 CFR Part 417, sections 417.6, 417.7, 417.9(c), 417.13, 417.14, and 417.15;

(32) Longshore and Harbor Workers' Compensation Act, 33 U.S.C. 907(j)(2); 20 CFR Part 702;

(33) Migrant and Seasonal Agricultural Worker Protection Act, 29

U.S.C. § 1813, 1853; 29 CFR Part 500, Subpart F;

(34) Motor Vehicle and Highway Safety Improvement Act of 2012, Section 31307 of the Moving Ahead for Progress in the 21st Century Act, 49 U.S.C. § 30171;

(35) National Apprenticeship Act, 29 U.S.C. § 50; 29 CFR Parts 29 and 30;

(36) National Transit Systems Security Act of 2007, 6 U.S.C. § 1142; 29 CFR Part 1982;

(37) Notification of Employee Rights Under Federal Labor Laws, 29 CFR Part 471;

(38) Older Americans Senior Community Service Employment Program, 42 U.S.C. § 3056, 20 CFR 641.900;

(39) Part B of the Black Lung Benefits Act, 30 U.S.C. §§ 921–924; Section 3(d)(3) of the Black Lung Consolidation of Administrative Responsibility Act (2002); 20 CFR Part 410 (2011);

(40) Pipeline Safety Improvement Act of 2002, 49 U.S.C. 60129; 29 CFR Part 1981;

(41) Program Fraud Civil Remedies Act of 1986, 31 U.S.C. § 3803; 29 CFR Part 22;

(42) Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5177(a) and 5189a; 20 CFR Part 625;

(43) Section 423(d)(1) of the Black Lung Benefits Act, 30 U.S.C. 933(d)(1); 20 CFR Part 726;

(44) Section 428 of the Black Lung Benefits Act, 30 U.S.C. § 938;

(45) Seaman's Protection Act, 46 U.S.C. § 2114;

(46) Section 402 of the FDA Food Safety Modernization Act, Public Law 111–353, 21 U.S.C. 399d;

(47) Section 503 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. § 793; 41 CFR Part 60–741, Subpart B;

(48) Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. § 794; 29 CFR Part 32;

(49) Safe Drinking Water Act, 42 U.S.C. 300j–9(i); 29 CFR Part 24;

(50) Sarbanes-Oxley Act of 2002, 18 U.S.C. 1514A, as amended by Sections 922 and 929A of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Public Law 111–203, 29 CFR Part 1980;

(51) Single Audit Act of 1984, as amended, 31 U.S.C. § 7501 et seq.; OMB Circular No. A–133, as amended; 29 CFR Part 96;

(52) Social Security Act, 42 U.S.C. § 503; 20 CFR Parts 601 and 602;

(53) Solid Waste Disposal Act, 42 U.S.C. § 6971; 29 CFR Part 24;

(54) Surface Transportation Assistance Act, 49 U.S.C. § 31105; 29 CFR Part 1978;

(55) Toxic Substances Control Act, 15 U.S.C. § 2622; 29 CFR Part 24;

(56) Trade Act of 1974, as amended, 19 U.S.C. § 2101–2321; 20 CFR Part 617;

(57) Unemployment Compensation for Federal Civilian Employees Program, 5 U.S.C. § 8501–8508; 20 CFR Part 609;

(58) Unemployment Compensation for Ex-Servicemembers Program, 5 U.S.C. § 8521–8525; 20 CFR Part 614;

(59) Vietnam Era Veterans Readjustment Assistance Act, as amended, 38 U.S.C. §§ 4211, 4212; 41 CFR Part 60–250, Subpart B, and Part 60–300, Subpart B;

(60) Wagner-Peyser Act, as amended, 29 U.S.C. § 49; 20 CFR Part 658;

(61) Walsh-Healey Public Contracts Act, as amended, 41 U.S.C. § 38; 41 CFR Part 50–203;

(62) Welfare to Work Act, 20 CFR 645.800(c);

(63) Wendell H. Ford Aviation Investment and Reform Act for the 21st Century, 49 U.S.C. § 42121; 29 CFR Part 1979;

(64) Workforce Investment Act of 1998, as amended, 29 U.S.C. § 2936; 20 CFR 667.830;

(65) Workforce Investment Act of 1998, as amended, 29 U.S.C. § 2938; 29 CFR Part 37 (see 37.110–112); and

(66) Any laws or regulation subsequently enacted or promulgated that provide for final decisions by the Secretary of Labor upon appeal or review of decisions, or recommended decisions, issued by ALJs, and any Federal law that extends or supplements unemployment compensation and provides for final decisions by the Secretary of Labor.

The Board shall not have jurisdiction to pass on the validity of any portion of the Code of Federal Regulations that has been duly promulgated by the Department of Labor and shall observe the provisions thereof, where pertinent, in its decisions. The Board also shall not have jurisdiction to review decisions to deny or grant exemptions, variations, and tolerances and does not have the authority independently to take such actions. In issuing its decisions, the Board shall adhere to the rules of decision and precedent applicable under each of the laws enumerated in Sections 5(a), 5(b), and 5(c) of this Order, until and unless the Board or other authority explicitly reverses such rules of decision or precedent. The Board's authority includes the discretionary authority to review interlocutory rulings in exceptional circumstances, provided such review is not prohibited by statute.

6. *Composition and Panel Configuration.*

a. The Board shall consist of a maximum of five Members, one of whom the Secretary shall designate as Chair, and a second of whom the Secretary shall designate as Vice-Chair. The Members of the Board shall be appointed by the Secretary of Labor, and shall be selected upon the basis of their qualifications and competence in matters within the authority of the Board.

b. Except as provided in Section 6(c), the Board shall sit, hear cases, render decisions, and perform all other related functions in panels of two or three Members, as may be assigned by the Chair, unless the Chair specifically directs that an appeal or review will be decided by the full Board.

c. Except as otherwise provided by law or duly promulgated regulation (see, e.g., 29 CFR Parts 7 and 8), if the petitioner(s) and the respondent(s) (or the appellant(s) and the appellees(s)) consent to disposition by a single Member, the Chair may determine that the decision shall be by a single Member. Upon an affirmative determination, the Chair of the Board shall, in his or her discretion, designate himself, herself, or any other Member of the Board to decide such an appeal under Section 8.

d. The Vice-Chair shall preside at meetings in the absence of the Chair. In the event of the vacancy of the Chair's position, the Vice-Chair shall assume all of the Chair's authority and shall act as Chair.

e. The Vice-Chair shall be responsible for the operational management of the Board and its affairs.

7. *Terms of the Members.*

a. Members of the Board shall be appointed for a term of two years or less.

b. Appointment of a Member of the Board to a term not to exceed a specified time period shall not affect the authority of the Secretary to remove, in his or her sole discretion, any Member at any time.

c. Vacancies in the membership of the Board shall not impair the authority of the remaining Member(s) to exercise all the powers and duties of the Board.

8. *Voting.* A petition for review may be granted upon the affirmative vote of one Member, except where otherwise provided by law or regulation. A decision in any matter, including the issuance of any procedural rules, shall be by a majority vote, except as provided in Section 6(c).

9. *Location of Board Proceedings.* The Board shall hold its proceedings in Washington, DC, unless for good cause the Board orders that proceedings in a particular matter be held in another location.

10. *Rules of Practice and Procedure.* The Board shall prescribe such rules of practice and procedure, as it deems necessary or appropriate, for the conduct of its proceedings. The rules (1) which are prescribed as of the date of this Order in 29 CFR Part 7 and Part 8 with respect to Sections 5(a) and 5(b), respectively, of this Order and (2) which apply as of the date of this Order to appeals and review described in Section 5(c) of this Order shall, until changed, govern the respective proceedings of the Board when it is deciding appeals described in Section 5 of this Order.

11. *Departmental Counsel.* The Solicitor of Labor shall have the responsibility for representing the Secretary, the Deputy Secretary, and other officials of the Department and the Board in any administrative or judicial proceedings involving agency decisions issued pursuant to this Order, including representing officials of the Department before the Board. In addition, the Solicitor of Labor shall have the responsibility for providing legal advice to the Secretary, the Deputy Secretary, and other officials of the Department with respect to decisions covered by this Order, as well as the implementation and administration of this Order. The Solicitor of Labor may also provide legal advice and assistance to the Chair and/or Vice-Chair of the Board, as appropriate.

12. *Effective Date.* This delegation of authority and assignment of responsibility is effective immediately.

Dated: October 19, 2012.

Hilda L. Solis,

Secretary of Labor.

[FR Doc. 2012–27805 Filed 11–15–12; 8:45 am]

BILLING CODE 4510–23–P

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