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Presidential Documents

Title 3—

The President

Proclamation 9203 of October 31, 2014

National College Application Month, 2014

By the President of the United States of America

A Proclamation

With hard work and determination, a great education should be within everyone's reach. At the heart of America's promise is the belief that we all deserve an equal opportunity to get ahead, and today more than ever—as we face greater global competition in a knowledge-based economy—a college degree is the surest path to a stable, middle-class life. During National College Application Month, we come together to encourage all students to take control of their own destiny by applying to continue their education beyond high school and to let them know that no matter where they come from or who they are—it does not matter if they are the first in their family to apply to college or if they have been told that they are simply not college material—there is an opportunity for them.

This fall, high school seniors across our Nation are making the decision to invest in their future by earning a post-secondary degree or credential, and as they navigate the college admissions process, my Administration is dedicated to supporting them with the tools and resources they need to succeed. To help more families afford a college degree, we have expanded grants, tax credits, and loans and invested in programs that help students manage and reduce the burdens of debt after they graduate. We created the College Scorecard to make it easier for students and families to compare colleges and find ones that are well-suited to their needs. And to help students better understand the costs of college and more easily compare aid packages offered by different institutions, we developed the Financial Aid Shopping Sheet. To access these and other resources—including College Navigator and a tool that helps determine the net price of any given college—Americans can go to *www.WhiteHouse.gov/ReachHigher.*

Applying to college is hard work, but it is only the beginning of a journey that requires persistence and focus. A college degree unlocks pathways to opportunity; it prepares today's students for the jobs of the future and is a requirement for the educated workforce and informed citizenry our country needs to create growth, bolster our economy, and strengthen our democracy. That is why as a Nation, we must lift up our students, help them achieve their greatest potential, and work together toward an important goal: to lead the world in college completion.

This month, we celebrate the limitless possibility within every child. We honor the teachers, school counselors, and parents who help students apply to college. We recognize the institutions that are taking steps to ensure they reach the best and brightest students, regardless of their background, and all those who ensure the next generation is prepared for success, including businesses who open their doors to interns and the alumni, foundations, and faith-based organizations that provide scholarships. Let us remind all students that it is never too early to start planning for their future or reaching for their dreams.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2014 as National College Application Month. I call upon public officials, educators,

parents, students, and all Americans to observe this month with appropriate ceremonies, activities, and programs designed to encourage students to make plans for and apply to college.

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

[FR Doc. 2014–26486
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Presidential Documents

Proclamation 9204 of October 31, 2014

National Diabetes Month, 2014

By the President of the United States of America

A Proclamation

Today, nearly 30 million Americans have diabetes. This devastating disease affects men and women of all backgrounds and ages, and can cause serious health complications, including blindness, kidney failure, heart disease, stroke, and the loss of lower limbs. During National Diabetes Month, we stand with all those battling this chronic, life-threatening disease and their families, and we pay tribute to the advocates, researchers, and health care professionals who are committed to supporting healthy lifestyles in communities across our country.

Most commonly diagnosed in young people, type 1 diabetes has no known method of prevention. However, it can be managed with regular exercise, good nutrition, and proper medication. Type 2 diabetes accounts for roughly 90 to 95 percent of diagnosed cases of diabetes in adults, and the risk of developing it is commonly associated with older age, obesity, physical inactivity, and a family history of diabetes. African Americans, Hispanic Americans, American Indians, and some Asian Americans and Pacific Islanders are at particularly high risk for this disease and its complications. In some cases, losing weight, eating healthy, and being more active can help prevent or delay type 2 diabetes. Americans who are at risk for this disease can consult with a health care provider to discuss the steps they can take to reduce their chances of developing diabetes.

My Administration is committed to finding a cure for both type 1 and type 2 diabetes, and we continue to invest in critical research to prevent this disease, increase the quality of care, and reduce its devastating complications. Established to help translate the important findings of this research into practice, the National Diabetes Education Program works to raise awareness of this disease among high risk individuals and to improve treatment and outcomes for those living with it. To learn more about diabetes, individuals can visit www.NDEP.NIH.gov.

The Affordable Care Act prevents health insurance companies from denying coverage due to a pre-existing condition, such as a diabetes diagnosis, and requires that insurers cover recommended diabetes screenings without a copay for adults with high blood pressure. My Administration also encourages public-private partnerships that are helping Americans at risk of type 2 diabetes take action to prevent the onset of the disease. And as more than one-third of American children and adolescents are overweight or obese—putting a new generation at risk for diabetes—First Lady Michelle Obama's *Let's Move!* initiative seeks to increase opportunities for young people to engage in physical activity and make healthy choices.

All Americans deserve the chance to lead healthy lives and achieve their full potential. During National Diabetes Month, we honor the memory of those we have lost to diabetes, and we recommit to pursuing solutions that will shed light on this disease, moving our Nation closer to a healthier tomorrow for all.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2014

as National Diabetes Month. I call upon all Americans, school systems, government agencies, nonprofit organizations, health care providers, research institutions, and other interested groups to join in activities that raise diabetes awareness and help prevent, treat, and manage the disease.

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

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Presidential Documents

Proclamation 9205 of October 31, 2014

National Entrepreneurship Month, 2014

By the President of the United States of America

A Proclamation

Across our Nation, in laboratories and around kitchen tables, passionate and creative entrepreneurs are developing new sources of clean energy, cures for life-threatening diseases, and inventions that will transform the way we see the world. America has always been a country of risk takers and dreamers—where anyone who is willing to work hard can turn a good idea into a thriving business—and our spirit of ingenuity remains a powerful engine of growth, creating jobs and bolstering our economy. This month, we recognize the grit and determination of American inventors and innovators and their many contributions to our Nation, and we reaffirm our commitment to support these entrepreneurs as they develop the products, services, and ideas of tomorrow.

Our country seeks to empower a rising generation of talented and striving innovators and to ensure they have opportunities to pursue their aspirations and take the risks that make America great. That is why my Administration has expanded grants, tax credits, and loans to help more families afford a college degree. We are investing in programs that encourage science, technology, engineering, and math education, especially for traditionally underrepresented groups. We have given nearly 5 million Americans the chance to cap their student loan payments at 10 percent of their income, freeing them to pursue new ideas and unsolved problems. And the Affordable Care Act enables entrepreneurs to set out and build the future they seek by providing the security of quality, affordable health care.

As we work to create a new foundation of growth and prosperity, my Administration is taking action to ensure startups and innovators have the resources and access to capital they need to take ideas from the drawing board to the factory floor to the store shelf. Now in its fourth year, our Startup America initiative has brought the Federal Government and private sector partners together to cut red tape for entrepreneurs, speed up innovation, and help get businesses off the ground and scale up more quickly. We are redoubling our support for an open Internet and open data as fundamentals of innovation. We have committed to investing billions of dollars in our small businesses and startups, and we are accelerating the transfer of federally funded research from the laboratory to the commercial marketplace. We have made new efforts to welcome entrepreneurial companies as customers of the Federal Government, and since taking office, I have signed 18 tax cuts for small businesses into law, as well as bipartisan legislation that has helped enable more emerging growth companies to access public capital markets. And because many of the highly skilled workers and talented thinkers on whom our startups depend are first-generation Americans, I continue to call on the Congress to enact comprehensive immigration reform—and I am prepared to address our broken immigration system through executive action in a way that is sustainable and effective, and within the confines of the law.

Bringing together America's best and brightest innovators creates important opportunities for mentorship within the startup and small business communities, and it allows policymakers to hear directly from entrepreneurs. This

year, we launched the Presidential Ambassadors for Global Entrepreneurship. A first-of-its-kind collaboration between successful American businesspeople and the Federal Government, this group is helping to cultivate startup communities and champion entrepreneurship both here at home and overseas. We also hosted inventors from around the country this year at the first-ever White House Maker Faire. And later this month, my Administration is supporting the 5th annual Global Entrepreneurship Summit in Morocco, to foster entrepreneurial success and prosperity around the world.

When we encourage entrepreneurs and the ideas they introduce to the world, we strengthen our communities and help secure America's promise for future generations. As we observe National Entrepreneurship Month and celebrate Global Entrepreneurship Week, let us continue our work to ensure America remains home to the best minds and the most innovative businesses on earth.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2014 as National Entrepreneurship Month. I call upon all Americans to commemorate this month with appropriate programs and activities, and to celebrate November 18, 2014, as National Entrepreneurs' Day.

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

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Presidential Documents

Proclamation 9206 of October 31, 2014

National Family Caregivers Month, 2014

By the President of the United States of America

A Proclamation

Each day, courageous individuals step forward to help care for family members in need, their quiet acts of selflessness and sacrifice telling a story of love and devotion. Across our country, parents and children, siblings and spouses, friends and neighbors heroically give of themselves to support those in their lives affected by illness, injury, or disability. During National Family Caregivers Month, we salute the people who play difficult and exhausting roles, and we recommit to lifting up these Americans as they care for their loved ones while protecting their dignity and individuality.

In the United States, more than 60 million caregivers provide invaluable strength and assistance to their family members, and as the number of older Americans rises, so will the number of caregivers. Many of these dedicated people work full time and raise children of their own while also caring for the needs of their loved ones. Caregivers support the independence of their family members and enable them to more fully participate in their communities, and as a Nation, we have an obligation to empower these selfless individuals.

My Administration continues to work to improve many of the resources on which caregivers depend. The Affordable Care Act invested in programs that expand home and community-based services. To lift up a new generation of service members—our 9/11 Generation—we are fighting to ensure those who care for them have access to the support they need, including financial assistance, comprehensive caregiver training, mental health services and counseling, and respite care. Many caregivers rely on workplace flexibility and reasonable accommodations, and this year my Administration held the first-ever White House Summit on Working Families to develop a comprehensive agenda that ensures hard-working Americans do not have to choose between being productive employees and responsible family members. And next year, we will host the White House Conference on Aging, which will focus on the needs of older Americans and those who care for them.

Not only this month, but every month, let us work alongside our Nation's caregivers and make certain they are able to provide the best possible care for their loved ones for as long as necessary. Together, we recognize those who place service above self, including the women and men looking after our veterans. By offering them the same comfort, social engagement, and stability they bring to others, may we remind them that they are not alone.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2014 as National Family Caregivers Month. I encourage all Americans to pay tribute to those who provide for the health and well-being of their family members, friends, and neighbors.

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

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Presidential Documents

Proclamation 9207 of October 31, 2014

National Native American Heritage Month, 2014

By the President of the United States of America

A Proclamation

Every year, our Nation pauses to reflect on the profound ways the First Americans have shaped our country's character and culture. The first stewards of our environment, early voices for the values that define our Nation, and models of government to our Founding Fathers—American Indians and Alaska Natives helped build the very fabric of America. Today, their spirit and many contributions continue to enrich our communities and strengthen our country. During National Native American Heritage Month, we honor their legacy, and we recommit to strengthening our nation-to-nation partnerships.

As we celebrate the rich traditions of the original peoples of what is now the United States, we cannot forget the long and unfortunate chapters of violence, discrimination, and deprivation they had to endure. For far too long, the heritage we honor today was disrespected and devalued, and Native Americans were told their land, religion, and language were not theirs to keep. We cannot ignore these events or erase their consequences for Native peoples—but as we work together to forge a brighter future, the lessons of our past can help reaffirm the principles that guide our Nation today.

In a spirit of true partnership and mutual trust, my Administration is committed to respecting the sovereignty of tribal nations and upholding our treaty obligations, which honor our nation-to-nation relationship of peace and friendship over the centuries. We have worked to fairly settle longstanding legal disputes and provide justice to those who experienced discrimination. We have taken unprecedented steps to strengthen tribal courts, especially when it comes to criminal sentencing and prosecuting individuals who commit violence against Native American women. And next month, my Administration will host our sixth annual White House Tribal Nations Conference, part of our ongoing effort to promote meaningful collaboration with tribal leaders as we fight to give all our children the tomorrow they deserve.

Today, as community and tribal leaders, members of our Armed Forces, and drivers of progress and economic growth, American Indians and Alaska Natives are working to carry forward their proud history, and my Administration is dedicated to expanding pathways to success for Native Americans. To increase opportunity in Indian Country, we are investing in roads and high-speed Internet and supporting job training and tribal colleges and universities. The Affordable Care Act provides access to quality, affordable health insurance, and it permanently reauthorized the Indian Health Care Improvement Act, which provides care to many Native Americans. And because the health of tribal nations depends on the health of tribal lands, my Administration is partnering with Native American leaders to protect these lands in a changing climate.

Every American, including every Native American, deserves the chance to work hard and get ahead. This month, we recognize the limitless potential of our tribal nations, and we continue our work to build a world where

all people are valued and no child ever has to wonder if he or she has a place in our society.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 2014 as National Native American Heritage Month. I call upon all Americans to commemorate this month with appropriate programs and activities, and to celebrate November 28, 2014, as Native American Heritage Day.

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

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Rules and Regulations

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

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DEPARTMENT OF THE TREASURY

5 CFR Part 3101

Supplemental Standards of Ethical Conduct for Employees of the Department of the Treasury

AGENCY: Department of the Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury (the ''Department'' or ''Treasury''), with the concurrence of the Office of Government Ethics (OGE), is amending the Supplemental Standards of Ethical Conduct for Employees of the Department of the Treasury (the ''Supplemental Standards''). The Supplemental Standards apply only to Department personnel and augment the Standards of Ethical Conduct for Employees of the Executive Branch (''OGE Standards''). This final rule amends the Supplemental Standards to account for current Department structure resulting from organizational changes that established new offices or bureaus within Treasury and transferred certain functions and/or bureaus from the Department. This final rule also amends the Supplemental Standards applicable to employees of the Office of the Comptroller of the Currency (OCC), which generally prohibit OCC employees from investing in or borrowing from OCC supervised institutions.

DATES: *Effective:* November 6, 2014.

FOR FURTHER INFORMATION CONTACT: Elizabeth Horton, Deputy Assistant General Counsel for Ethics, Office of the General Counsel, Department of the Treasury, 1500 Pennsylvania Avenue NW., Room 2221, Washington DC 20220; (202) 622–0450.

SUPPLEMENTARY INFORMATION:

I. Background

On August 7, 1992, OGE published the OGE Standards. See 57 FR 35006–35067, as corrected at 57 FR 48557, 57 FR 52483, and 60 FR 51167, with additional grace period extensions for certain existing provisions at 59 FR 4779–4780, 60 FR 6390–6391, and 60 FR 66857–66858. The OGE Standards, codified at 5 CFR part 2635, effective February 3, 1993, established uniform standards of ethical conduct that apply to all executive branch personnel. Section 2635.105 of the OGE Standards authorizes an agency, with the concurrence of OGE, to adopt agency-specific supplemental regulations that are necessary to properly implement its ethics program. In 1995, the Department, with OGE's concurrence, established the Supplemental Standards. *See* 60 FR 22249–22255 (May 5, 1995), as codified at 5 CFR part 3101. Employees of the Department are subject to standards of ethical conduct promulgated by OGE and Treasury. The Supplemental Standards are necessary for successful implementation of the Department's ethics program in light of Treasury's unique programs and operations.

Treasury is now amending the Supplemental Standards to account for current Department structure resulting from organizational changes that established new offices or bureaus within Treasury and transferred certain functions and/or bureaus from the Department. This rule also amends the Supplemental Standards applicable to employees of the Office of the Comptroller of the Currency (OCC), which generally prohibit OCC employees from investing in or borrowing from OCC supervised institutions.

II. Amendments Related to Treasury Organizational Changes

This final rule amends the Supplemental Standards to reflect current organizational structure mandated by various statutes that resulted in the establishment of new offices or bureaus within Treasury and the transfer of certain functions and/or bureaus from the Department. As currently organized and relevant to the Supplemental Standards, the Bureaus of Alcohol, Tobacco and Firearms (ATF), Federal Law Enforcement Training Center (FLETC), the United States Customs Service (USCS), and the United States Secret Service (USSS) are no longer bureaus of the Department. New bureaus and/or offices include the Alcohol and Tobacco Tax and Trade Bureau (TTB), the Office of the Treasury Inspector General for Tax Administration (TIGTA), and the Office of the Special Inspector General for the Troubled Asset Relief Program (SIGTARP). Additionally, the Office of Thrift Supervision (OTS) was abolished by statute and certain functions of OTS have been integrated into OCC. The Department also consolidated the Bureau of Public Debt (BPD) and the Financial Management Service (FMS) into a new Bureau of the Fiscal Service (BFS).

These amendments to the Supplemental Standards are necessary in light of Title I of the Internal Revenue Service Restructuring and Reform Act of 1998 (''RRA '98''),[1] Title III, section 361(a)(2), of the USA PATRIOT Act,[2] Titles IV, VIII and XI of the Homeland Security Act of 2002 (Homeland Security Act),[3] Title I of the Emergency Economic Stabilization Act of 2008 (EESA),[4] and Title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act).[5]

Office of Treasury Inspector General for Tax Administration (TIGTA): Section 1103 of RRA '98 established TIGTA. Consistent with its authority, TIGTA exercises the duties and responsibilities of an Inspector General organization on all matters relating to the Internal Revenue Service (IRS), Treasury's largest bureau. Generally, TIGTA provides independent oversight of IRS activities. While TIGTA is organizationally placed within Treasury, it exercises distinct and separate functions from other Treasury offices and bureaus. Section 2635.203(a) of the OGE Standards authorizes an executive department, by supplemental regulation, to designate as a separate agency a component of the department that exercises a distinct and separate function. Pursuant to this authority, the Department amends the Supplemental

[1] Title I section 1103 of RRA '98 amended the Inspector General Act of 1978 at 5 U.S.C. App. 3 § 2.

[2] 31 U.S.C. 310.

[3] 6 U.S.C. 203, 381, and 531.

[4] 12 U.S.C. 5231.

[5] Title III section 313 of Public Law 111–203 (2010), 12 U.S.C. 5413.

Standards to designate TIGTA as a separate agency in § 3101.102 for purposes of the OGE regulations contained in subpart B of 5 CFR part 2635 governing gifts from outside sources (the ''OGE Gift Rules'') and 5 CFR 2635.807 governing teaching, speaking or writing (the ''OGE Teaching-Speaking-Writing Rules'').

This rule further amends § 3101.106 of the Supplemental Standards, *Additional rules for Internal Revenue Service employees,* to include TIGTA staff in the restrictions against making certain attorney or accountant recommendations in connection with IRS official business, from engaging in particular outside employment and business activities related to Federal, state or local government tax matters, and from engaging in accounting, interpretation of financial records or the record-making phase of accounting related to tax matters. TIGTA personnel provide oversight of IRS activities, and the prohibitions in this section are consistent with TIGTA's oversight role of IRS and its longstanding internal policy.

The Financial Crimes Enforcement Network (FinCEN): The USA PATRIOT Act established FinCEN as a bureau of the Treasury in 2001. FinCEN is dedicated to enhancing the integrity of the financial systems by facilitating the detection and deterrence of financial crime through a legislative framework commonly known as the Bank Secrecy Act. FinCEN exercises distinct and separate functions from other Treasury bureaus and offices. Pursuant to 5 CFR 2635.203(a), this final rule amends § 3101.102 of the Supplemental Standards to designate FinCEN as a separate agency for purposes of the OGE Gift Rules and the OGE Teaching-Speaking-Writing Rules.

Transfer of Certain Bureaus and/or Functions out of Treasury: The Homeland Security Act established a new agency, the Department of Homeland Security, which integrated all or a part of 22 different Federal departments and agencies. Relevant to Treasury, Titles IV and VIII of the Act mandated, with some exceptions, the transfer of all Department functions, personnel, assets and liabilities of the U.S. Customs Service (USCS), the Federal Law Enforcement Training Center (FLETC), and the U.S. Secret Service (USSS) to the Secretary of Homeland Security. Effective in 2003, these Bureaus are no longer a part of Treasury. Accordingly, § 3101.102 is amended to remove USCS, FLETC, and USSS as designated separate agencies. Moreover, §§ 3101.110 and 3101.111, which provide additional rules for USCS and USSS employees, respectively, are hereby removed from part 3101.

Title XI of the Homeland Security Act of 2002 also created the Bureau of Alcohol, Tobacco, Firearms and Explosives within the Department of Justice, comprised in part of the transferred authorities, functions, personnel and assets of Treasury's Bureau of Alcohol, Tobacco and Firearms (ATF). Accordingly, § 3101.102 is also amended to remove ATF as a designated separate agency. Per section 1111(c) of the Act, however, Treasury retained certain revenue collection functions under chapters 51 and 52 of the Internal Revenue Code of 1986, sections 4181 and 4182 of the Internal Revenue Code of 1986, and title 27 of the United States Code. Effective in 2003, Treasury exercised these retained duties through the establishment of a new bureau, the Alcohol and Tobacco Tax and Trade Bureau (TTB). TTB's duties generally focus on excise taxation of alcohol, tobacco, firearms and ammunition products and the regulation of the operations and practices of certain alcohol and tobacco producers. TTB exercises distinct and separate functions from other Treasury bureaus and offices. Pursuant to 5 CFR 2635.203(a), the Department amends § 3101.102 to designate TTB as a separate agency for purposes of the OGE Gift Rules and the OGE Teaching-Speaking-Writing Rules. In addition, § 3101.105, *Additional rules for Bureau of Alcohol, Tobacco and Firearms employees,* is amended to remove references to ATF and add TTB references in their place.

Office of the Special Inspector General for the Troubled Asset Relief Program (SIGTARP): EESA established the Office of Financial Stability within the Department of the Treasury and authorized the Troubled Asset Relief Program (TARP). In Title I, EESA also created SIGTARP. Like TIGTA, SIGTARP exercises the duties and responsibilities of an Inspector General organization, focusing on matters relating to the purchase, management and sale of assets under TARP. SIGTARP is organizationally placed within Treasury, but exercises distinct and separate functions from other Treasury offices and bureaus. Pursuant to 5 CFR 2635.203(a), the Department amends the Supplemental Standards to designate SIGTARP as a separate agency in § 3101.102 for purposes of the OGE Gift Rules and the OGE Teaching-Speaking-Writing Rules.

The Offices of Thrift Supervision and Comptroller of the Currency (OTS and OCC): The Dodd-Frank Act provides for a comprehensive overhaul of financial services regulation in the United States. Under Title III of the Dodd-Frank Act, OCC assumed, as of July 21, 2011, all functions of OTS related to Federal savings associations and the rulemaking authority of OTS related to all savings associations, both Federal and state. OTS was abolished ninety days later.[6] Title III also provided for the transfer of OTS employees to either OCC or the Federal Deposit Insurance Corporation (FDIC), allocated as necessary to perform or support OTS functions transferred to OCC and FDIC, respectively.[7] This rule amends the Supplemental Standards to reflect the foregoing changes. Pursuant to 5 CFR 2635.203(a), this final rule removes OTS from § 3101.102 as a separate agency and removes § 3101.109, *Additional rules for Office of Thrift Supervision employees,* from part 3101.

Bureau of the Fiscal Service: Effective in October 2012, Treasury consolidated the Financial Management Service (FMS) and Bureau of the Public Debt (BPD) into a new Bureau of the Fiscal Service (BFS). BFS will carry out the former missions of FMS and BPD, generally, engaging in the borrowing of money needed to operate the Federal government, administering the public debt, receiving and disbursing public monies, and maintaining government accounts. BFS exercises distinct and separate functions from other Treasury bureaus and offices. Pursuant to 5 CFR 2635.203(a), this final rule amends § 3101.102 of the Supplemental Standards to designate BFS as a separate agency for purposes of the OGE Gift Rules and the OGE Teaching-Speaking-Writing Rules.

III. Additional Amendments to OCC Supplemental Standards

The Supplemental Standards, at 5 CFR 3101.108, set forth rules that apply solely to employees of OCC. The Supplemental Standards address potential conflicts of interest by prohibiting OCC employees, subject to certain exceptions, from investing in or

[6] Dodd-Frank Act section 312(b)(2)(B)(i), 12 U.S.C. 5412(b)(2)(B)(i). Title III provides for the transfer of all supervisory functions of the OTS relating to state savings associations to the Federal Deposit Insurance Corporation (FDIC) and all functions relating to the supervision of any savings and loan holding company and non-depository institution subsidiaries of such holding companies, as well as rulemaking authority for savings and loan holding companies, to the Board of Governors of the Federal Reserve System (Board).

[7] Dodd-Frank Act section 322(a), 12 U.S.C. 5432(a). Title X of the Dodd-Frank Act provided for the transfer of certain authorities regarding a number of consumer protection laws from the Federal banking agencies to the Consumer Financial Protection Bureau.

borrowing from the institutions supervised by the agency. This rule amends both the borrowing and securities prohibitions, and the exceptions thereto, to ensure that a single set of ethics rules, covering transactions and relationships with all types of entities now supervised by OCC, is in place for all OCC employees.

In addition, other amendments to the Supplemental Standards implement changes to 18 U.S.C. 212 and 213, which generally prohibit an examiner from accepting a loan or gratuity from a financial institution that he or she examines.[8] These statutes were amended by the Preserving Independence of Financial Institution Examinations Act of 2003 (Examinations Act),[9] which creates two exceptions to the general prohibition. Under the Examinations Act, it is no longer prohibited for an examiner to hold a consumer credit card account or obtain a loan secured by residential real property that is used as the principal residence of the examiner if: (1) The examiner satisfies any financial requirements for the credit card or residential real property loan that are generally applicable to all applicants for the same type of credit card account or residential real property loan; and (2) the terms and conditions for the card or loan are generally no more favorable to the examiner than those generally applicable to credit card accounts or residential real property loans offered by the financial institution to other cardholders or borrowers in comparable circumstances.[10] Those exceptions to the borrowing prohibition are included in this rule.

A. Prohibited Financial Interests

1. General Prohibition

Section 3108.108(a)(1) currently prohibits OCC employees (and their spouses and minor children) from owning, directly or indirectly, securities of any commercial bank (including both national and state-chartered banks) or commercial bank affiliate, including a bank holding company. Because OCC now directly supervises Federal savings associations, the final rule amends 5 CFR. 3101.108(a) to expand this list of institutions in which an OCC employee may not invest to include Federal savings associations, state savings associations, affiliates of savings associations (including savings and loan holding companies), and foreign banks, which may own U.S. commercial banks or savings associations. In addition, the final rule clarifies the following exceptions to this general prohibition.

2. Exceptions to the Securities Prohibition

a. Mutual Funds

The final rule also amends § 3101.108(a)(3)(i) to clarify the types of publicly traded or publicly available mutual funds in which OCC employees (and their spouses or minor children) may invest. The current rule provides an exception for OCC employees (and their spouses or minor children) to invest in a publicly traded or publicly available mutual fund or other collective investment fund or in a widely held pension or similar fund provided that the fund does not invest more than 25 percent of its assets in the securities of the institutions in which OCC employees are prohibited from investing. The inclusion of a percentage test in this provision has made the exception difficult to administer because the percentage of a mutual fund's investment in a particular sector may change frequently. The final rule eliminates the 25 percent asset test and provides instead that OCC employees (and their spouses or minor children) may invest in any publicly traded or publicly available mutual fund, collective investment fund or pooled investment fund, or widely-held pension or similar fund that does not have a stated policy of concentration in the financial services industry, provided that neither the employee nor the employee's spouse exercises or has the ability to exercise control over the financial interests held by the fund or the selection of fund holdings.

b. Exempt Holding Companies

The final rule also amends 5 CFR 3101.108(a)(3)(ii) to expand the exception to the investment prohibition for certain holding companies that own nonbank banks or credit card banks to also include savings and loan holding companies where the ownership or operation of savings associations is not a significant activity (generally less than 15 percent of the assets) of the holding company. However, an employee who owns such an interest would be disqualified from participating in the regulation or supervision of the savings associations. This exception is intended to permit interests of a character unlikely to raise questions regarding the objective and impartial performance of OCC employees' official duties or the possible misuse of their positions. An example of an exempt holding company would be a large retailer that is a savings and loan holding company where the savings association constitutes only 14 percent of the holding company's assets. The companies to which this exception applies will be identified on a list maintained by the OCC Ethics Counsel and updated on a quarterly basis.

c. Foreign Bank Securities

The final rule also includes a new exception at 5 CFR 3101.108(a)(3)(iii) that establishes the conditions under which OCC employees (and their spouses or minor children) may invest in the securities of foreign banks. The exception permits OCC employees (and their spouses or minor children) to invest in the securities of any foreign bank that does not own a commercial bank or savings association in the United States. The exception is available to OCC employees (and their spouses or minor children), except where the OCC employee is assigned to examine a Federal branch or agency of that foreign bank.

d. Use of Institution as Custodian or Trustee

The final rule amends the redesignated § 3101.108(a)(3)(iv) to expand the exception that permits OCC employees to use institutions under OCC's supervision as custodian or trustee of accounts containing tax-deferred retirement accounts. Because the general investment prohibition will be expanded to include Federal and state savings associations, it is appropriate to correspondingly expand the exception to include those institutions as well. The amended provision will permit OCC employees to use a commercial bank, a savings association or an affiliate of a commercial bank or savings association as custodian or trustee of accounts containing tax-deferred retirement funds.

B. Prohibited Borrowing

1. General Prohibition

Section 3101.108(b)(1) of the current Supplemental Standards generally prohibits covered OCC employees,[11] subject to certain exceptions discussed below, from seeking or obtaining credit

[8] 18 U.S.C. 213 generally prohibits an examiner from accepting a loan or gratuity from a financial institution examined by the examiner. The companion statute, 18 U.S.C. 212, prohibits officers, directors or employees of financial institutions from offering a loan or gratuity to an examiner. Criminal penalties apply for violations of these statutes.

[9] Pub. L. 108–198, 117 Stat. 2900 (2003), *codified at* 18 U.S.C. 212(c)(4).

[10] 18 U.S.C. 212(c)(4).

[11] ''Covered'' OCC employees include bank examiners and all other employees designated by the Comptroller under OCC ethics policies. *See* 5 CFR 3101.108(b)(3). Under these policies, ''covered employee'' means any employee, except any administrative employee, who is required to file financial disclosure reports.

from a national bank or from any officer, director, employee or subsidiary of any national bank.[12] This prohibition extends to the spouses and minor children of covered OCC employees, unless the loan or extension of credit meets certain standards.[13] To reflect the OCC's assumption of supervisory duties for Federal savings associations, the final rule amends 5 CFR 3101.108(b)(1) to prohibit covered OCC employees from seeking or obtaining credit from any national bank or Federal savings association as well as any officer, director, employee or subsidiary of those institutions.

2. Exceptions to the Borrowing Prohibition

a. Credit Cards

The Supplemental Standards currently include an exception to the general borrowing prohibition for credit card accounts. Under the current rule, covered OCC employees, except examiners, may obtain and hold a credit card from a national bank or its subsidiary if the credit card is issued on terms and conditions no more favorable than those offered to the general public.[14] The regulations state that an examiner (or a spouse or minor child of an examiner) may obtain and hold a credit card from a national bank or its subsidiary only if the credit card is issued on terms and conditions no more favorable than those offered to the general public *and* the examiner submits to the Chief Counsel or designee a written disqualification from the examination of that bank.[15]

With the passage of the Examinations Act, examiners are no longer prohibited from obtaining and holding credit cards from national banks, Federal savings associations and their subsidiaries.[16] The final rule amends the Supplemental Standards to implement this change and to remove the requirement for written disqualification as unnecessary because the terms and conditions of a credit card account are generally established according to a formula of creditworthiness and income rather than as a result of negotiation and, therefore, the risk of examiner conflicts of interest is minimal. Thus, the final rule permits all covered OCC employees (and their spouses or minor children) to seek, obtain and hold credit cards issued by national banks, Federal savings associations and their subsidiaries if: the applicant satisfies all financial requirements set by the lender that are generally applicable to all applicants for the same type of credit card account; and the applicable terms and conditions are no more favorable than those generally applicable to credit card accounts offered by the same lender to other cardholders in comparable circumstances.

An employee who holds a credit card (or whose spouse or minor child holds a credit card) must submit a written recusal notice to his or her supervisor and ethics official if the cardholder becomes involved in an adversarial dispute with the issuer of the credit card account. A cardholder is involved in an adversarial dispute if he or she is delinquent in payments on the credit card account; the issuer and the cardholder are negotiating to restructure the credit card debt; the cardholder disputes the terms and conditions of the account; or the cardholder becomes involved in any disagreement with the issuer that may cast doubt on the employee's ability to remain impartial with respect to the issuer.

b. Loans Secured by Principal Residence

The Supplemental Standards currently do not provide an exception to the borrowing prohibition that would permit any OCC employees to obtain principal residence mortgage loans from supervised institutions. As noted previously, under the Examinations Act, examiners may now obtain such loans. The final rule therefore includes a new exception to the borrowing prohibition to permit all covered OCC employees to seek and obtain these loans from national banks, Federal savings associations, and their subsidiaries under certain conditions that ensure compliance with 18 U.S.C. 213.

Under this exception the applicant must satisfy all financial requirements set by the lender for the residential real property loan that are generally applicable to borrowers for the same type of loan, and the terms and conditions applicable to the loan must be no more favorable than those generally applicable to the same type of loan offered by the same lender to other borrowers in comparable circumstances. In order to manage the risks of real or perceived conflicts of interest that may be associated with the negotiation of a real property loan, the OCC will require a covered employee who seeks or obtains (or whose spouse or minor child seeks or obtains) from a national bank, a Federal savings association or a subsidiary of either institution a real property loan secured by the applicant's principal residence to observe from the time of the initial application any recusal established under OCC ethics policy.[17]

3. Pre-existing Credit

Section 3101.108(b)(5) currently permits covered OCC employees (and their spouses and minor children) to retain pre-existing credit from national banks if the loan was incurred prior to employment with the OCC or is held by a national bank as a result of the sale or transfer of the loan to the bank or due to the conversion or merger of the lender into a national bank. Due to the OCC's expanded supervisory responsibilities over Federal savings associations as of the transfer date, the final rule amends 5 CFR 3101.108(b)(5) to provide the same treatment for pre-existing credit from both national banks and Federal savings associations, including credit obtained from Federal savings associations prior to the transfer of the supervision of those institutions to the OCC. An employee who retains pre-existing credit (or whose spouse or minor child retains pre-existing credit) from a national bank or Federal savings association must observe any recusal established under OCC ethics policy.

4. Prohibited Recommendations

Section 3101.108(d) currently prohibits OCC employees from making recommendations or suggestions, directly or indirectly, concerning the acquisition or sale or other divestiture of securities of any commercial bank or commercial bank affiliate, including a bank holding company. The OCC has determined that OCC employees should be prohibited from making recommendations with regard to the same set of institutions in which they are prohibited from investing. Therefore, the final rule expands this section to prohibit OCC employees from making any recommendations with regard to any commercial bank (including both national and state-chartered banks), Federal savings association, state savings association, or any affiliate of these institutions (including bank holding companies, savings and loan holding companies, and the non-bank subsidiaries of either type of holding company), and foreign banks that own a commercial bank or savings association in the United States.

C. Technical Changes

The final rule amends certain other provisions of the Supplemental Standards to expand existing references

[12] 5 CFR 3101.108(b)(1) (2005).

[13] 5 CFR 3101.108(b)(2).

[14] 5 CFR 3101.108(b)(4)(i).

[15] 5 CFR 3101.108(b)(4)(ii).

[16] The term ''subsidiary'' has the meaning set forth in 12 U.S.C. 1813(w)(4).

[17] Covered OCC employees will also be required to disclose the status of such loans on their annual financial disclosure reports.

to banks, commercial banks, national banks and national bank affiliates to include references to Federal savings associations. The definition of covered employee in § 3101.108(b)(3) is amended to refer to ''OCC examiner,'' rather than ''OCC bank examiner.'' Section 3101.108(e) is amended to prohibit the purchase of assets from Federal savings associations as well as national banks. Section 3101.108(f)(1) is amended to prohibit outside employment with banks, savings associations, and the affiliates of both banks and savings associations, and the definition of covered OCC employee, for purposes of this section, is amended to refer to ''OCC examiner,'' rather than ''OCC bank examiner.''

Administrative Procedure Act

Under 5 U.S.C. 553(a)(2), rules relating to agency management or personnel are exempt from the rulemaking requirements of the Administrative Procedure Act (APA). As set forth in the description of the final rule, this rule affects only the Department and its personnel. Even if this rulemaking were subject to APA proposed rulemaking procedures, the Department finds good cause, pursuant to 5 U.S.C. 553(b) and (d), to waive the requirements for notice and comment because the rule affects only Treasury staff and also operates to put in place a set of ethical rules appropriate for OCC employees after the transfer date.

Regulatory Flexibility Act Analysis

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) requires an agency to prepare a budgetary impact statement before promulgating a rule that includes a federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. This rule generally accounts for changes to Treasury's mission and organization and restricts OCC employees, subject to certain exceptions, from engaging in certain borrowing, investment, and outside employment activities. The Department therefore has determined that the rule will not result in expenditures by state, local or tribal governments or by the private sector of $100 million or more. Accordingly, the Department has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

Lists of Subjects in 5 CFR Part 3101

Conflict of interests, Ethics, Extensions of credit, Government employees, OCC employees.

For the reasons set forth in the preamble, the Department, with the concurrence of OGE, amends 5 CFR part 3101 as follows:

PART 3101—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE DEPARTMENT OF THE TREASURY

■ 1. The authority citation for part 3101 continues to read as follows:

Authority: 5 U.S.C 301, 7301, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); 18 U.S.C. 212, 213, 26 U.S.C. 7214(b); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.203(a), 2635.403(a), 2635.803, 2635.807(a)(2)(ii).

■ 2. Revise § 3101.102 to read as follows:

§ 3101.102 Designation of separate agency components.

Pursuant to 5 CFR 2635.203(a), each of the following components of the Department of the Treasury is designated as a separate agency for purposes of the regulations contained in subpart B of 5 CFR part 2635 governing gifts from outside sources and 5 CFR 2635.807 governing teaching, speaking or writing:

(a) Alcohol and Tobacco Tax and Trade Bureau (TTB);

(b) Bureau of Engraving and Printing;

(c) Bureau of the Fiscal Service (BFS);

(d) Financial Crimes Enforcement Network (FinCEN);

(e) Internal Revenue Service (IRS);

(f) Office of the Comptroller of the Currency (OCC);

(g) Office of the Inspector General;

(h) Office of the Special Inspector General for the Troubled Asset Relief Program (SIGTARP);

(i) Office of the Treasury Inspector General for Tax Administration (TIGTA); and

(j) United States Mint.

Note to § 3101.102: As a result of the designations contained in this section, employees of the remaining parts of the Department of the Treasury (e.g., employees in Departmental Offices) will also be treated as employees of an agency that is separate from all of the above listed bureaus and offices for purposes of determining whether the donor of a gift is a prohibited source under 5 CFR 2635.203(d) and for identifying an employee's ''agency'' under 5 CFR 2635.807 governing teaching, speaking and writing. For purposes of this section, employees in the Legal Division shall be considered to be part of the bureaus or offices in which they serve.

■ 3. Section 3101.105 is revised to read as follows:

§ 3101.105 Additional rules for Alcohol and Tobacco Tax and Trade Bureau employees.

The following rules apply to the employees of the Alcohol and Tobacco Tax and Trade Bureau and are in addition to §§ 3101.101 through 3101.104.

(a) *Prohibited financial interests.* Except as provided in this section, no employee of TTB, or spouse or minor child of a TTB employee, shall have, directly or indirectly, any financial interest, including compensated employment, in the alcohol, tobacco, firearms or explosives industries. The term financial interest is defined in § 2635.403(c) of this title.

(b) *Waiver.* An agency designee, with the advice and legal clearance of the DAEO or Office of the Chief Counsel, may grant a written waiver of the prohibition in paragraph (a) of this section on a determination that the financial interest is not prohibited by 26 U.S.C. 7214(b) and that, in the mind of a reasonable person with knowledge of the particular circumstances, the financial interest will not create an appearance of misuse of position or loss of impartiality, or call into question the impartiality and objectivity with which TTB's programs are administered. A waiver under this paragraph may require appropriate conditions, such as execution of a written disqualification.

■ 4. Section 3101.106 is revised to read as follows:

§ 3101.106 Additional rules for Internal Revenue Service and Treasury Inspector General for Tax Administration employees.

The following rules apply to the employees of the Internal Revenue Service and the Treasury Inspector General for Tax Administration and are in addition to §§ 3101.101 through 3101.104.

(a) *Prohibited recommendations.* Employees of the IRS or TIGTA shall not recommend, refer or suggest, specifically or by implication, any attorney, accountant, or firm of attorneys or accountants to any person in connection with any official business which involves or may involve the IRS.

(b) *Prohibited outside employment.* Involvement by an employee of the IRS or TIGTA in the following types of outside employment or business activities is prohibited and shall constitute a conflict with the employee's official duties pursuant to 5 CFR 2635.802:

(1) Performance of legal services involving Federal, State or local tax matters;

(2) Appearing on behalf of any taxpayer as a representative before any Federal, State, or local government agency, in an action involving a tax matter except on written authorization of the Commissioner of Internal Revenue or the Treasury Inspector General for Tax Administration;

(3) Engaging in accounting, or the use, analysis, and interpretation of financial records when such activity involves tax matters;

(4) Engaging in bookkeeping, the recording of transactions, or the record-making phase of accounting, when such activity is directly related to a tax determination; and

(5) Engaging in the preparation of tax returns for compensation, gift, or favor.

(c) *Seasonal employees.* Seasonal employees of the IRS while in non-duty status may engage in outside employment or activities other than those prohibited by paragraph (b) of this section without obtaining prior written permission.

■ 5. Section 3101.108 is amended by:

■ a. Revising paragraphs (a)(1) and (a)(3)(i) and (ii);

■ b. Redesignating paragraphs (a)(3)(iii) and (iv) as paragraphs (a)(3)(iv) and (v), respectively, and adding a new paragraph (a)(3)(iii);

■ c. Revising newly designated paragraph (a)(3)(iv) and paragraphs (b)(1), (b)(3)(i), (b)(4) and (5), (d), (e), (f)(1), and (f)(2)(i).

The addition and revisions read as follows.

§ 3101.108 Additional rules for Office of the Comptroller of the Currency employees.

* * * * *

(a) * * *

(1) *Prohibition.* Except as provided in paragraphs (a)(3) and (g) of this section, no OCC employee, or spouse or minor child of an OCC employee, shall own, directly or indirectly, securities of any commercial bank (including both national and state-chartered banks), Federal savings association, state savings association, or of any affiliate of these institutions (including bank holding companies, savings and loan holding companies, and non-bank subsidiaries of either type of holding company), or of any foreign bank.

* * * * *

(3) * * *

(i) Owning an interest in a publicly traded or publicly available mutual fund, other collective investment fund or pooled investment product, or a widely-held pension or other similar fund if the fund does not have a stated policy of concentration in the financial services industry and neither the employee nor the employee's spouse exercises or has the ability to exercise control over the financial interests held by the fund or the selection of fund holdings;

(ii) Owning securities in a publicly traded company owning banks or savings associations if—

(A) By virtue of the limited activities of the banks or savings associations, the ownership of banks or savings associations does not cause their parent holding company to become a bank holding company under the Bank Holding Company Act of 1956, *12 U.S.C. 1841* et seq, (for example, a bank engaged only in credit card activities);

(B) For savings and loan holding companies, the ownership or operation of savings associations is not a significant activity (generally less than 15% of the assets) of the holding company;

(C) The company is identified as meeting the requirements of (A) or (B) above on a list maintained by the OCC Ethics Counsel; and

(D) The employee owning or seeking to purchase the securities does not participate in the regulation or supervision of any bank or savings association owned or operated by the company;

(iii) Owning the securities of a foreign bank that does not own a commercial bank or savings association in the United States provided that the employee owning the securities does not participate in the regulation or supervision of any Federal branch or agency operated by the foreign bank;

(iv) Using a commercial bank, a savings association or an affiliate of a commercial bank or savings association as custodian or trustee of accounts containing tax-deferred retirement funds; or

(b) * * *

(1) Prohibition on employee borrowing. Except as provided in this section, no covered OCC employee shall seek or obtain credit from any national bank or Federal savings association or from any officer, director, employee or subsidiary of a national bank or Federal savings association.

* * * * *

(3) * * *

(i) An OCC examiner; and

* * * * *

(4) *Exceptions*—(i) *Credit cards.* A covered OCC employee or the spouse or minor child of such a covered OCC employee may seek, obtain or hold a credit card from a national bank, a Federal savings association or a subsidiary of a national bank or Federal savings association if—

(A) The applicant satisfies all financial requirements set by the lender that are generally applicable to all applicants for the same type of credit card account;

(B) The terms and conditions applicable with respect to the credit card account and any credit extended under the account are no more favorable generally to the applicant than the terms and conditions that are generally applicable to credit card accounts offered by the same lender to other cardholders in comparable circumstances;

(C) An employee who holds a credit card (or whose spouse or minor child holds a credit card) must submit a written recusal notice to his or her supervisor and ethics official if the cardholder becomes involved in an adversarial dispute with the issuer of the credit card account. A cardholder is involved in an adversarial dispute if he or she is delinquent in payments on the credit card account; the issuer and the cardholder are negotiating to restructure the credit card debt; the cardholder disputes the terms and conditions of the account; or the cardholder becomes involved in any disagreement with the issuer that may cast doubt on the employee's ability to remain impartial with respect to the issuer.

(ii) *Loans secured by principal residence.* A covered OCC employee or the spouse or minor child of a covered OCC employee may seek and obtain a loan from a national bank, a Federal savings association or a subsidiary of a national bank or Federal savings association subject to the following conditions:

(A) The loan is secured by residential real property that is the applicant's principal residence;

(B) The applicant must satisfy all financial requirements set by the lender for the residential real property loan that are generally applicable to borrowers for the same type of residential real property loan; and

(C) The terms and conditions applicable with respect to the residential real property loan and any credit extended under the loan must be no more favorable generally to the

applicant than the terms and conditions that are generally applicable to residential real property loans offered by the same lender to other borrowers in comparable circumstances.

(iii) A covered employee who seeks or obtains a real property loan from a national bank, Federal savings association or a subsidiary of a national bank or Federal savings association or whose spouse or minor child obtains a real property loan under the requirements of paragraph (b)(4)(ii) above must observe from the time of the initial application any recusal established under OCC ethics policy.

(5) *Pre-existing credit.* (i) This section does not prohibit a covered OCC employee, or spouse or minor child of a covered OCC employee from retaining a loan or extension of credit from a national bank or Federal savings association on its original terms, and subject to any recusal established under OCC ethics policy, if the loan or extension of credit:

(A) Was incurred prior to employment by the OCC;

(B) Was obtained from a lender that was not supervised by the OCC at the time it was obtained; or

(C) Is held by a national bank or Federal savings association or subsidiary thereof as the result of the sale or transfer of a loan to the national bank or Federal savings association or the conversion or merger of the lender into a national bank or Federal savings association.

(ii) Any renewal or renegotiation of a pre-existing loan or extension of credit will be treated as a new loan subject to the prohibitions in paragraph (b)(1) of this section.

* * * * *

(d) *Prohibited recommendations.* Employees of the OCC shall not make recommendations or suggestions, directly or indirectly, concerning the acquisition or sale or other divestiture of securities of any commercial bank (including both national and state-chartered banks), Federal savings association, state savings association, affiliate of these institutions (including bank holding companies, savings and loan holding companies, and any non-bank subsidiaries of either type of holding company), or foreign bank that owns a commercial bank or savings association in the United States.

(e) *Prohibited purchase of assets.* No employee of the OCC, or spouse or minor child of an OCC employee, shall purchase, directly or indirectly, an asset (i.e. real property, automobiles, furniture, or similar items) from a national bank or Federal savings association or an affiliate of a national bank or a Federal savings association, including a bank or savings and loan holding company, unless it is sold at a public auction or by other means which ensure that the selling price is the asset's fair market value.

(f) *Outside employment*—(1) *Prohibition on Outside Employment.* No covered OCC employee shall perform services for compensation for any bank, savings association or a bank or savings association affiliate, or for any officer, director or employee of, or for any person connected in any capacity with a bank, savings association or bank or savings association affiliate.

(2) * * *

(i) An OCC examiner; and

* * * * *

§ 3101.109 [Removed]

■ 5. Remove § 3101.109.

§ 3101.110 [Removed]

■ 6. Remove § 3101.110.

§ 3101.111 [Removed]

■ 7. Remove reserved § 3101.111.

Dated: October 14, 2014.

By the Department of the Treasury.

Christopher J. Meade,

General Counsel.

Dated: October 24, 2014.

By the Office of Government Ethics.

Walter M. Shaub,

Director.

[FR Doc. 2014–26173 Filed 11–5–14; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2013–0894; Special Conditions No. 25–532–SC]

Special Conditions: Airbus A350–900 Series Airplane; Interaction of Systems and Structures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions, request for comments; correction.

SUMMARY: This document corrects errors that appeared in final special conditions docket no. FAA–2013–0894, which was published in the **Federal Register** on December 20, 2013 (78 FR 76980). The errors are in the document's special conditions stage (notice vs. final) and special conditions number.

DATES: This action is effective November 6, 2014.

FOR FURTHER INFORMATION CONTACT: Todd Martin, FAA, Airframe/Cabin Safety, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone (425) 227–1178; facsimile (425) 227–1320.

SUPPLEMENTARY INFORMATION: The final special conditions document designated as ''Docket No. FAA–2013–0894; Notice No. 25–13–16–SC'' was published in the **Federal Register** on December 20, 2013 (78 FR 76980). The document issued special conditions pertaining to interaction of systems and structures on Airbus A350–900 series airplanes.

As published, the document contained two errors: One referring to the document's special conditions stage, ''Notice no.,'' instead of ''Special Conditions No.;'' and one in the special conditions number itself, 25–13–16–SC (a notice number), instead of 25–532–SC (the assigned final special conditions number).

Because this error and correction do not affect the regulatory content of the special conditions, the special conditions are not being re-published.

Correction

In the final special conditions, request for comments document [FR Doc. 2013–30235, Filed 12–19–13; 8:45 a.m.] published on December 20, 2013 (78 FR 76980), make the following correction:

On page 76980, in the first column, in the heading, correct ''Notice No. 25–13–16–SC'' to read ''Special Conditions No. 25–532–SC''.

Issued in Renton, Washington, on October 31, 2014.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–26341 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–1064; Directorate Identifier 2012–NM–101–AD; Amendment 39–17991; AD 2014–20–18]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2005–23–08 for certain Airbus Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R airplanes; and Model A300 C4–605R Variant F airplanes. AD 2005–23–08 required repetitive inspections to detect cracks of certain attachment holes, installation of new fasteners, follow-on inspections or repair if necessary, and modification of the angle fittings of fuselage frame FR47. This new AD adds new repetitive ultrasonic inspections for cracks of the center wing box lower panel; and repair if necessary. This new AD also removes certain airplanes from the applicability. This AD was prompted by reports of cracks found on the horizontal flange of the Frame 47 internal corner angle fitting while accomplishing the modification required by AD 2005–23–08. We are issuing this AD to detect and correct fatigue cracking of the forward fitting of fuselage frame FR47, which could result in reduced structural integrity of the frame.

DATES: This AD becomes December 11, 2014.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 11, 2014.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of December 19, 2005 (70 FR 69056, November 14, 2005).

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of July 8, 2002 (67 FR 38193, June 3, 2002).

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2013-1064;* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

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

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

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005). AD 2005–23–08 applied to certain Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes; Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R airplanes; and Model A300 C4–605R Variant F airplanes. The NPRM published in the **Federal Register** on December 26, 2013 (78 FR 78285).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2012–0092, dated May 25, 2012; Correction dated June 4, 2012 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''); to correct an unsafe condition for the specified products. The MCAI states:

> Prompted by cracks found on the Frame 47 angle fitting, DGAC France published AD 2000–533–328 [*http://ad.easa.europa.eu/ad/F-2000-533-328R1*] to require [a] repetitive inspection programme for fuselage frame 47. If not detected and corrected, these cracks could affect the structural integrity of the Centre Wing Box (CWB) of the aeroplane.
>
> Subsequent to the publication of a new repetitive inspection programme for fuselage frame 47 at certain fasteners of the CWB angle fitting, DGAC France issued AD F–2004–159 [*http://ad.easa.europa.eu/ad/F-2004-159*] [which corresponds to AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005)], superseding AD 2000–533–328.
>
> After DGAC France AD F–2004–159 was issued, cracks were reportedly found on the horizontal flange of the Frame 47 internal corner angle fitting during accomplishment of routine maintenance structural inspection and modification in accordance with Airbus SB A300–57–6050.
>
> Prompted by these findings, Airbus reviewed and amended the inspection programme for the internal lower angle fitting flange (horizontal face). The inspection programme for the lower angle fitting web (vertical face) related to SB A300–57–6049 and internal lower angle fitting modification programme related to SB A300–57–6050 remain unchanged.
>
> For the reasons explained above, this new [EASA] AD retains the requirements of DGAC France AD F–2004–159, which is superseded, and requires additional repetitive [ultrasonic] inspections [for cracks] of the CWB lower panel through the ultrasonic method and, depending on findings, [e.g., repair] re-installation of removed fasteners in transition fit instead of interference.
>
> This [EASA] AD has been republished to correct a typographical error * * *.

The repetitive interval for the new ultrasonic inspection is either 1,260 flight cycles or 2,720 flight hours, whichever occurs first; or 1,360 flight cycles or 2,200 flight hours, whichever occurs first; depending on average flight time of the airplane. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-1064-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (78 FR 78285, December 26, 2013) and the FAA's response to each comment.

Requests To Remove Requirement To Refer to This AD in Repair Approvals

Airlines for America, Inc. (A4A), on behalf of seven affected member airlines, requested that we revise paragraphs (m)(1), (m)(2), and (o)(2) of the NPRM (78 FR 78285, December 26, 2013) to remove the requirement to include the AD reference in repair approvals. The commenters have made this request because the proposed requirement is overly broad and would add significant cost and complexity to their operations. The commenters were concerned that this proposed requirement would set a precedent for how repairs are approved, and could negatively affect all U.S. operators of foreign-manufactured airplanes.

We concur with the commenters' request to remove from this AD the requirement that repair approvals must specifically refer to this AD.

Since late 2006, we have included a standard paragraph titled ''Airworthy Product'' in all MCAI ADs in which the FAA develops an AD based on a foreign authority's AD. The MCAI or referenced service information in an FAA AD often directs the owner/operator to contact the manufacturer for corrective actions, such as a repair. Briefly, the Airworthy Product paragraph allowed owners/operators to use corrective actions provided by the manufacturer if those actions were FAA-approved. In addition, the paragraph stated that any actions approved by the State of Design Authority (or its delegated agent) are considered to be FAA-approved.

In the NPRM (78 FR 78285, December 26, 2013), we proposed to prevent the

use of repairs that were not specifically developed to correct the unsafe condition, by requiring that the repair approval provided by the State of Design Authority or its delegated agent specifically refer to this FAA AD. This change was intended to clarify the method of compliance and to provide operators with better visibility of repairs that are specifically developed and approved to correct the unsafe condition. In addition, we proposed to change the phrase ''its delegated agent'' to include ''the Design Approval Holder (DAH) with a State of Design Authority's design organization approval (DOA)'' to refer to a DAH authorized to approve required repairs for the proposed AD.

One commenter to the NPRM (78 FR 78285, December 26, 2013), United Parcel Service (UPS), stated the following: ''The proposed wording, being specific to repairs, eliminates the interpretation that Airbus messages are acceptable for approving minor deviations (corrective actions) needed during accomplishment of an AD mandated Airbus service bulletin.''

This comment has made the FAA aware that some operators have misunderstood or misinterpreted the Airworthy Product paragraph to allow the owner/operator to use messages provided by the manufacturer as approval of deviations during the accomplishment of an AD-mandated action. The Airworthy Product paragraph does not approve messages or other information provided by the manufacturer for deviations to the requirements of the AD-mandated actions. The Airworthy Product paragraph only addresses the requirement to contact the manufacturer for corrective actions for the identified unsafe condition and does not cover deviations from other AD requirements. However, deviations to AD-required actions are addressed in 14 CFR 39.17, and anyone may request the approval for an alternative method of compliance to the AD-required actions using the procedures found in 14 CFR 39.19.

To address this misunderstanding and misinterpretation of the Airworthy Product paragraph, we have changed that paragraph and retitled it ''Contacting the Manufacturer.'' This paragraph now clarifies that for any requirement in this AD to obtain corrective actions from a manufacturer, the actions must be accomplished using a method approved by the FAA, EASA, or Airbus's EASA DOA.

The Contacting the Manufacturer paragraph also clarifies that, if approved by the DOA, the approval must include the DOA-authorized signature. The DOA signature indicates that the data and information contained in the document are EASA-approved, which is also FAA-approved. Messages and other information provided by the manufacturer that do not contain the DOA-authorized signature approval are not EASA-approved, unless EASA directly approves the manufacturer's message or other information.

This clarification does not remove flexibility afforded previously by the Airworthy Product paragraph. Consistent with long-standing FAA policy, such flexibility was never intended for required actions. This is also consistent with the recommendation of the AD Implementation Aviation Rulemaking Committee to increase flexibility in complying with ADs by identifying those actions in manufacturers' service instructions that are ''Required for Compliance'' with ADs. We continue to work with manufacturers to implement this recommendation. But once we determine that an action is required, any deviation from the requirement must be approved as an alternative method of compliance.

Other commenters pointed out that in many cases the foreign manufacturer's service bulletin and the foreign authority's MCAI may have been issued some time before the FAA AD. Therefore, the DOA may have provided U.S. operators with an approved repair, developed with full awareness of the unsafe condition, before the FAA AD is issued. Under these circumstances, to comply with the FAA AD, the operator would be required to go back to the manufacturer's DOA and obtain a new approval document, adding time, and expense to the compliance process with no safety benefit.

Based on these comments, we removed from this AD the requirement that the DAH-provided repair specifically refer to this AD. Before adopting such a requirement in the future, the FAA will coordinate with affected DAHs and verify they are prepared to implement means to ensure that their repair approvals consider the unsafe condition addressed in the AD. Any such requirements will be adopted through the normal AD rulemaking process, including notice-and-comment procedures, when appropriate.

We have also decided not to include a generic reference to either the ''delegated agent'' or the ''DAH with State of Design Authority design organization approval'' for new requirements, but instead we will provide the specific delegation approval granted by the State of Design Authority for the DAH.

Request To Revise Costs of Compliance

One commenter, FedEx, requested assurance that two inspections (the rotating probe of the attachment holes of the horizontal flange of the internal corner angle fitting, and the ultrasonic inspection of the aft bottom panel of the center wing box) specified in the NPRM (78 FR 78285, December 26, 2013) are to be conducted as two separate inspections at two separate thresholds and intervals. FedEx observed that both inspections are contained in the same service information, and that these two inspections appear to be combined in the Costs of Compliance paragraph of the NPRM. FedEx requested that the estimated costs be presented separately for the two inspection actions, and added that the Costs of Compliance paragraph should specify 4 work-hours for the new ultrasonic inspection.

We agree to clarify the Costs of Compliance paragraph. There are two inspection actions (rotating probe and ultrasonic inspections) identified in Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012, and these are listed separately in the Costs of Compliance paragraph. The second row of the table in the Costs of Compliance paragraph should reflect the costs for the rotating probe inspections identified in Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012; we have revised the second row of the table in the Costs of Compliance paragraph accordingly. We have also revised the fourth row of the table in the Costs of Compliance paragraph to refer to Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012, to reflect costs for the new ultrasonic inspection.

In addition, we agree with FedEx that the ultrasonic inspection takes 4 work-hours, as specified in Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012. In addition, Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012, specifies 12 work-hours for access and close procedures. Therefore, we have revised the work-hours for the ultrasonic inspection specified in the fourth row of the table in the Costs of Compliance paragraph from 35 to 16 work-hours.

Conclusion

We reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these changes:

• Are consistent with the intent that was proposed in the NPRM (78 FR 78285, December 26, 2013) for correcting the unsafe condition; and

• Do not add any additional burden upon the public than was already proposed in the NPRM (78 FR 78285, December 26, 2013).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Costs of Compliance

We estimate that this AD affects 65 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane
Inspection for attachment holes on internal angles [retained action from AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005)].	13	$85	$0	$1,105.
Rotating probe inspections for attachment holes in the horizontal flange (specified in Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012) [retained action from AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005)].	30	85	Between $6,637 and $19,091.	Between $9,187 and $21,641 per inspection cycle.
Modification [retained action from AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005)].	Between 65 and 365	85	$3,370	Between $8,895 and $34,395.
New ultrasonic inspections of the aft bottom panel of the center wing box (specified in Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012).	16	85	Between $11,750 and $18,720.	Between $13,110 and $20,080 per inspection cycle.

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

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to 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 control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is 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.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2013-1064;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this 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.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005), and adding the following new AD:

2014–20–18 Airbus: Amendment 39–17991. Docket No. FAA–2013–1064; Directorate Identifier 2012–NM–101–AD.

(a) Effective Date

This AD becomes effective December 11, 2014.

(b) Affected ADs

This AD replaces AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005).

(c) Applicability

This AD applies to Airbus Model B4–603, B4–620, and B4–622 airplanes; Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R airplanes; and Model A300 C4–605R Variant F airplanes; certificated in any category; except airplanes on which Airbus Modification 12171 or 12249 has been embodied in production, or on which Airbus Service Bulletin A300–57–6069 has been embodied in service.

(d) Subject

Air Transport Association (ATA) of America Code 57: Wings.

(e) Reason

This AD was prompted by reports of cracks found on the horizontal flange of the Frame 47 internal corner angle fitting while accomplishing the modification required by AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005). We are issuing this AD to detect and correct fatigue cracking of the forward fitting of fuselage frame FR47, which could result in reduced structural integrity of the frame.

(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 Inspections for Attachment Holes on the Internal Angles of the Wing Center Box, and Corrective Action

This paragraph restates the requirements of paragraphs (f), (g), and (h) of AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005), with revised service information. Perform a rotating probe inspection to detect cracking of the applicable attachment holes on the left and right internal angles of the wing center box in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6049, Revision 06, dated July 15, 2004; or Airbus Service Bulletin A300–57–6049, Revision 07, dated December 22, 2006. Do the inspection at the applicable time specified by paragraph 1.E.(2), Accomplishment Timescale, of Airbus Service Bulletin A300–57–6049, Revision 06, dated July 15, 2004; except as required by paragraph (j) of this AD. Repeat the rotating probe inspection specified in this paragraph thereafter at intervals not to exceed the applicable interval specified in Airbus Service Bulletin A300–57–6049, Revision 06, dated July 15, 2004, except that all touch-and-go landings must be counted in determining the total number of flight cycles between consecutive inspections. As of the effective date of this AD, only Airbus Service Bulletin A300–57–6049, Revision 07, dated December 22, 2006, may be used to accomplish the actions required by this paragraph.

(1) If no cracking is found during any inspection required by paragraph (g) of this AD: Prior to further flight, install new fasteners in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6049, Revision 06, dated July 15, 2004; or Airbus Service Bulletin A300–57–6049, Revision 07, dated December 22, 2006. As of the effective date of this AD, only Airbus Service Bulletin A300–57–6049, Revision 07, dated December 22, 2006, may be used to accomplish the actions required by this paragraph.

(2) If any cracking is found during any inspection required by paragraph (g) of this AD: Prior to further flight, perform applicable corrective actions (including reaming, drilling, drill-stopping holes, chamfering, performing follow-on inspections, and installing new or oversize fasteners), in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6049, Revision 06, dated July 15, 2004; or Airbus Service Bulletin A300–57–6049, Revision 07, dated December 22, 2006; except as required by paragraph (k) of this AD. As of the effective date of this AD, only Airbus Service Bulletin A300–57–6049, Revision 07, dated December 22, 2006, may be used to accomplish the actions required by this paragraph.

(h) Retained Inspections for Attachment Holes in the Horizontal Flange of the Internal Corner Angle Fitting of Fuselage Frame FR47, and Corrective Action

This paragraph restates the requirements of paragraphs (i), (j), and (k) of AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005), with revised service information. Perform a rotating probe inspection to detect cracking of the applicable attachment holes in the horizontal flange of the internal corner angle fitting of fuselage frame FR47, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6086, Revision 01, dated April 2, 2002; or Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012. Do the inspection at the applicable time specified in paragraph 1.E., Compliance, of Airbus Service Bulletin A300–57–6086, Revision 01, dated April 2, 2002, except as provided by paragraph (j) of this AD; or within 1,500 flight cycles after July 8, 2002 (the effective date of AD 2002–11–04, Amendment 39–12765 (67 FR 38193, June 3, 2002)); whichever occurs later. Repeat the rotating probe inspection specified in this paragraph thereafter at intervals not to exceed the applicable interval specified in Airbus Service Bulletin A300–57–6086, dated June 6, 2000, except that all touch-and-go landings must be counted in determining the total number of flight cycles between consecutive inspections. As of the effective date of this AD, only Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012, may be used to accomplish the actions required by this paragraph.

(1) If no cracking is found during any inspection required by paragraph (h) of this AD: Prior to further flight, install new fasteners in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6086, Revision 01, dated April 2, 2002; or Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012. As of the effective date of this AD, only Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012, may be used to accomplish the actions required by this paragraph.

(2) If any cracking is found during any inspection required by paragraph (h) of this AD: Prior to further flight, perform applicable corrective actions (including inspecting hole T if any cracking is found at hole G, reaming the holes, and installing oversize fasteners), in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6086, Revision 01, dated April 2, 2002; or Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012; except as required by paragraph (k) of this AD. As of the effective date of this AD, only Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012, may be used to accomplish the actions required by this paragraph.

(i) Retained Modification of Angle Fittings of the Wing Center Box

This paragraph restates the requirements of paragraph (l) of AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005). Modify the left and right internal angle fittings of the wing center box. The modification includes performing a rotating probe inspection to detect cracking, repairing cracks, cold expanding holes, and installing medium interference fitting bolts. Perform the modification in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6050, Revision 03, dated May 31, 2001; and at the applicable time specified by paragraph 1.B.(4), Accomplishment Timescale, of Airbus Service Bulletin A300–57–6050, Revision 03, dated May 31, 2001; except as required by paragraphs (j) and (k) of this AD.

(j) Retained Compliance Time Exception to Service Information Specified in Paragraphs (g), (h), and (i) of This AD

This paragraph restates the requirements of paragraph (m) of AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005). Where the service information specified in paragraphs (g), (h), and (i) of this AD specify a grace period relative to receipt of the service bulletin, this AD requires compliance within the applicable grace period following December 19, 2005 (the effective date of AD 2005–23–08), if the threshold has been exceeded.

(k) Retained Corrective Action Exception to Service Information Specified in Paragraphs (g), (h), and (i) of This AD

This paragraph restates the requirements of paragraph (n) of AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005). If any crack is detected during any inspection required by paragraph (g), (h), or (i) of this AD, and the applicable service information specifies to contact the manufacturer for disposition of certain corrective actions: Prior to further flight, repair in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the Direction Générale de l'Aviation Civile (DGAC) (or its delegated agent).

(l) Credit for Previous Actions

(1) This paragraph restates the credit provided by paragraph (o) of AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005): This paragraph provides credit for actions required by paragraph (h) of this AD, if those actions were performed before December 19, 2005 (the effective date of AD 2005–23–08), using Airbus Service Bulletin A300–57–6086, dated June 6, 2000.

(2) This paragraph restates the credit provided by paragraph (p) of AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005): This paragraph provides credit for the modification required by paragraph (i) of this AD, if the modification was performed before December 19, 2005 (the effective date of AD 2005–23–08), using Airbus Service Bulletin A300–57–6050, Revision 02, dated February 10, 2000.

(m) New Requirements of This AD: Repetitive Ultrasonic Inspections and Corrective Action

(1) For airplanes on which Airbus Service Bulletin A300–57–6050, Revision 03, dated May 31, 2001, has not been done, or on which Airbus Modification 10155 has been done: Perform an ultrasonic inspection for cracking of the left- and right-hand aft bottom panel of the center wing box (CWB), in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012. Do the inspection at the later of the times specified in paragraphs (m)(1)(i) and (m)(1)(ii) of this AD. If any cracking is found, before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). Repeat the inspection thereafter at intervals not to exceed the applicable interval specified in paragraph 1.E.(2), Accomplishment Timescale, of Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012.

(i) Within 13,400 flight cycles or 34,600 flight hours after the first flight of the airplane, whichever occurs first.

(ii) Within 650 flight cycles or 8 months after the effective date of this AD, whichever occurs first.

(2) For airplanes on which Airbus Service Bulletin A300–57–6050, Revision 03, dated May 31, 2001, has been done: Perform an ultrasonic inspection for cracking of the left- and right-hand aft bottom panel of the center wing box (CWB), in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012. Do the inspection at the later of the times specified in paragraphs (m)(2)(i) and (m)(2)(ii) of this AD. If any cracking is found, before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). Repeat the inspection thereafter at intervals not to exceed the applicable interval specified in paragraph 1.E.(2), Accomplishment Timescale, of Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012.

(i) Within 13,400 flight cycles or 34,600 flight hours after accomplishing Airbus Service Bulletin A300–57–6050, whichever occurs first.

(ii) Within 650 flight cycles or 8 months after the effective date of this AD, whichever occurs first.

(n) New Reporting Requirement

Submit a report of the findings (both positive and negative) of the inspection required by paragraph (m) of this AD to the Design Approval Holder, at the applicable time specified in paragraph (n)(1) or (n)(2) of this AD. The report must include the inspection results, a description of any discrepancies found, the airplane serial number, and the number of flight cycles and flight hours on the airplane. The inspection report form in Appendix 01 of Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012, may be used.

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

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(o) Other FAA AD Provisions

The following provisions also apply to this AD:

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

(i) 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.

(ii) AMOCs approved previously in accordance with AD 2005–23–08, Amendment 39–14366 (70 FR 69056, November 14, 2005), are approved as AMOCs for the corresponding provision of this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(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.

(p) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) 2012–0092, dated May 25, 2012; Correction dated June 4, 2012; for related information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2013-10640002.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (q)(5) and (q)(6) of this AD.

(q) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on December 11, 2014.

(i) Airbus Service Bulletin A300–57–6049, Revision 07, dated December 22, 2006.

(ii) Airbus Service Bulletin A300–57–6086, Revision 05, dated January 30, 2012.

(4) The following service information was approved for IBR on December 19, 2005 (70 FR 69056, November 14, 2005).

(i) Airbus Service Bulletin A300–57–6049, excluding Appendix 01, Revision 06, dated July 15, 2004.

(ii) Airbus Service Bulletin A300–57–6050, Revision 03, dated May 31, 2001. This document contains the effective pages specified in paragraphs (q)(4)(ii)(A), (q)(4)(ii)(B), (q)(4)(ii)(C), and (q)(4)(ii)(D) of this AD.

(A) Pages 1, 4, 10A through 11, 75, and 76 are identified as Revision 03, dated May 31, 2001.

(B) Pages 2, 8, 9, 17 through 32, 41, 42, 57, 58, 61 through 63, and 77 are identified as Revision 02, dated February 10, 2000.

(C) Pages 3, 5 through 7, 10, 12, 33, 34, 37, 38, 47, 59, and 60 are identified as Revision 01, dated May 31, 1999.

(D) Pages 13 through 16, 35, 36, 39, 40, 43 through 46, 48 through 56, and 64 through 74 are identified as original, dated September 9, 1994.

(iii) Airbus Service Bulletin A300–57–6086, Revision 01, dated April 2, 2002.

(5) The following service information was approved for IBR on July 8, 2002 (67 FR 38193, June 3, 2002).

(i) Airbus Service Bulletin A300–57–6086, dated June 6, 2000.

(ii) Reserved.

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

(7) You may view this 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.

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

Issued in Renton, Washington, on September 24, 2014.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–26356 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0288; Directorate Identifier 2013–NM–101–AD; Amendment 39–18009; AD 2014–22–04]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model DC–9–10, DC–9–20, and DC–9–30 series airplanes. This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the improved (shot-peened) aft fuselage non-ventral pressure bulkhead tee is subject to widespread fatigue damage (WFD). This AD requires repetitive inspections for cracking of the improved (shot-peened) non-ventral aft pressure bulkhead tees, and replacement if necessary. We are issuing this AD to detect and correct fatigue cracking of the improved (shot-peened) non-ventral aft pressure bulkhead tees connecting the bulkhead web to the fuselage, which could result in reduced structural integrity and rapid decompression of the airplane.

DATES: This AD is effective December 11, 2014.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 11, 2014.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; Internet *https://www.myboeingfleet.com.* You may view this 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* by searching for and locating Docket No. FAA–2014–0288; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Eric Schrieber, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5348; fax: 562–627–5210; email: *eric.schrieber@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model DC–9–10, DC–9–20, and DC–9–30 series airplanes. The NPRM published in the **Federal Register** on May 29, 2014 (79 FR 30753). The NPRM was prompted by an evaluation by the DAH indicating that the improved (shot-peened) aft fuselage non-ventral pressure bulkhead tee is subject to WFD. The NPRM proposed to require repetitive inspections for cracking of the improved (shot-peened) non-ventral aft pressure bulkhead tees, and replacement if necessary. We are issuing this AD to detect and correct fatigue cracking of the improved (shot-peened) non-ventral aft pressure bulkhead tees connecting the bulkhead web to the fuselage, which could result in reduced structural integrity and rapid decompression of the airplane.

Comments

We gave the public the opportunity to participate in developing this AD. We have considered the comment received. Boeing supported the NPRM (79 FR 30753, May 29, 2014).

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (79 FR 30753, May 29, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 30753, May 29, 2014).

Costs of Compliance

We estimate that this AD affects 48 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	Up to 148 work-hours × $85 per hour = $12,580 per inspection cycle.	$0	$12,580 per inspection cycle	Up to $603,840 per inspection cycle.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement (per tee)	4,000 work-hours × $85 per hour = $340,000	$26,000	$366,000

Authority for this Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2014–22–04 The Boeing Company: Amendment 39–18009 ; Docket No. FAA–2014–0288; Directorate Identifier 2013–NM–101–AD.

(a) Effective Date

This AD is effective December 11, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model DC–9–11, DC–9–12, DC–9–13, DC–9–14, DC–9–15, and DC–9–15F airplanes; Model DC–9–21 airplanes; and Model DC–9–31, DC–9–32, DC–9–32 (VC–9C), DC–9–32F, DC–9–33F, DC–9–34, DC–9–34F, and DC–9–32F (C–9A, C–9B) airplanes; certificated in any category; equipped with a non-ventral aft pressure bulkhead.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the improved (shot-peened) non-ventral aft pressure bulkhead tee is subject to widespread fatigue damage (WFD). We are issuing this AD to detect and correct fatigue cracking of the improved (shot-peened) non-ventral aft pressure bulkhead tees connecting the bulkhead web to the fuselage, which could result in reduced structural integrity and rapid decompression of the airplane.

(f) Compliance

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

(g) Definitions

(1) For the purposes of this AD, the term ''original tee section'' refers to the original (non-peened) non-ventral aft pressure bulkhead web to fuselage skin attach tee sections.

(2) For the purposes of this AD, the term ''improved tee section'' refers to improved (shot peened) non-ventral aft pressure bulkhead web to fuselage skin attach tee sections.

(h) Inspection

For airplanes on which an improved tee section having P/N 5910163–257, 5910163–259, 5910163–260, 5910163–261, 5910163–262, 5910163–263, SR09530001–3, SR09530001–5, SR09530001–6, SR09530001–7, SR09530001–8, SR09530001–9, SR09530001–29, SR09530001–30, SR09530001–31, SR09530001–32, SR09530001–33, SR09530001–35, SR09530056–3, SR09530056–5, SR09530056–6, SR09530056–7, SR09530056–8, SR09530056–9, SR09530056–11, SR09530056–13, SR09530056–14, SR09530056–15, SR09530056–16, SR09530056–17, SR09530056–19, SR09530056–21, SR09530056–22, SR09530056–23, SR09530056–24, or SR09530056–25, is installed: At the applicable time specified in paragraph (i)(1) or (i)(2) of this AD, do a general visual and low frequency eddy current (LFEC) inspection (Option I), or a high and low

frequency eddy current inspection (Option II), for cracking of the improved tee sections, in accordance with the Accomplishment Instructions of McDonnell Douglas DC–9 Alert Service Bulletin A53–231, Revision 2, dated June 25, 1993, including Service Sketch 3683D, Revision C, dated July 19, 1989.

(i) Compliance Times

(1) For Option I and Option II inspections specified in paragraph (h) of this AD: If the time of installation of an improved tee section having a part number listed in paragraph (h) of this AD is known, do the initial inspection required by paragraph (h) of this AD within 50,000 flight cycles after installation of the improved tee section, or within 1,500 flight cycles after the effective date of this AD, whichever occurs later.

(2) For Option I and Option II inspections specified in paragraph (h) of this AD: If the time of installation of an improved tee section having a part number identified in paragraph (h) of this AD is not known, do the initial inspection required by paragraph (h) of this AD before the accumulation of 75,000 total flight cycles, or within 1,500 flight cycles after the effective date of this AD, whichever occurs later.

(j) Repetitive Inspections

If no cracking is found during the inspection required by paragraph (h) of this AD: Do the actions specified in paragraph (j)(1) or (j)(2) of this AD, as applicable, in accordance with the Accomplishment Instructions of McDonnell Douglas DC–9 Alert Service Bulletin A53–231, Revision 2, dated June 25, 1993, including Service Sketch 3683D, Revision C, dated July 19, 1989.

(1) For Option I: If Option I was used for the inspection required by paragraph (h) of this AD, do the actions at the applicable intervals, as specified in paragraphs (j)(1)(i), (j)(1)(ii), and (j)(1)(iii) of this AD.

(i) Repeat the LFEC inspection for cracking of the side areas above the floor between longerons L7 and L17 on the fuselage left and right sides, at intervals not to exceed 2,000 flight cycles.

(ii) Repeat the general visual inspection for cracking of the top and lower areas from longeron L7 left side to L7 right side, and lower fuselage longeron L17 to L20 on the fuselage left and right sides, at intervals not to exceed 1,500 flight cycles.

(iii) Repeat the general visual inspection for cracking of the bottom areas from longeron L20 left side to L20 right side, at intervals not to exceed 3,500 flight cycles.

(2) For Option II: If Option II was used for the inspection required by paragraph (h) of this AD, repeat the high and low eddy frequency eddy current inspections for cracking around the entire periphery of the fuselage from the forward side of the bulkhead at intervals not to exceed 2,500 flight cycles.

(k) Corrective Action and Post-Replacement Inspections

If any cracking is found during any inspection required by paragraph (h) or (j) of this AD: Before further pressurized flight, replace each cracked tee section with an airworthy tee section having a part number identified in paragraph (h) of this AD, or with an original tee section having P/N 5910163–89, 5910163–91, 5910163–92, 5910163–93, 5910163–94, or 5910163–95, in accordance with the Accomplishment Instructions of McDonnell Douglas DC–9 Alert Service Bulletin A53–231, Revision 2, dated June 25, 1993, including Service Sketch 3683D, Revision C, dated July 19, 1989.

(1) If the tee section is replaced with an improved tee section listed in paragraph (h) of this AD, prior to the accumulation of 50,000 flight cycles after installation, inspect the tee section in accordance with paragraph (h) of this AD and do all applicable corrective actions and repetitive inspections in accordance with and at the times specified in paragraphs (j) and (k) of this AD.

(2) If the tee section is replaced with an original tee section listed in paragraph (k) of this AD, prior to the accumulation of 25,000 flight cycles after installation, inspect the tee section in accordance with paragraph (h) of this AD and do all applicable corrective actions and repetitive inspections in accordance with and at the times specified in paragraphs (j) and (k) of this AD.

(l) Alternative Methods of Compliance (AMOCs)

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

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and 14 CFR 25.571, Amendment 45, and the approval must specifically refer to this AD.

(m) Related Information

For more information about this AD, contact Eric Schrieber, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5348; fax: 562–627–5210; email: *eric.schrieber@faa.gov.*

(n) Material Incorporated by Reference

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

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

(i) McDonnell Douglas DC–9 Alert Service Bulletin A53–231, Revision 2, dated June 25, 1993, including Service Sketch 3683D, Revision C, dated July 19, 1989.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at 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.

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

Issued in Renton, Washington, on October 28, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–26330 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0192; Directorate Identifier 2013–NM–221–AD; Amendment 39–17992; AD 2014–20–19]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2013–10–06, for all Airbus Model A330–200 Freighter, A330–200, A330–300, A340–200, A340–300, A340–500, and A340–600 series airplanes. AD 2013–10–06 required an inspection to identify the installed windshields, and replacement of any affected windshield. This new AD requires expanding the inspection area to 15 additional windshields' serial numbers. This AD was prompted by several reports of a burning smell and/or smoke in the cockpit during cruise phase, leading in some cases, to

diversion to alternate airports. We are issuing this AD to prevent significantly increased workload for the flightcrew, which could, under some flight phases and/or circumstances, constitute an unsafe condition.

DATES: This AD becomes effective December 11, 2014.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 11, 2014.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2014-0192;* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

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 view this 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.

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

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2013–10–06, Amendment 39–17459 (78 FR 32347, May 30, 2013). AD 2013–10–06 applied to all Airbus Model A330–200 Freighter, A330–200, A330–300, A340–200, A340–300, A340–500, and A340–600 series airplanes. The NPRM published in the **Federal Register** on April 9, 2014 (79 FR 19548).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2013–0256, dated October 21, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes; and Model A340–211, –212, –213, –311, –312, –313, –541, and –642 airplanes. The MCAI states:

> Several operators reported cases of burning smell and/or smoke in the cockpit during cruise phase leading in some cases to diversion. Findings showed that the cause of these events is the burning of the Saint-Gobain Sully (SGS) windshield connector terminal block.
>
> This condition, if not corrected, could significantly increase the flight crew workload which would, under some flight phases and/or circumstances constitute an unsafe condition.
>
> To address this unsafe condition, Airbus published 3 different Service Bulletins (SB) and EASA issued AD 2011–0242 [*http://ad.easa.europa.eu/blob/easa_ad_2011_0242_Correction_superseded.pdf/AD_2011-0242_1*] (later corrected) which required the identification of the installed windshields and replacement of the affected part.
>
> Since issuance of that [EASA] AD, a new occurrence in service led Airbus to identify a new batch of affected parts.
>
> For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2011–0242 [*http://ad.easa.europa.eu/blob/easa_ad_2011_0242_Correction_superseded.pdf/AD_2011-0242_1*], which is superseded, and requires identification and replacement of the additionally identified windshields.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2014-0192-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (79 FR 19548, April 9, 2014) or on the determination of the cost to the public.

''Contacting the Manufacturer'' Paragraph in This AD

Since late 2006, we have included a standard paragraph titled ''Airworthy Product'' in all MCAI ADs in which the FAA develops an AD based on a foreign authority's AD.

We have become aware that some operators have misunderstood or misinterpreted the Airworthy Product paragraph to allow the owner/operator to use messages provided by the manufacturer as approval of deviations during the accomplishment of an AD-mandated action. The Airworthy Product paragraph does not approve messages or other information provided by the manufacturer for deviations to the requirements of the AD-mandated actions. The Airworthy Product paragraph only addresses the requirement to contact the manufacturer for corrective actions for the identified unsafe condition and does not cover deviations from other AD requirements. However, deviations to AD-required actions are addressed in 14 CFR 39.17, and anyone may request the approval for an alternative method of compliance to the AD-required actions using the procedures found in 14 CFR 39.19.

To address this misunderstanding and misinterpretation of the Airworthy Product paragraph, we have changed the paragraph and retitled it ''Contacting the Manufacturer.'' This paragraph now clarifies that for any requirement in this AD to obtain corrective actions from a manufacturer, the actions must be accomplished using a method approved by the FAA, the EASA, or Airbus's EASA Design Organization Approval (DOA).

The Contacting the Manufacturer paragraph also clarifies that, if approved by the DOA, the approval must include the DOA-authorized signature. The DOA signature indicates that the data and information contained in the document are EASA-approved, which is also FAA-approved. Messages and other information provided by the manufacturer that do not contain the DOA-authorized signature approval are not EASA-approved, unless EASA directly approves the manufacturer's message or other information.

This clarification does not remove flexibility previously afforded by the Airworthy Product paragraph. Consistent with long-standing FAA policy, such flexibility was never intended for required actions. This is also consistent with the recommendation of the Airworthiness Directive Implementation Aviation Rulemaking Committee to increase flexibility in complying with ADs by identifying those actions in manufacturers' service instructions that are ''Required for Compliance'' with ADs. We continue to work with manufacturers to implement this recommendation. But once we determine that an action is required, any deviation from the requirement must be approved as an alternative method of compliance.

We also have decided not to include a generic reference to either the ''delegated agent'' or ''design approval holder (DAH) with State of Design Authority design organization approval,'' but instead we have provided the specific delegation approval granted by the State of Design Authority for the DAH throughout this AD.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 19548, April 9, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 19548, April 9, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Costs of Compliance

We estimate that this AD affects 60 airplanes of U.S. registry.

The actions required by AD 2013–10–06, Amendment 39–17459 (78 FR 32347, May 30, 2013), and retained in this AD take about 2 work-hours per product, at an average labor rate of $85 per work-hour. Required parts cost about $0 per product. Based on these figures, the estimated cost of the actions that were required by AD 2013–10–06 is $170 per product.

We also estimate that it would take about 2 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts would cost about $0 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be $10,200, or $170 per product.

In addition, we estimate that any necessary follow-on actions would take about 10 work-hours and require parts costing $0, for a cost of $850 per product. We have no way of determining the number of aircraft that might need this action.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2014-0192;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this 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.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2013–10–06, Amendment 39–17459 (78 FR 32347, May 30, 2013), and adding the following new AD:

2014–20–19 Airbus: Amendment 39–17992. Docket No. FAA–2014–0192; Directorate Identifier 2013–NM–221–AD.

(a) Effective Date

This AD becomes effective December 11, 2014.

(b) Affected ADs

This AD supersedes AD 2013–10–06, Amendment 39–17459 (78 FR 32347, May 30, 2013).

(c) Applicability

This AD applies to all airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category, all manufacturer serial numbers.

(1) Airbus Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes.

(2) Airbus Model A340–211, –212, –213, –311, –312, –313, –541, and –642 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 56, Windows.

(e) Reason

This AD was prompted by several reports of a burning smell and/or smoke in the cockpit during cruise phase, leading in some cases, to diversion to alternate airports. We are issuing this AD to prevent significantly increased workload for the flightcrew, which could, under some flight phases and/or circumstances, constitute an unsafe condition.

(f) Compliance

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

(g) Retained Inspection With Revised Service Information

This paragraph restates the requirements of paragraph (g) of AD 2013–10–06, Amendment 39–17459 (78 FR 32347, May 30, 2013), with revised service information. Within 1,200 flight hours after July 5, 2013 (the effective date of AD 2013–10–06), inspect to identify the manufacturer, the part number, and the serial number of the left-hand (LH) and right-hand (RH) windshields installed on the airplane, in accordance with the Accomplishment Instructions of the applicable Airbus service information specified in paragraph (g)(1), (g)(2), or (g)(3) of this AD. A review of airplane delivery or

maintenance records is acceptable in lieu of this inspection if the manufacturer, part number, and serial number of the installed windshields can be conclusively determined from that review.

(1) For Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes: Airbus Service Bulletin A330–56–3009, Revision 02, including Appendix 01, dated February 8, 2012; or Airbus Service Bulletin A330–56–3009, Revision 03, including Appendixes 01 and 02, dated August 1, 2013. As of the effective date of this AD, use only Airbus Service Bulletin A330–56–3009, Revision 03, including Appendixes 01 and 02, dated August 1, 2013, to do the actions required by paragraph (g) of this AD.

(2) For Model A340–211, –212, –213, –311, –312, and –313 airplanes: Airbus Service Bulletin A340–56–4008, Revision 01, including Appendix 01, dated February 8, 2012; or Airbus Service Bulletin A340–56–4008, Revision 02, including Appendixes 01 and 02, dated August 1, 2013. As of the effective date of this AD, use only Airbus Service Bulletin A340–56–4008, Revision 02, including Appendixes 01 and 02, dated August 1, 2013, to do the actions required by paragraph (g) of this AD.

(3) For Model A340–541 and –642 airplanes: Airbus Service Bulletin A340–56–5002, Revision 01, including Appendix 01, dated February 8, 2012; or Airbus Service Bulletin A340–56–5002, Revision 02, including Appendixes 01 and 02, dated August 1, 2013. As of the effective date of this AD, use only Airbus Service Bulletin A340–56–5002, Revision 02, including Appendixes 01 and 02, dated August 1, 2013, to do the actions required by paragraph (g) of this AD.

(h) Retained Replacement With Revised Service Information

This paragraph restates the requirements of paragraph (h) of AD 2013–10–06, Amendment 39–17459 (78 FR 32347, May 30, 2013), with revised service information. If it is found, during the inspection required by paragraph (g) of this AD, that any installed LH or RH windshield was manufactured by Saint-Gobain Sully (SGS) and the part number and serial number are specified in the applicable Airbus service information specified in paragraph (g)(1), (g)(2), or (g)(3) of this AD: Within 9 months or 1,200 flight hours after July 5, 2013 (the effective date of AD 2013–10–06), whichever occurs first, replace all affected LH and RH windshields, in accordance with the Accomplishment Instructions of the applicable Airbus service information specified in paragraph (h)(1), (h)(2), or (h)(3) of this AD.

(1) For Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes: Airbus Service Bulletin A330–56–3009, Revision 02, including Appendix 01, dated February 8, 2012; or Airbus Service Bulletin A330–56–3009, Revision 03, including Appendixes 01 and 02, dated August 1, 2013. As of the effective date of this AD, use only Airbus Service Bulletin A330–56–3009, Revision 03, including Appendixes 01 and 02, dated August 1, 2013, to do the actions required by paragraph (h) of this AD.

(2) For Model A340–211, –212, –213, –311, –312, and –313 airplanes: Airbus Service Bulletin A340–56–4008, Revision 01, including Appendix 01, dated February 8, 2012; or Airbus Service Bulletin A340–56–4008, Revision 02, including Appendixes 01 and 02, dated August 1, 2013. As of the effective date of this AD, use only Airbus Service Bulletin A340–56–4008, Revision 02, including Appendixes 01 and 02, dated August 1, 2013, to do the actions required by paragraph (h) of this AD.

(3) For Model A340–541 and –642 airplanes: Airbus Service Bulletin A340–56–5002, Revision 01, including Appendix 01, dated February 8, 2012; or Airbus Service Bulletin A340–56–5002, Revision 02, including Appendixes 01 and 02, dated August 1, 2013. As of the effective date of this AD, use only Airbus Service Bulletin A340–56–5002, Revision 02, including Appendixes 01 and 02, dated August 1, 2013, to do the actions required by paragraph (h) of this AD.

(i) New Requirement of This AD: Inspection

Within 6 months after the effective date of this AD, inspect to identify the manufacturer, the part number, and the serial number of the LH and RH windshields installed on the airplane, in accordance with the Accomplishment Instructions of the applicable Airbus service information specified in paragraph (i)(1), (i)(2), or (i)(3) of this AD. A review of airplane delivery or maintenance records is acceptable in lieu of this inspection if the manufacturer, part number, and serial number of the installed windshields can be conclusively determined from that review.

(1) For Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes: Airbus Service Bulletin A330–56–3009, Revision 03, including Appendixes 01 and 02, dated August 1, 2013.

(2) For Model A340–211, –212, –213, –311, –312, and –313 airplanes: Airbus Service Bulletin A340–56–4008, Revision 02, including Appendixes 01 and 02, dated August 1, 2013.

(3) For Model A340–541 and –642 airplanes: Airbus Service Bulletin A340–56–5002, Revision 02, including Appendixes 01 and 02, dated August 1, 2013.

(j) New Requirement of This AD: Replacement

If it is found, during the inspection required by paragraph (i) of this AD, that any installed LH or RH windshield was manufactured by Saint-Gobain Sully (SGS) and the part number and serial number are specified in Appendix 02 of the applicable Airbus service information specified in paragraph (j)(1), (j)(2), or (j)(3) of this AD, or if the manufacturer or part number or serial number is not identifiable: Within 6 months after the effective date of this AD, replace the affected LH and/or RH windshield with a serviceable part, in accordance with the Accomplishment Instructions of the applicable Airbus service information specified in paragraph (j)(1), (j)(2), or (j)(3) of this AD.

(1) For Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes: Airbus Service Bulletin A330–56–3009, Revision 03, including Appendixes 01 and 02, dated August 1, 2013.

(2) For Model A340–211, –212, –213, –311, –312, and –313 airplanes: Airbus Service Bulletin A340–56–4008, Revision 02, including Appendixes 01 and 02, dated August 1, 2013.

(3) For Model A340–541 and –642 airplanes: Airbus Service Bulletin A340–56–5002, Revision 02, including Appendixes 01 and 02, dated August 1, 2013.

(k) Definition of Serviceable Windshield

For the purposes of this AD, a serviceable windshield is a windshield not identified in Appendix 01 of the applicable Airbus service information as specified in paragraphs (j)(1), (j)(2), or (j)(3) of this AD; or it is specified in Appendix 01 but has a suffix ''U'' added to the serial number on the identification plate.

(l) Parts Installation Limitations

As of the effective date of this AD, no person may install, on any airplane, an affected windshield from SGS having a part number and serial number identified in Appendix 01 of the applicable Airbus service information as specified in paragraph (l)(1), (l)(2), or (l)(3) of this AD, unless a suffix ''U'' has been added on the serial number identification plate.

(1) For Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes: Airbus Service Bulletin A330–56–3009, Revision 03, including Appendixes 01 and 02, dated August 1, 2013.

(2) For Model A340–211, –212, –213, –311, –312, and –313 airplanes: Airbus Service Bulletin A340–56–4008, Revision 02, including Appendix 01 and 02, dated August 1, 2013.

(3) For Model A340–541 and –642 airplanes: Airbus Service Bulletin A340–56–5002, Revision 02, including Appendixes 01 and 02, dated August 1, 2013.

(m) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using the applicable Airbus service information specified in paragraphs (m)(1) through (m)(4) of this AD, provided that the actions were accomplished on the airplane, and no replacement windshield has been installed with a part number and serial number identified in Appendix 02 of the applicable Airbus service information as specified in paragraphs (j)(1) through (j)(3) of this AD.

(1) Airbus Service Bulletin A330–56–3009, dated May 4, 2010 (for Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes), which is not incorporated by reference in this AD.

(2) Airbus Service Bulletin A330–56–3009, Revision 01, dated January 27, 2011 (for Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes), which is not incorporated by reference in this AD.

(3) Airbus Service Bulletin A340–56–4008, dated May 4, 2010 (for Model A340–211,

–212, –213, –311, –312, and –313 airplanes), which is not incorporated by reference in this AD.

(4) Airbus Service Bulletin A340–56–5002, dated May 4, 2010 (for Model A340–541 and –642 airplanes), which is not incorporated by reference in this AD.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 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, WA 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.

(2) Contacting the Manufacturer: As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2013–0256, dated October 21, 2013, for related information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2014-0192-0002.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(3) and (p)(4) of this AD.

(p) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A330–56–3009, Revision 03, including Appendixes 01 and 02, dated August 1, 2013.

(ii) Airbus Service Bulletin A340–56–4008, Revision 02, including Appendix 01 and 02, dated August 1, 2013.

(iii) Airbus Service Bulletin A340–56–5002, Revision 02, including Appendixes 01 and 02, dated August 1, 2013.

(3) 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.*

(4) You may view this 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.

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

Issued in Renton, Washington, on September 24, 2014.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–24964 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0232; Directorate Identifier 2013–NM–100–AD; Amendment 39–18010; AD 2014–22–05]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model DC–9–10, DC–9–20, DC–9–30, DC–9–40, and DC–9–50 series airplanes. This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the bulkhead dome tees, which connect the bulkhead web to the fuselage, are subject to widespread fatigue damage (WFD). This AD requires repetitive inspections of the improved ventral aft pressure bulkhead tees, and replacement if necessary. We are issuing this AD to detect and correct fatigue cracking of the bulkhead dome tees, which could result in reduced structural integrity and rapid decompression of the airplane.

DATES: This AD is effective December 11, 2014.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 4, 1996 (61 FR 39860, July 31, 1996).

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; Internet *https://www.myboeingfleet.com.* You may view this 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* by searching for and locating Docket No. FAA–2014–0232; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Eric Schrieber, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5348; fax: 562–627–5210; email: *eric.schrieber@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model DC–9–10, DC–9–20, DC–9–30, DC–9–40, and DC–9–50 series airplanes. The NPRM published in the **Federal Register** on April 17, 2014 (79 FR 21655). The NPRM was prompted by an evaluation by the DAH indicating that the bulkhead dome tees, which connect the bulkhead web to the fuselage, are subject to WFD. The NPRM proposed to require repetitive inspections of the improved ventral aft pressure bulkhead tees, and replacement if necessary. We are issuing this AD to detect and correct

fatigue cracking of the bulkhead dome tees, which could result in reduced structural integrity and rapid decompression of the airplane.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (79 FR 21655, April 17, 2014) or on the determination of the cost to the public.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (79 FR 21655, April 17, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 21655, April 17, 2014).

Costs of Compliance

We estimate that this AD affects 48 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	Up to 148 work hours × $85 per hour = $12,580 per inspection cycle.	$0	Up to $12,580 per inspection cycle.	Up to $603,840 per inspection cycle.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	4,000 work-hours × $85 per hour = $340,000	$26,000	$366,000

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2014–22–05 The Boeing Company: Amendment 39–18010; Docket No. FAA–2014–0232; Directorate Identifier 2013–NM–100–AD.

(a) Effective Date

This AD is effective December 11, 2014.

(b) Affected ADs

This AD affects certain requirements of AD 96–16–04, Amendment 39–9704 (61 FR 39860, July 31, 1996).

(c) Applicability

This AD applies to The Boeing Company Model DC–9–11, DC–9–12, DC–9–13, DC–9–14, DC–9–15, and DC–9–15F airplanes; Model DC–9–21 airplanes; Model DC–9–31, DC–9–32, DC–9–32 (VC–9C), DC–9–32F, DC–9–33F, DC–9–34, DC–9–34F, and DC–9–32F (C–9A, C–9B) airplanes; Model DC–9–41 airplanes; and Model DC–9–51 airplanes; certificated in any category; equipped with a ventral aft pressure bulkhead.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the improved (shot-peened) ventral aft pressure bulkhead dome tees, which connect the bulkhead web to the fuselage, are subject to widespread fatigue damage (WFD). We are issuing this AD to detect and correct fatigue cracking of the improved (shot-peened) ventral aft pressure bulkhead dome tees connecting the bulkhead web to the fuselage, which could result in reduced structural

integrity and rapid decompression of the airplane.

(f) Compliance

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

(g) Definitions

(1) For the purposes of this AD, the term ''original tee section'' refers to the original (non-peened) ventral aft pressure bulkhead web to fuselage skin attach tee sections.

(2) For the purposes of this AD, the term ''improved tee section'' refers to improved (shot peened) ventral aft pressure bulkhead web to fuselage skin attach tee sections.

(h) Inspections

For airplanes on which an improved tee section having P/N 5910130–389, 5910130–391, 5910130–392, 5910130–393, 5910130–394, 5910130–387, SR09530001–19, SR09530001–21, SR09530001–22, SR09530001–23, SR09530001–24, SR09530001–25, SR09530001–29, SR09530001–30, SR09530001–31, SR09530001–32, SR09530001–33, SR09530001–35, SR09530056–3, SR09530056–5, SR09530056–6, SR09530056–7, SR09530056–8, SR09530056–9, SR09530056–19, SR09530056–21, SR09530056–22, SR09530056–23, SR09530056–24, or SR09530056–25, is installed: At the applicable time specified in paragraph (i)(1) or (i)(2) of this AD, do general visual and low frequency eddy current inspections (Option I), or high and low frequency eddy current inspections (Option II), for cracking of the improved tee sections, in accordance with the Accomplishment Instructions of McDonnell Douglas Alert Service Bulletin A53–232, Revision 2, dated April 28, 1995.

(i) Compliance Times

(1) For Option I and Option II inspections specified in paragraph (h) of this AD: If the time of installation of an improved tee section having a part number listed in paragraph (h) of this AD, is known, do the initial inspection required by paragraph (h) of this AD within 70,000 flight cycles after installation of the improved tee section, or within 1,500 flight cycles after the effective date of this AD, whichever occurs later.

(2) For Option I and Option II inspections specified in paragraph (h) of this AD: If the time of installation of an improved tee section having a part number listed in paragraph (h) of this AD, is not known, do the initial inspection required by paragraph (h) of this AD before the accumulation of 105,000 total flight cycles on the airplane or within 1,500 flight cycles after the effective date of this AD, whichever occurs later.

(j) Repetitive Inspections

If no cracking is found during the inspection required by paragraph (h) of this AD: Do the actions specified in paragraph (j)(1) or (j)(2) of this AD, as applicable, in accordance with the Accomplishment Instructions of McDonnell Douglas Alert Service Bulletin A53–232, Revision 2, dated April 28, 1995.

(1) For Option I: If Option I was used for the inspection required by paragraph (h) of this AD, repeat the inspections specified in paragraphs (j)(1)(i), (j)(1)(ii), and (j)(1)(iii) of this AD at the intervals specified in paragraphs (j)(1)(i), (j)(1)(ii), and (j)(1)(iii) of this AD.

(i) Repeat the low frequency eddy current inspection for cracking of side areas above the floor between longerons L7 and L17 on the fuselage, at intervals not to exceed 1,500 flight cycles.

(ii) Repeat the general visual inspection for cracking of the top and lower areas from longeron L7 left side to longeron L7 right side, and lower fuselage longeron L17 to longeron L20 on the left and right sides, at intervals not to exceed 1,500 flight cycles.

(iii) Repeat the general visual inspection for cracking of the bottom areas from longeron L20 left side to longeron L20 right side, at intervals not to exceed 3,500 flight cycles.

(2) For Option II: If Option II was used for the inspection required by paragraph (h) of this AD, repeat the high and low frequency eddy current inspection for cracking around the entire periphery of the fuselage on the forward side of the bulkhead, at intervals not to exceed 2,500 flight cycles.

(k) Corrective Actions and Post-Replacement Inspections

If any cracking is found during any inspection required by paragraph (h) or (j) of this AD: Before further pressurized flight, replace each cracked tee section with an airworthy tee section having a part number listed in paragraph (h) of this AD, or with an original tee section having P/N 5910130–47, 5910130–51, 5910130–53, 5910130–54, 5910130–55, or 5910130–56, in accordance with the Accomplishment Instructions of McDonnell Douglas Alert Service Bulletin A53–232, Revision 2, dated April 28, 1995.

(1) If the tee section is replaced with an improved tee section listed in paragraph (h) of this AD, prior to the accumulation of 70,000 flight cycles after installation, inspect the tee section in accordance with paragraph (h) of this AD and do all applicable corrective actions and repetitive inspections in accordance with and at the times specified in paragraphs (j) and (k) of this AD.

(2) If the tee section is replaced with an original tee section listed in paragraph (k) of this AD, prior to the accumulation of 35,000 flight cycles after installation, inspect the tee section in accordance with paragraph (h) of this AD and do all applicable corrective actions and repetitive inspections in accordance with and at the times specified in paragraphs (j) and (k) of this AD.

(l) Alternative Methods of Compliance (AMOCs)

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

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and 14 CFR 25.571, Amendment 45, and the approval must specifically refer to this AD.

(m) Related Information

For more information about this AD, contact Eric Schrieber, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5348; fax: 562–627–5210; email: *eric.schrieber@faa.gov.*

(n) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on September 4, 1996 (61 FR 39860, July 31, 1996).

(i) McDonnell Douglas Alert Service Bulletin A53–232, Revision 2, dated April 28, 1995.

(ii) Reserved.

(4) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; Internet *https://www.myboeingfleet.com.*

(5) You may view this service information 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.

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

Issued in Renton, Washington, on October 28, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–26331 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2014–0305; Airspace Docket No. 14–AWP–2]

Establishment and Amendment of Class D and E Airspace; Santa Rosa, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace and modifies Class D and E airspace at Charles M. Schulz-Sonoma County Airport, Santa Rosa, CA. This action, initiated by the FAAs biennial review of the airspace area, enhances the safety and management of instrument flight rules (IFR) operations at the airport. Class D and E airspace is amended to reflect the airport's name change. Also, a minor adjustment is made to the geographic coordinates of the airport.

DATES: Effective date, 0901 UTC, January 8, 2015. 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.

ADDRESSES: FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/*. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783.

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4517.

SUPPLEMENTARY INFORMATION:

History

On July 15, 2014 the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend controlled airspace at Charles M. Shulz-Sonoma County Airport, Santa Rosa, CA (79 FR 41148). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Subsequent to publication, the FAA found an adjustment to the geographic coordinates of the airport was needed. Except for editorial changes, and the changes noted above, this rule is the same as that published in the NPRM.

Class D airspace and Class E airspace designations are published in paragraphs 5000, 6004 and 6005, respectively, of FAA Order 7400.9Y, dated August 6, 2014, and effective September 15, 2014, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E airspace designated as an extension to the Class D and E surface area with a segment extending 14 miles northwest from the 4.3-mile radius of Charles M. Schulz-Sonoma County Airport, Santa Rosa, CA. Class E airspace extending upward from 700 feet above the surface is modified with segments extending 23 miles northwest, 28 miles southeast, and 13 miles southwest of the airport, and adds the airport name and geographic coordinates missing in the airspace designation. A biennial review of the airspace found these modifications necessary for the safety and management of IFR operations at the airport. The description for the Class D airspace reflects the airport name change from Santa Rosa/Sonoma County Airport to Charles M. Schulz-Sonoma County Airport. The geographic coordinates of the airport are updated to coincide with the FAA's aeronautical database.

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

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 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014 is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

AWP CA D Santa Rosa, CA [Amended]

Charles M. Schulz-Sonoma County Airport, CA

(Lat. 38°30′32″ N., long. 122°48′46″ W.)

That airspace extending upward from the surface to and including 2,600 feet MSL within a 4.3-mile radius of Santa Rosa/Charles M. Schulz-Sonoma County Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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

* * * * *

AWP CA E4 Santa Rosa, CA [New]

Charles M. Schulz-Sonoma County Airport, CA

(Lat. 38°30′32″ N., long. 122°48′46″ W.)

That airspace extending upward from the surface within 2 miles either side of the 342° bearing from the Charles M. Schulz-Sonoma County Airport, CA, extending from the 4.3 mile radius of the airport to 14 miles northwest of the airport.

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

* * * * *

AWP CA E5 Santa Rosa, CA [Amended]

Charles M. Schulz-Sonoma County Airport, CA

(Lat. 38°30′32″ N., long. 122°48′46″ W.)

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 38°53′25″ N., long. 122°52′34″ W.; to lat. 38°37′07″ N., long. 122°46′02.00″ W.; to 38°22′08″ N., long. 122°38′28″ W.; lat. 38°06′41″ N., long. 122°29′59″ W.; lat. 38°02′10″ N., long. 122°44′09″ W.; lat. 38°17′57″ N., long. 122°54′37″ W.; lat. 38°22′58″ N., long. 123°02′34″ W.; lat. 38°29′12″ N., long. 122°56′32″ W.; lat. 38°33′48″ N., long. 123°00′47″ W.; lat. 38°50′14″ N., long. 123°07′20″ W. thence to the point of origin; that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 45°49′00″ N., long. 118°00′00″ W.; to lat. 45°49′00″ N., long. 119°45′00″ W.; to lat. 47°00′00″ N., long. 119°45′00″ W.; to lat. 47°00′00″ N., long. 118°00′00″ W.; thence to the point of origin.

Issued in Seattle, Washington, on October 27, 2014.

Clark Desing,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2014–26283 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2014–0419]

RIN 1625–AA00

Safety Zone; University of Cincinnati Bearcats Football Fireworks; Ohio River, Mile 470.4–470.8; Cincinnati, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all waters of the Ohio River, surface to bottom, extending from Ohio River mile 470.4 to mile 470.8 at Cincinnati, Ohio. This temporary safety zone is necessary to protect persons and property from potential damage and safety hazards during the University of Cincinnati Bearcats Football Fireworks. During the period of enforcement, no vessels may be located within this Coast Guard safety zone. Entry into this Coast Guard safety zone is prohibited unless specifically authorized by the Captain of the Port Ohio Valley or other designated representative.

DATES: This rule is effective without actual notice from November 6, 2014 until December 6, 2014. For the purposes of enforcement, actual notice will be used from September 12, 2014, until November 6, 2014.

The scheduled enforcement times and dates for this rule are: From 9:30 p.m. until 11:30 p.m. on September 12 and 20; October 4 and 24; November 13; and December 6, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2014–0419. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Chief Petty Officer Kevin Cador, Marine Safety Detachment Cincinnati, U.S. Coast Guard; telephone 513–921–9033 x2109, email *Kevin.L.Cador@uscg.mil* or Petty Officer John Joeckel, Marine Safety Detachment Cincinnati, U.S. Coast Guard; telephone 513–921–9033 x2114, email *John.R.Joeckel@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. The Coast Guard was made aware of the schedule for the University of Cincinnati Bearcats Football Fireworks on August 6, 2014. There are potential hazards associated with fireworks displays over or on the Ohio River and a safety zone is required to protect persons and property on or near the waterway during the displays. Completing the NPRM process and providing notice and a comment period is contrary to the public interest because it would delay this rule and the immediate safety measures it provides. Additionally, the University of Cincinnati's game schedule and these fireworks displays are advertised to the local community by and through the University of Cincinnati organization. Delaying the safety zone effective date to complete the NPRM process would be impracticable as it would interfere with the advertised and planned for displays and would unnecessarily interfere with contractual obligations related to these events.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Providing a full 30 days notice would be impracticable and would unnecessarily delay the effective date of this rule. Delaying the effective date would also be contrary to public interest since immediate action is necessary to protect

persons and property from potential hazards associated with fireworks displays over or on the Ohio River.

B. Basis and Purpose

Multiple fireworks displays are planned to conclude the University of Cincinnati Bearcats football games scheduled on September 12 & 20; October 4 & 24; November 13; and December 6, 2014. These displays will feature fireworks being launched from a barge located in front of the Paul Brown Stadium, between miles 470.4 and 470.8 on the Ohio River at Cincinnati, OH. The Coast Guard determined that a safety zone is necessary to keep persons and property clear of any potential hazards associated with the launching of fireworks on or over the waterway.

The legal basis and authorities for this rule are found in 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; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish and define regulatory safety zones.

The purpose of the rule is to establish the necessary temporary safety zone to provide protection for persons and property, including spectators, commercial and recreational vessels, and others that may be in the area during the noticed fireworks display times from the hazards associated with the fireworks display on and over the waterway.

C. Discussion of the Final Rule

The COTP Ohio Valley is establishing a temporary safety zone from 9:30 p.m. to 11:30 p.m. on September 12 & 20; October 4 & 24; November 13; and December 6, 2014 for the University of Cincinnati Bearcats Football Fireworks. The fireworks will be launched from a barge located in front of the Paul Brown Stadium and the safety zone will include all waters between Ohio River miles 470.4 and 470.8 at Cincinnati, Ohio. The Coast Guard will enforce the temporary safety zone and may be assisted by other federal, state and local agencies and the Coast Guard Auxiliary. During the periods of enforcement, no vessels may transit into, through, or remain within this Coast Guard safety zone. Deviation from this safety zone may be requested by contacting the COTP Ohio Valley or other designated representative. Deviations will be considered on a case-by-case basis.

D. Regulatory Analyses

We developed this 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 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.

This temporary final rule establishes a safety zone that will be enforced for limited time periods following certain University of Cincinnati Bearcats Football home games. During enforcement periods, vessels are prohibited from entering into or remaining within the safety zone unless specifically authorized by the COTP Ohio Valley or other designated representative. Based on the location, limited safety zone size, and short duration of each enforcement period, this rule does not pose a significant regulatory impact. Additionally, notice of this safety zone or any changes in the planned schedule will be made via Broadcast Notices to Mariners, Local Notices to Mariners, and/or Marine Safety Information Bulletins as appropriate. Deviation from this rule may be requested from the COTP Ohio Valley and will be considered on a case-by-case basis.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor between Ohio River miles 470.4 to 470.8 from 9:30 p.m. to 11:30 p.m. on September 12 & 20; October 4 & 24; November 13; and December 6, 2014.

This safety zone would not have a significant economic impact on a substantial number of small entities because it is limited in size and will be enforced for a limited time period following certain scheduled University of Cincinnati Bearcats Football home games. The Coast Guard will provide notice of enforcement and changes in the planned schedule through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Marine Safety Information Bulletins as appropriate.

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 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.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

This 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 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 rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will 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 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

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

11. Indian Tribal Governments

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

12. Energy Effects

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined 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 rule involves establishment of a temporary safety zone to protect persons and property from potential hazards associated with the scheduled University of Cincinnati Bearcats Football Fireworks taking place on or over the Ohio River. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An 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 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 amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. A new temporary safety zone § 165.T08–0419 is added to read as follows:

§ 165.T08–0419 Safety Zone; University of Cincinnati Bearcats Football Fireworks; Ohio River, Mile 470.4–470.8, Cincinnati, OH.

(a) *Location.* The following area is a temporary safety zone: All waters of the Ohio River, surface to bottom, from mile 470.4 to mile 470.8 on the Ohio River at Cincinnati, Ohio. These markings are based on the United States Army Corps of Engineers' *Ohio River Navigation Charts* (Chart 115 June 2010).

(b) *Effective dates and enforcement periods.* This safety zone is effective from September 12, 2014 through December 6, 2014, and will be enforced from 9:30 p.m. to 11:30 p.m. on the following dates: September 12 and 20; October 4 and 24; November 13; and December 6, 2014. For purposes of enforcement, actual notice will be given beginning September 12, 2014.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, movement within, or departure from this zone is prohibited unless authorized by the Captain of the Port Ohio Valley or a designated representative.

(2) Persons or vessels requiring entry into, departure from, or movement within a regulated area must request permission from the Captain of the Port Ohio Valley or a designated representative. They may be contacted on VHF–FM Channel 13 or 16, or through Coast Guard Sector Ohio Valley at 1–800–253–7465.

(3) All persons and vessels shall comply with the instructions of the Captain of the Port Ohio Valley and designated on-scene U.S. Coast Guard patrol personnel. On-scene U.S. Coast Guard patrol personnel includes Commissioned, Warrant, and Petty Officers of the U.S. Coast Guard.

(d) *Informational broadcasts.* The COTP Ohio Valley or a designated representative will inform the public through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Marine Safety Information Bulletins as appropriate of the enforcement period for each safety zone as well as any changes in the planned and published dates and times of enforcement.

Dated: September 9, 2014.

R.V. Timme,

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

[FR Doc. 2014–26427 Filed 11–5–14; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 22

[EPA–HQ–OECA–2014–0551; FRL–9914–32–OECA]

RIN 2020–AA50

Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This direct final rule revises the scope of the Environmental

Protection Agency's (EPA) Consolidated Rules of Practice governing the administrative assessment of civil penalties to encompass the assessment of civil penalties under the air pollution control provisions of the Act to Prevent Pollution from Ships. The EPA has not previously established adjudicatory procedures for the assessment of civil penalties under that statute. Establishment of such procedures will provide for the efficient and effective adjudication, including administrative appeals, of such proceedings consistent with statutory requirements. This rule also revises the address for the Environmental Appeals Board to reflect its relocation to the William Jefferson Clinton East Building.

DATES: This rule is effective on January 5, 2015 without further notice, unless the EPA receives adverse comment by December 8, 2014. If the EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OECA–2014–0551, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email:* [*docket.oeca@epa.gov.*]
3. *Fax:* (202) 566–9744.
4. *Mail:* Environmental Protection Agency, OECA Docket, Mail-Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
5. *Hand Delivery:* EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004. Attention Docket No. EPA–HQ–OECA–2014–0551. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OECA–2014–0551. 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 the 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 the 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, the 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 the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or at the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004. 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 OECA Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: Meetu Kaul, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, William Jefferson Clinton Building South, Room 1117B, 1200 Pennsylvania Ave. NW., Mail Code 2242A, Washington, DC 20460, phone number (202) 564–5472 or by email at *kaul.meetu@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is the EPA using a direct final rule?

The EPA is publishing this rule in advance of receipt of public comment on the companion proposed rule because the EPA anticipates that this rule is noncontroversial and does not anticipate adverse comment. In the ''Proposed Rules'' section of this **Federal Register**, the EPA is publishing an otherwise identical companion proposed rule to invite public comment on the provisions of this direct final rule. Any parties interested in commenting on the provisions of the proposed rule must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document. If the EPA receives adverse comment, the EPA will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. The EPA would address adverse comments received either in that notice or in a subsequent final rule based on the proposed rule.

II. Does this action apply to me?

This action may affect parties involved in EPA administrative adjudicatory proceedings for the assessment of civil penalties under section 1908(b) of the Act to Prevent Pollution from Ships (33 U.S.C. 1908(b)). You may direct questions regarding the applicability of this action as noted in **FOR FURTHER INFORMATION CONTACT**.

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

A. Submitting CBI

Do not submit this information to the EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

B. Tips for Preparing Your Comments

When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- 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.

• Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
• Describe any assumptions and provide any technical information and/or data that you used.
• If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
• Provide specific examples to illustrate your concerns, and suggest alternatives.
• Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
• Make sure to submit your comments by the comment period deadline identified.

IV. Summary of Rule

A. EPA's Consolidated Rules of Practice Governing Adjudication of Administrative Penalty Assessments

The EPA is authorized to institute administrative enforcement proceedings against alleged violators under a variety of environmental statutes, including the Clean Air Act, the Clean Water Act, and the Federal Insecticide, Fungicide, and Rodenticide Act, among others. Such cases are generally heard by the Administrative Law Judges (ALJs) within EPA's Office of Administrative Law Judges and by presiding officers in administrative proceedings not governed by section 554 of the Administrative Procedure Act. The federal regulations that govern the proceedings before the ALJs and presiding officers are codified at 40 CFR Part 22, entitled ''Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits'' (Rules of Practice). The EPA promulgated the Rules of Practice to establish uniform procedural rules for administrative enforcement proceedings required to be held on the record after opportunity for a hearing in accordance with section 554 of the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* The Rules of Practice also establish uniform procedural rules for proceedings not governed by section 554 of the Administrative Procedure Act. Additionally, the Rules of Practice establish procedures for appeals from decisions of the ALJs and presiding officers to the Environmental Appeals Board. The purpose of this action is to apply the Rules of Practice to include adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority. This rule also revises the mailing and hand delivery address for the Environmental Appeals Board (EAB or Board) to reflect the Board's relocation.

B. The Act To Prevent Pollution From Ships (APPS)

The International Convention for the Prevention of Pollution from Ships (MARPOL) is the primary international treaty applicable to prevention of pollution of the marine environment by ships from operational or accidental causes. Annex VI to MARPOL addresses the prevention of air pollution from ships through the use of both engine-based and fuel-based standards. MARPOL is implemented in the United States through the Act to Prevent Pollution from Ships (APPS), 33 U.S.C. 1901–1915. The provisions of APPS implementing certain provisions of MARPOL Annex VI are jointly administered and enforced by the U.S. Coast Guard and the EPA. Under the authority of APPS, the EPA, in consultation with the U.S. Coast Guard, promulgated regulations codifying the requirements specified in Regulations 13, 14 and 18 of Annex VI and addressing issues, for example, relating to nonparty vessel compliance. See 40 CFR Part 1043. Section 1907(f) of APPS authorizes the EPA to enforce regulations 17 and 18 of Annex VI for cases involving shoreside violations, and for any other matters that have been referred to the EPA by the U.S. Coast Guard. In addition, section 1908(b) of APPS authorizes the U.S. Coast Guard or the EPA to assess civil penalties against persons who have been found, after notice and an opportunity for a hearing, to have violated MARPOL, APPS, or the implementing regulations. In order to provide consistency and uniformity in all of EPA's administrative penalty proceedings, this action would expand the scope of the EPA's Rules of Practice to also apply to any administrative proceedings brought by the EPA under its APPS authority for the assessment of civil penalties.

V. Statutory and Executive Order Reviews

A. Executive Orders 12866: Regulatory Planning and Review and 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). This action will apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this rule on small entities, I certify that this rule will not have a significant economic impact on a substantial number of small entities. This rule will not impose any additional requirements on small entities. This rule will apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The action imposes no enforceable duty on any State, local or tribal governments or the private sector. Therefore, this action

is not subject to the requirements of sections 202 or 205 of the UMRA.

This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. The purpose of this action is to apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and to revise the mailing and hand delivery address for the EAB to reflect the Board's relocation.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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, as specified in Executive Order 13132. This action will apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175 Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This action will apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs the EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, the EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

The EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This action will apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation.

K. Congressional Review Act

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

VI. Statutory Authority

Statutory authority for this action comes from 1903 and 1908 of the Act to Prevent Pollution from Ships (APPS) (33 U.S.C. 1901 *et seq.*).

List of Subjects in 40 CFR Part 22

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Hazardous waste, Penalties, Pesticides and pests, Poison prevention, Water pollution control.

Dated: October 20, 2014.

Gina McCarthy,

Administrator.

For the reasons set out in the preamble, 40 CFR part 22 is amended as follows:

PART 22—CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENT OF CIVIL PENALTIES AND THE REVOCATION/TERMINATION OR SUSPENSION OF PERMITS

■ 1. The authority citation for part 22 continues to read as follows:

Authority: 7 U.S.C. 136(l); 15 U.S.C. 2615; 33 U.S.C. 1319, 1342, 1361, 1415 and 1418; 42 U.S.C. 300g–3(g), 6912, 6925, 6928, 6991e and 6992d; 42 U.S.C. 7413(d), 7524(c), 7545(d), 7547, 7601 and 7607(a), 9609, and 11045.

Subpart A—General

■ 2. Section 22.1 is amended by adding paragraph (a)(11) to read as follows:

§ 22.1 Scope of this part.

(a) * * *

(11) The assessment of any administrative civil penalty under

section 1908(b) of the Act To Prevent Pollution From Ships (''APPS''), as amended (33 U.S.C. 1908(b)).

* * * * *

■ 3. Section 22.3, paragraph (a), is amended by revising the definition for ''Clerk of the Board'' to read as follows:

§ 22.3 Definitions.

(a) * * *

Clerk of the Board means an individual duly authorized to serve as Clerk of the Environmental Appeals Board.

* * * * *

■ 4. Section 22.5, paragraph (a)(1), is amended by revising the third sentence to read as follows:

§ 22.5 Filing, service, and form of all filed documents; business confidentiality claims.

(a) *Filing of documents.* (1) * * * Documents filed in proceedings before the Environmental Appeals Board shall be sent to the Clerk of the Board either by U.S. Mail (except by U.S. Express Mail) to U.S. Environmental Protection Agency, Environmental Appeals Board, 1200 Pennsylvania Avenue NW., Mail Code 1103M, Washington, DC 20460–0001; or delivered by hand or courier (including deliveries by U.S. Express Mail or by a commercial delivery service) to U.S. Environmental Protection Agency, Environmental Appeals Board, 1201 Constitution Avenue NW., WJC East, Room 3332, Washington, DC 20004.* * *

* * * * *

Subpart F—Appeals and Administrative Review

■ 5. Section 22.30, paragraph (a)(1), is amended by revising the first sentence to read as follows:

§ 22.30 Appeal from or review of initial decision.

(a) *Notice of appeal.* (1) Within 30 days after the initial decision is served, any party may appeal any adverse order or ruling of the Presiding Officer by filing an original and one copy of a notice of appeal and an accompanying appellate brief with the Environmental Appeals Board as set forth in § 22.5(a).* * *

* * * * *

[FR Doc. 2014–26321 Filed 11–5–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2014–0169; FRL–9918–73–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Allegheny County; Control of Outdoor Wood-Fired Boilers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania pertaining to the control of particulate matter (PM) emissions from the operation of outdoor wood-fired boilers (OWBs) in Allegheny County. EPA is approving this revision in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on December 8, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2014–0169. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy for public inspection 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 Commonwealth's submittal are available at the Allegheny County Health Department, Bureau of Environmental Quality, Division of Air Quality, 301 39th Street, Pittsburgh, Pennsylvania 15201.

FOR FURTHER INFORMATION CONTACT: Ellen Schmitt, (215) 814–5787, or by email at *schmitt.ellen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On August 5, 2014, EPA published a notice of proposed rulemaking (NPR) proposing approval of a revision to the Allegheny County portion of the Pennsylvania SIP for the control of PM from the operation of OWBs in Allegheny County. 79 FR 45395. The formal SIP revision was submitted on January 15, 2014 by the Pennsylvania Department of Environmental Protection (PADEP) on behalf of Allegheny County. In the NPR, EPA proposed approval of the SIP revision because EPA's review of the revision indicated that the regulations submitted would reduce problems associated with the operation of OWBs, including smoke and burning prohibited fuels, including garbage, tires, and hazardous waste. *Id.* at 45396.

II. Summary of SIP Revision

The SIP revision consists of: (1) adding Section 2104.09 (Outdoor Wood-Fired Boiler) to Article XXI, ''Air Pollution Control Rules and Regulations''; and (2) adding new related definitions to Section 2101.20 (Definitions) of Article XXI. Section 2104.09 contains the requirements pertaining to the sale, manufacture, installation, and operation of OWBs in Allegheny County. The specific requirements pertaining to the regulation of OWBs in Allegheny County, as well as EPA's rationale for approving these changes, are explained in the NPR and the accompanying Technical Support Document (TSD) and will not be restated here. These documents are contained in the electronic docket available online at *www.regulations.gov,* Docket number EPA–R03–OAR–2014–0169.[1]

III. Public Comments

EPA received two sets of comments on the August 5, 2014 NPR proposing approval of Allegheny County's January 15, 2014 SIP submission for control of OWBs in the County. A full set of comments is provided in the docket for this final rulemaking action. A summary of each comment and EPA's response is provided in this section.

A. Clean Air Council Comments

Comment: Clean Air Council (CAC) urges EPA to disapprove the proposed SIP revision based on several factors and states that an outright ban on OWBs in Allegheny County is appropriate asserting, ''greater action is necessary to sufficiently protect residents from harmful wood smoke'' from OWBs. Specifically, CAC states that an outright ban of OWBs in Allegheny County is appropriate given the local terrain, proximity of neighbors, and magnitude of other emissions in the Allegheny County airshed.

[1] In the TSD, EPA stated that the SIP revision would reduce emissions of fine particulate matter ($PM_{2.5}$) from OWBs which would promote benefits such as improved visibility.

To support this argument, CAC cites a study which indicates setback regulations and stack height requirements for OWBs are insufficient to protect public health. CAC also mentions that EPA's proposed residential wood heater new source performance standards (NSPS) point to site-specific criteria that states have considered in the past when developing rules for OWBs including: (1) local terrain; (2) proximity of neighbors; and (3) magnitude of other emissions in the airshed. Regarding terrain, CAC states the Allegheny County terrain is such that emissions are frequently ''trapped'' which contributes to poor air quality events and states the area is prone to temperature inversions which prevent air movement and leads to stagnation. CAC contends inversions typically occur during cooler months when OWBs would likely be used more often which would lead to potentially dangerous periods of high PM levels in the County. In addition, CAC refers to Allegheny County's population density as more dense than the average density for Pennsylvania and compares it to the density for the State of Washington which banned OWBs.

Finally, CAC asserts concerns with the magnitude of emissions in the Allegheny County airshed and refers to the County as downwind of West Virginia nonattainment areas for $PM_{2.5}$ and sulfur dioxide (SO_2) and of a maintenance area for ozone. CAC notes the Pittsburgh-Beaver Valley area is also designated nonattainment for the 1997 and 2008 ozone National Ambient Air Quality Standards (NAAQS) and the 1997 and 2006 $PM_{2.5}$ NAAQS while Allegheny County and Beaver County are designated nonattainment for the 2010 SO_2 NAAQS.[2] Finally, CAC cites to the recent, proposed designation of Allegheny County as nonattainment for the 2012 $PM_{2.5}$ NAAQS. CAC states EPA's proposed designation found Allegheny County has high emissions of PM-precursor pollutants, including nitrogen oxides (NO_X), volatile organic compounds (VOCs), ammonia, and SO_2, and states EPA identified nine major sources of PM-precursor pollutants.

Overall, CAC claims continued operation of OWBs in the County will only ''exacerbate'' the County's struggle to attain the NAAQS and requested EPA disapprove the proposed SIP revision as CAC believes only a complete ban on OWBs can protect County residents given these factors.

[2] CAC notes a portion of Beaver County is also designated nonattainment for the 2008 lead NAAQS.

Response: EPA appreciates CAC's concern regarding Allegheny County's air quality and CAC's suggestion for a ban on OWBs. Present laws and regulations in the Commonwealth of Pennsylvania and in Allegheny County specifically permit operation and use of OWBs with certain conditions. This SIP revision includes regulations from the Allegheny County Health Department (ACHD) providing additional restrictions on operation and use of OWBs within the County which EPA believes will reduce smoke and PM emissions therefore also improving visibility. EPA believes approving ACHD's regulations into the Allegheny County portion of the Pennsylvania SIP will strengthen the SIP through pollution reductions within the County.

Section 110 of the CAA provides the statutory framework for approval and disapproval of SIP revisions. Under the CAA, EPA establishes NAAQS for certain pollutants. The CAA establishes a joint Federal and state program to control air pollution and protect the public health. States are required to prepare SIPs for each designated ''air quality region'' within their borders. The SIP must specify emission limits and other measures necessary for that area to attain and maintain the required NAAQS. Pursuant to section 107(a) of the CAA, the states have the *primary* responsibility to assure air quality within the state by submitting a SIP to attain and maintain the NAAQS. Each SIP must be submitted to the EPA for its review and approval; in reviewing SIP submissions, EPA's role is to approve state choices provided the SIP revision is found to meet the minimum requirements of the CAA or any applicable EPA regulations. *See* section 110(k)(3) of the CAA; *see also Union Elec. Co.* v. *EPA,* 427 U.S. 246, 265 (1976).

EPA's authority to approve SIP revisions is governed by CAA section 110(k). EPA does not have authority under the CAA to condition (or otherwise require) as a prerequisite for approval of a state's SIP submittal the adoption of the most stringent or most protective control measure possible for achieving the NAAQS within the state as long as the SIP meets the minimum requirements of the CAA or its implementing regulations. *See Commonwealth of Virginia, et al.,* v. *EPA,* 108 F.3d 1397, 1410 (D.C. Cir. 1997) (citing *Natural Resources Defense Council, Inc.* v. *Browner,* 57 F.3d 1122, 1123 (D.C. Cir.1995)). EPA cannot condition approval of Pennsylvania's SIP submission of ACHD's regulations upon inclusion of a particular emission reduction program such as banning OWBs as long as the SIP otherwise meets the requirements of the CAA. As explained in the NPR and the TSD, ACHD's regulations should reduce emissions of PM and $PM_{2.5}$ and should improve visibility within the County which should aid in the County's attainment of the $PM_{2.5}$ NAAQS. EPA believes including ACHD's regulations within the Pennsylvania SIP will strengthen the SIP and believes the SIP revision meets the requirements of the CAA including section 110 of the CAA. Thus, EPA disagrees that the submitted SIP revision should be disapproved for not including in the regulations more stringent provisions.

Regarding EPA's 2014 proposed NSPS for OWBs, EPA stated in the proposed residential heater NSPS, which EPA proposed pursuant to section 111 of the CAA, that additional actions *may be needed* by local regulatory authorities in addressing impacts from residential heaters due to site-specific concerns, such as local terrain, meteorology, proximity of neighbors and other exposed individuals. 79 FR 6330, 6336 (February 3, 2014). Thus, in keeping with Congressional intent for states to design emission reduction programs within their states for SIPs in accordance with sections 107(a) and 110, local and state regulatory authorities may consider requirements for residential wood heaters for SIPs which are beyond the requirements EPA has proposed for the NSPS and may consider such factors as local terrain, meteorology, proximity of neighbors and other exposed individuals. These factors are not mandatory for states to consider for emission reduction measures for SIPs and were not used by EPA in developing the 2014 NSPS proposal; they are also not mandatory minimum requirements in the CAA for approvability of Pennsylvania's SIP revision to include ACHD's regulations for OWBs.[3]

EPA also notes that CAC correctly indicated the attainment status of several areas in West Virginia as well as in Allegheny County. However, EPA is approving this SIP revision pursuant to section 110 of the CAA as the PM reductions and visibility improvement from ACHD's regulations will strengthen the Pennsylvania SIP. Pennsylvania did not submit this SIP

[3] In the 2014 NSPS proposal, EPA stated, ''our BSER [Best System of Emission Reduction] determination rests on: (1) the achievability of the proposed emission levels (i.e., the fact that top-performing models for each appliance type are already achieving the proposed emission levels); and (2) the cost effectiveness of the proposed standards when considering the design life span and the emitting life span of the appliances in residences.'' 79 FR at 6354.

revision as an attainment plan for any NAAQS, thus, no provisions in part D, Title I of the CAA, relating to attainment planning, are applicable to this rulemaking action. EPA notes that when Pennsylvania develops any required attainment plans for Allegheny County for any NAAQS it could consider whether a total ban on OWBs might be appropriate to demonstrate timely attainment or represent reasonably available control measures, and EPA would consider the potential availability of such controls in reviewing any attainment SIPs for Allegheny County.

In summary, nothing in the CAA requires EPA to consider the terrain, proximity of neighbors, or magnitude of other emissions in the airshed before determining the approvability of a particular regulation for a SIP revision. EPA finds the SIP revision to include ACHD's regulations for OWBs strengthens the Pennsylvania SIP with pollution reduction requirements, particularly for PM, and therefore meets the requirements for SIP approval in section 110 of the CAA.

Comment: CAC also claims that the enforceability of ACHD's prohibition on the use of OWBs during air quality action days (in Section 2104.09(h) of Article XXI, Rules and Regulations of the ACHD) is ''dubious at best'' as it will be difficult for ACHD to assess compliance and take corrective action when needed. CAC claims an outright ban of OWBs is therefore appropriate for Allegheny County.

Response: EPA appreciates CAC's concern with the enforceability of ACHD's regulation; however, EPA disagrees that CAC's concern with enforceability of the regulation impacts our ability to approve this SIP revision.[4] EPA is approving ACHD's OWB regulations for inclusion in the Pennsylvania SIP because the regulations will reduce PM and improve visibility within Allegheny County, and therefore the SIP revision meets requirements in CAA section 110 as the revision strengthens the Pennsylvania SIP. CAC has presented no factual or legal argument supporting its concern for the enforceability of ACHD's OWB regulations. EPA has previously concluded the Pennsylvania SIP includes enforceable emission limitations and control measures and provides necessary assurances that Pennsylvania has adequate personnel, funding and authority to implement the Pennsylvania SIP. [5] CAC provides no factual or legal argument to challenge our prior conclusions. EPA believes ACHD's regulations include clear and practically enforceable terms for fuel requirements for OWBs and for sale, distribution and operation of OWBs, including a prohibition on OWB operation on Air Quality Action Days in Allegheny County.[6] As EPA has previously concluded Pennsylvania has adequate funding and other tools such as personnel to implement its SIP, EPA disagrees with CAC that its unsubstantiated concerns with enforceability of ACHD's OWB regulations lead to any conclusion that a ban on OWBs is appropriate or required instead of approval of this SIP revision. In addition, including the OWB regulations in the Pennsylvania SIP ensures Federal enforceability of the regulations providing additional assurance the SIP will be implemented. *See* section 113(a) of the CAA.

Comment: CAC cites to a 2010 study by Environment and Human Health, Inc. (EHHI) that indicates setback regulations and stack height requirements for OWBs have been insufficient to protect human health. CAC asserts the study concluded OWBs should be banned as no regulations put in place protect neighboring properties or health of families in homes on those properties. CAC requests that EPA disapprove the proposed SIP revision in light of the study.

Response: EPA disagrees with the CAC that EPA should disapprove the SIP revision for ACHD's regulations on OWBs based on this EHHI study. The 2010 EHHI study investigated how homes are affected by neighboring OWBs and the health implications for the families living *inside* homes impacted by wood smoke. The EHHI study measured *indoor* PM ($PM_{2.5}$ and even finer particulate matter less than 0.5 micrometers ($PM_{0.5}$)) inside homes varying in distance from an operating OWB in the State of Connecticut over the course of three days. The proposed SIP revision from ACHD is intended to reduce *outdoor* air pollution. As discussed previously, EPA is approving this SIP revision because it strengthens the SIP and will provide benefits by reducing PM and $PM_{2.5}$ emissions from OWBs overall and improving visibility. Congress did not design the CAA (including the SIP process, NAAQS pollutants, or area nonattainment designations) to have any effect on indoor air pollution. Even though concentrations of PM from OWBs may enter nearby resident's homes, the CAA does not require states to control outdoor pollution based on indoor impacts. The CAC has not articulated any legal argument regarding why a study of indoor PM impacts EPA's ability to approve a SIP revision which EPA finds benefits emissions of $PM_{2.5}$ to outdoor air. EPA recognizes that there may be ancillary health benefits in a community that coincide with OWB programs. As mentioned in the TSD accompanying our NPR, EPA noted the ACHD regulations for OWBs, which are in addition to Pennsylvania's requirements for OWBs in 25 Pa. Code 123.14, should provide further protections to the residents of Allegheny County. However, as previously discussed, states have primary responsibility for deciding how to attain and maintain the NAAQS. Under the CAA, the sole issue for EPA's consideration in this rulemaking action is whether ACHD's OWB regulations, as an additional PM control measure for the Pennsylvania SIP, would be consistent with CAA provisions. EPA is approving the inclusion of ACHD's OWB regulations into the SIP because the approval is consistent with the requirements of section 110 of the CAA, including attainment and maintenance of the NAAQS, including the PM NAAQS. CAC's request for a ban on OWBs in Allegheny County based on health concerns, particularly concerns for indoor air pollution, may be considered and implemented at the local level without EPA's review or approval. *See* 77 FR 1414 (January 10, 2012) (final action approving revisions to the Alaska SIP relating to removing the motor vehicle inspection and maintenance program for control of carbon monoxide in Anchorage).

B. American Lung Association Comments

The American Lung Association (ALA) provides several comments in order to ''amplify'' comments received from CAC.

Comment: With respect to the issue of proximity of neighbors, ALA emphasizes that this factor renders

[4] As part of the SIP submittal, Pennsylvania included ACHD's response to comments received during ACHD's public comment process on these OWB regulations. In the responses, ACHD stated it regularly implements effective enforcement of all Article XXI regulations and expects to do the same with the proposed new OWB regulations.

[5] *See* 77 FR 58955 (approving Pennsylvania's infrastructure SIPs as meeting requirements in CAA section 110(a)(2) including 110(a)(2)(A) and (E) for the 1997 8-Hour Ozone and the 1997 and 2006 $PM_{2.5}$ NAAQS).

[6] ''Air Quality Action Day'' is clearly defined in section 2101.20 of ACHD's Article XXI to mean ''a day for which a forecast has been issued by the Pennsylvania Department of Environmental Protection, the Allegheny County Health Department or the Southwest Pennsylvania Air Quality Partnership indicating that ambient concentrations of ozone, particulate matter, carbon monoxide, sulfur dioxide, or nitrogen dioxide might reach unhealthful levels or exceed the National Ambient Air Quality Standards.''

OWBs problematic for the City of Pittsburgh and the remainder of Allegheny County, which has a population density nearly five times that of the state average. ALA states the areas of the County beyond the City of Pittsburgh are also at increased risk from OWBs. ALA asserts that any rule regulating any air pollution source should address the issue from the macro scale of air pollution inventories and that source's impacts on ambient air quality for the region as a whole, and should not institutionalize highly localized adverse air pollution impacts. ALA asserts it could support a rule for OWBs if ACHD could demonstrate widespread use of OWBs (operating with the local topographic variations and uneven compliance with rules for feedstock quality and operating conditions) would not produce significantly elevated concentrations of air pollutants in neighboring properties. ALA claims evidence it has seen shows such a rule is unlikely to be so effective. ALA also asserts any rule on OWBs must not only be workable for the current locations and prevalence of these units but should be forward-looking and able to handle possible future expansions of this source. ALA claims the regulatory burden of managing emissions from a much larger local inventory of OWBs, along with all of the issues related to cumulative adverse effects of individually, apparently ''well-controlled'' sources, and even neighbor-versus-neighbor disputes, should not be regarded as inconsiderable. ALA claims once OWBs are widely used it will be difficult to return to non-use.

Finally, ALA notes studies done in southwestern Pennsylvania and in Allegheny County in particular show evidence that current levels of air pollution and emissions of carcinogens already pose higher risks to health and lives of regional and county residents. ALA claims such a situation does not support taking less than a strict health-protective approach with respect to sources of air pollution that are already problematic, both in terms of emission factors, and in terms of the necessary surveillance and enforcement resources to control them properly.

Response: EPA appreciates the health-based concerns expressed by ALA. EPA notes that it considers health based impacts when setting the NAAQS, including in particular the 2012 $PM_{2.5}$ NAAQS. EPA sets the NAAQS to protect public health with an adequate margin of safety. As previously discussed, Congress placed the role of implementing the NAAQS and devising measures to attain and maintain the NAAQS with the states. *See* section 107(a) of CAA. EPA's role is to approve SIP submittals that meet minimum criteria in the CAA and its implementing regulations. EPA believes ACHD's OWB regulations strengthen the Pennsylvania SIP as the regulations should reduce overall emissions of $PM_{2.5}$ from OWBs. Pennsylvania's SIP submittal discussed how ACHD tailored its OWB regulations to the specific situations encountered in Allegheny County and how ACHD expected the regulations to benefit the health of citizens of Allegheny County.[7] EPA's TSD, supporting the approval of the SIP revision, stated the ACHD regulations would reduce problems associated with the operation of OWBs, including smoke and burning prohibited fuels, and would reduce ambient levels of $PM_{2.5}$ which would improve visibility. To approve these regulations as a SIP-strengthening measure, EPA does not have to determine if the emissions reductions from the regulations are or are not significant or address health concerns in Allegheny County. EPA merely needs to determine if the regulations will generate *some* additional emissions reductions that would not be achieved by the current Pennsylvania SIP. EPA has reviewed these regulations in accordance with that framework and finds the provisions approvable for the SIP as the regulations will reduce $PM_{2.5}$ and improve visibility. EPA has concluded the OWB regulations meet the minimum criteria for SIP approvability. No provision in the CAA, or in its implementing regulations, requires consideration of additional health impacts available from alternative, more stringent emission control measures before EPA may approve emission control measures submitted by a state for SIP approval, nor requires EPA to take a ''strict health-protective approach'' before approving SIPs as suggested by ALA. *See Commonwealth of Virginia v. EPA,* 108 F.3d 1397 (limiting role of EPA to reviewing SIP submissions for compliance with CAA requirements). As discussed in a prior response, and in the TSD, EPA recognizes that there may be ancillary health benefits in Allegheny County from the OWB regulations from reduced exposure to $PM_{2.5}$ emissions. However, as discussed previously, states have primary responsibility for deciding how to attain and maintain the NAAQS, which EPA set to protect health with an adequate margin of safety. Under the CAA, the sole issue for EPA's consideration in this rulemaking action is whether adding the OWB regulations from ACHD in the SIP would be consistent with CAA provisions. EPA has found the ACHD regulations are a PM control measure and approval is therefore consistent with the requirements of the CAA, including attainment and maintenance of the NAAQS. Concerns regarding population density, institutionalized air pollution impacts, cumulative adverse health impacts, property impacts, and increased usage of OWBs are not criteria for approving SIP submissions under the CAA. ACHD is able to consider on its own any additional restrictions on OWBs or other emission sources to benefit the health of residents of Allegheny County given ALA's concerns for air pollution in the area.

Finally, operation of OWBs is permissible generally within Allegheny County and the Commonwealth of Pennsylvania. ACHD's regulations add restrictions on OWB operations and therefore reduce impacts from the OWB operation. Therefore, contrary to ALA's comments, ACHD's regulations should reduce air pollutant concentrations and not lead to elevated concentrations of air pollutants. Thus, EPA appreciates ALA's comments and concerns but finds the submitted SIP provision approvable and in accordance with the CAA.

IV. Correction

During the course of this rulemaking action EPA became aware of three inadvertent errors involving Section 2101.20 in the ''EPA-Approved Allegheny County Health Department (ACHD) Regulations'' at 40 CFR 52.2020(c), table (2). The first error occurs at the second entry for Section 2101.20. The title of the section should read ''Definitions'' not ''Definitions related to gasoline volatility.'' The second error occurs at the fourth entry for Section 2101.20. The EPA approval date should read ''12/28/10, 75 FR 81480'' not ''12/28/10, 75 FR 81*555.*'' The third error occurs at the fifth entry for Section 2101.20. The EPA approval date should read ''1/2/14, 79 FR 54'' not ''1/2/14, 79 FR.'' In this rulemaking action, EPA corrects these errors.

V. Final Action

EPA is approving the Pennsylvania SIP revision consisting of: (1) The addition of Section 2104.09 (Outdoor Wood-Fired Boilers) to Article XXI, ''Air Pollution Control Rules and Regulations''; and (2) the addition of related new definitions to Section 2101.20. EPA is also correcting minor typographical errors found in 40 CFR

[7] The SIP submittal is available in the electronic docket online at *www.regulations.gov,* Docket number EPA–R03–OAR–2014–0169.

52.2020(c), table (2), related to Section 2101.20 (Definitions).

VI. Statutory and Executive Order Reviews

A. General Requirements

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

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

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

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 5, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action, pertaining to the regulation of OWBs in Allegheny County, may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter, Reporting and recordkeeping requirements.

Dated: October 23, 2014.

William C. Early,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart NN—Pennsylvania

■ 2. In § 52.2020, the table in paragraph (c)(2) is amended by:

■ a. Under Part A, revising the second, fourth, and fifth entries for ''2101.20'', and adding a new entry for ''2120.20'' and

■ b. Under Part D, adding in numerical order an entry for ''2104.09''.

The revised and added text reads as follows:

§ 52.2020 Identification of plan.

* * * * *

(c) * * *

(2) * * *

Article XX or XXI citation	Title/Subject	State effective date	EPA Approval date	Additional explanation/ § 52.2063 citation
Part A—General				
*	*	*	*	*
2101.20	Definitions	5/15/98, 9/1/99	4/17/01, 66 FR 19724	(c)(151); See Part I of the IBR document.
*	*	*	*	*
2101.20	Definitions	5/24/10	12/28/10, 75 FR 81480	Addition of four new definitions: Exterior panels, interior panels, flat wood panel coating, and tileboard. See Part III of the IBR document.
2101.20	Definitions	5/24/10	1/2/14, 79 FR 54	Addition of ''$PM_{2.5}$'' definition.

Article XX or XXI citation	Title/Subject	State effective date	EPA Approval date	Additional explanation/ § 52.2063 citation
2101.20	Definitions	6/8/13	11/6/14 [Insert **Federal Register** citation].	Added seven definitions related to Outdoor Wood-Fired Boilers.
*	*	*	*	*
Part D—Pollutant Emission Standards				
*	*	*	*	*
2104.09	Outdoor Wood-Fired Boilers	6/8/13	11/6/14 [Insert **Federal Register** citation].	Added new regulation.
*	*	*	*	*

* * * * *

[FR Doc. 2014–26300 Filed 11–5–14; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, 2, 15, 27, 73, and 74

[GN Docket No. 12–268; FCC 14–143]

Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions

AGENCY: Federal Communications Commission.

ACTION: Clarification.

SUMMARY: This document clarifies how the Commission intends to preserve the ''coverage area'' as well as the ''population served'' of eligible broadcasters in the repacking process associated with the broadcast television spectrum incentive auction. This action is taken in order to remove any uncertainty regarding the repacking approach the Commission adopted in the *Incentive Auction R&O.*

DATES: Effective November 6, 2014.

FOR FURTHER INFORMATION CONTACT: Aspasia Paroutsas, Office of Engineering and Technology, 202–418–7285, *Aspasia.Paroutsas@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Declaratory Ruling, GN Docket No. 12–268, FCC 14–143, adopted September 20, 2014 and released September 30, 2014. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.* People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Summary of Declaratory Ruling

1. In this Declaratory Ruling, the Commission clarifies how it intends to preserve the ''coverage area'' as well as the ''population served'' of eligible broadcasters in the repacking process associated with the broadcast television spectrum incentive auction. The Commission takes this action in order to remove any uncertainty regarding the repacking approach it adopted in the *Incentive Auction R&O,* 79 FR48442, August 15, 2014. The Commission addresses each of these factors independently and in a manner that fully comports with Congress's mandate to make ''all reasonable efforts'' to ''preserve'' both coverage area and population served as of the enactment date of the Spectrum Act.

Background

2. The Spectrum Act requires the Commission, in repacking the television bands to repurpose spectrum through the incentive auction, to ''make all reasonable efforts to preserve, as of the date of the enactment of the Act [February 22, 2012], the coverage area and population served of each broadcast television licensee, as determined using the methodology described in OET Bulletin 69.'' In the *Incentive Auction R&O,* the Commission interpreted ''coverage area,'' consistent with the definition of ''service area'' in OET Bulletin 69 (OET–69) and 47 CFR 73.622(e), as the area within a full power station's noise-limited F(50,90) contour where the signal strength is predicted to exceed the noise-limited service level, and as the area within a Class A station's protected contour. The Commission interpreted ''population served,'' consistent with OET–69 and 47 CFR 73.616(e), to mean persons who reside within a station's ''coverage area'' at locations where the signal is not subject to interference from other stations.

3. Section 6403(b)(2) requires that the Commission determine each eligible station's ''coverage area'' and ''population served'' using ''the methodology described in OET Bulletin 69.'' The OET–69 methodology has two major steps. First, ''service area or coverage''—the area within a station's relevant contour where the signal strength is predicted to exceed a specified level—is determined using 2-kilometer spacing increments or ''cells.'' Second, interference from other stations is evaluated on a cell-by-cell basis within that area. The result of the interference analysis is data that indicate the population and area (in square kilometers) within the ''coverage area'' lost to interference from other stations.

4. While OET–69 does not provide standards for preserving a television station's coverage area or population served, the Commission's rules provide that applications for new or modified digital television station facilities are acceptable if they are not predicted to cause interference ''to more than an additional 0.5 percent of the population served . . . by another DTV station.'' In other words, the rules protect from interference populated portions of a station's coverage area that are not lost to existing interference from other stations. Consistent with this standard, the Commission adopted a 0.5 percent interference threshold in the *Incentive Auction R&O.* The Commission also

determined that preserving service for the specific viewers who had access to a station's signal as of February 22, 2012, would best comport with the ''all reasonable efforts'' mandate. However, the Commission rejected arguments that section 6403(b)(2) ''is a 'hold harmless' provision that requires the Commission to identify 'extraordinary' or 'truly exceptional' circumstances before altering a station's coverage area and population served.''

Discussion

5. The Commission is concerned that the *Incentive Auction R&O* left some uncertainty regarding how it intends to carry out the statutory preservation mandate in the repacking process. The Commission now clarifies that it will independently protect each eligible station's ''coverage area'' and its ''population served'' as defined in the *Incentive Auction R&O.* In doing so, the Commission will seek to preserve each station's coverage area as determined using the methodology described in OET–69. If the station is reassigned to a different channel, its coverage area on its original channel will be replicated as closely as possible, using the same antenna pattern and other technical parameters and allowing power adjustments as necessary to enable the signal to reach the same geographic area at the same field strength as before the repacking process. As the Commission explained in the *Incentive Auction R&O,* this ''equal area'' approach will enable a station to ''replicat[e] the area within the station's existing contour as closely as possible using the station's existing antenna pattern.'' Consistent with OET–69 and our rules, the Commission will seek to preserve coverage area without regard to interference from other stations or population.

6. Independent of our efforts to preserve each station's ''coverage area,'' the Commission also will seek to preserve its population served, again as determined using the methodology described in OET–69, by prohibiting any channel assignment in the repacking process that would cause one station to interfere with 0.5 percent or more of another station's population served. As ''population served'' by definition excludes unpopulated areas and areas where a station's signal cannot be received due to existing interference from other stations, the Commission will not protect such areas from new interference in the repacking process.

7. The *Incentive Auction R&O* stated that the constraint files the Commission will use during the repacking process ''will match the coverage area of a station to the degree that the area is populated.'' The Commission clarifies that this statement concerns the mechanics of the repacking process, not the ''coverage area'' or ''population served'' that it will seek to preserve for each eligible station as set forth above. The Commission further clarifies that area's where a station's signal is lost to existing interference from other stations, as determined using the methodology in OET–69, will *not* be protected in the repacking process.

8. The Commission's approach is consistent with the statutory preservation mandate. First, as indicated, our approach comports with OET–69 and FCC rules. ''Congress is presumed to be cognizant of, and legislate against the background of, existing interpretations of law.'' Although the statutory terms ''coverage area'' and ''population served'' are related—in particular, ''population served'' is limited by the boundaries of ''coverage area''—they have independent significance under OET–69 and our rules. ''Coverage area'' defines the geographic region within which a signal is predicted to have a specified field strength, whereas ''population served'' represents the populated areas within that region where the signal is not subject to existing interference from other stations. The Commission fulfills the statutory obligation to ''preserve'' a station's coverage area in our repacking process by ensuring that they can continue to operate at technical parameters sufficient to maintain their coverage areas as of February 22, 2012. The Commission ''preserves'' the station's population served by protecting it from interference from other stations in areas where viewers received the station's signal as of that date. Our interpretation does not negate the statutory mandate for preservation of a station's coverage area — as would arguably be the case, for instance, if we required a station to reduce its transmission power or otherwise modify their facilities to reduce their coverage area to conform it to the area of population served. By contrast, according interference protection to ''coverage area'' without regard to ''population served'' would depart from OET–69 and our rules.

9. Second, the Commission's interpretation is consistent with Congress's mandate to ''preserve'' service as of the statutory enactment date, which we observed in the *Incentive Auction R&O* ''suggests that the goal is to maintain the *status quo,*'' consistent with the Commission's historical concern ''with avoiding disruption of service to existing viewers.'' By seeking to preserve each station's ''coverage area'' as set forth, the Commission will ensure that its signal reaches substantially the same geographic area at the same field strength after the repacking process as it did before. By independently protecting each station's ''population served'' from interfering signals, the Commission will ensure that its signal reaches the same viewers before and after the repacking process, subject only to the *de minimis* interference permitted under the Commission's rules for new or modified station facilities. In contrast, protecting a station's ''coverage area'' from interfering signals without regard to its ''population served'' would result in more expansive protection than stations received under the rules in effect at the time the Spectrum Act was enacted.

10. Third, the Commission's interpretation is consistent with Congress's ''all reasonable efforts'' mandate. As explained in the *Incentive Auction R&O,* in the context of a statute with important goals other than preservation of existing television service, in particular the goal of repurposing spectrum, the ''all reasonable efforts'' mandate militates against a statutory interpretation that would limit our ability to repack the television bands efficiently and thereby threaten the auction's overall success in repurposing spectrum. Expanding the interference protection provided in the repacking process beyond that provided under the pre-Spectrum Act rules to unpopulated or unserved (due to existing interference from other stations) portions of each station's coverage area would significantly constrain our flexibility in the repacking process and impair the efficiency of the final television channel assignment scheme: A station could not be assigned to a channel if the assignment would cause signal overlap with another station within either station's coverage area, even if such overlap occurred only in geographic areas where the stations do not have viewers because the areas are uninhabited, uninhabitable, or service was unavailable in the areas due to existing interference from other stations. As a result of such inefficiency, the prospects for the auction's overall success would be substantially threatened.

Ordering Clauses

11. The actions in this Declaratory Ruling has not changed the Final Regulatory Flexibility Analysis (FRFA), which was set forth in the *Incentive Auction R&O.* Thus, no supplemental FRFA is necessary. In addition, the action contained herein does not change

the information collection requirements subject to the Paperwork Reduction Act of 1995 (''PRA''), Public Law 104–13, contained in the *Incentive Auction R&O.* As a result, no new submission to the Office of Management and Budget is necessary to comply with the PRA requirements.

12. Pursuant to the authority found in Sections 1, 4, 301, 303, and 307 of the Communications Act of 1934, as amended, and sections 6402 and 6403 of Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, 126 Stat. 156, 47 U.S.C. 151, 154, 301, 303, and 307, and section 1.2 of the Commission's rules, 47 CFR 1.2, the *Declaratory Ruling is adopted.*

13. The Declaratory Ruling adopted herein shall be effective upon release.

14. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this *Declaratory Ruling* in GN Docket No. 12–268 to the Chief Counsel for Advocacy of the Small Business Administration.

15. The Commission will not send a copy of the Declaratory Ruling pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because the Commission did not adopt any new rules here.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2014–26038 Filed 11–5–14; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 79, No. 215
Thursday, November 6, 2014

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 ENERGY

10 CFR Part 460

[Docket No. EERE–2013–BT–NOC–0005]

Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC)

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Notice of open teleconference/webinar.

SUMMARY: This notice announces open meetings for the Appliance Standards and Rulemaking Federal Advisory Committee. The Federal Advisory Committee Act requires that agencies publish notice of an advisory committee meeting in the **Federal Register**.

DATES: DOE will host a public teleconference/webinar on December 1, 2014 from 3:00 p.m. to 5:00 p.m.

ADDRESSES: The meeting will be held by webinar. To register for the webinar and receive call-in information, please register at *https://www1.gotomeeting.com/register/584796697.*

Methods and addresses for submitting comments are listed in **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: John Cymbalsky, ASRAC Designated Federal Officer, U.S. Department of Energy (DOE), Office of Energy Efficiency and Renewable Energy, 950 L'Enfant Plaza, SW., Washington, DC 20024. Telephone: (202) 287–1692. Email: *asrac@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of Meeting

Purpose of Meeting: To provide advice and recommendations to the Energy Department on the development of standards and test procedures for residential appliances and commercial equipment, certification and enforcement of standards, and product labeling.

Tentative Agenda: (Subject to change; final agenda will be posted at *http://www.appliancestandards.energy.gov*):

• Update on Manufactured Housing Working Group and Regional Enforcement Working Group efforts. The Committee will discuss the Working Groups' term sheets and decide whether or not to accept the term sheets and formally recommend them to DOE.

Public Participation

Members of the public are welcome to observe the business of the meeting and, if time allows, may make oral statements during the specified period for public comment. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, email *asrac@ee.doe.gov.* In the email, please indicate your name, organization (if appropriate), citizenship, and contact information.

Members of the public will be heard in the order in which they request to make a statement at the public meeting. Time allotted per speaker will depend on the number of individuals who wish to speak but will not exceed five minutes. Reasonable provision will be made to include the scheduled oral statements on the agenda.

1. Federal eRulemaking Portal: *www.regulations.gov.* Follow the instructions for submitting comments.

2. Email: *ASRAC@ee.doe.gov.* Include docket number EERE–2013–BT–NOC–0005 in the subject line of the message.

3. Mail: Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. Hand Delivery/Courier: Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586–2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted.

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

Issued in Washington, DC, on October 31, 2014.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2014–26401 Filed 11–5–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2014–F–1669]

The Iams Company; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that The Iams Company has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a *Salmonella*-specific bacteriophage preparation as a food additive as an antimicrobial processing aid to reduce *Salmonella* in the production of dry dog and cat pet food.

DATES: Submit either electronic or written comments on the petitioner's request for categorical exclusion from preparing an environmental assessment or environmental impact statement by December 8, 2014.

ADDRESSES: Submit electronic comments to: *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8225.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act

(section 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2289) has been filed by The Iams Company, 315 Cool Springs Blvd., Franklin, TN 37067. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of a *Salmonella*-specific bacteriophage preparation as a food additive as an antimicrobial processing aid to reduce *Salmonella* in the production of dry dog and cat pet food. The petitioner has requested a categorical exclusion from preparing an environmental assessment or environmental impact statement under 21 CFR 25.32(r).

Interested persons may submit either electronic or written comments regarding this request for categorical exclusion to the Division of Dockets Management (see **DATES** and **ADDRESSES**). 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.*

Dated: November 3, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–26405 Filed 11–5–14; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 22

[EPA–HQ–OECA–2014–0551; FRL–9914–33–OECA]

RIN 2020–AA50

Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This proposed rule revises the scope of the Environmental Protection Agency's (EPA) Consolidated Rules of Practice governing the administrative assessment of civil penalties to encompass the assessment of civil penalties under the air pollution control provisions of the Act to Prevent Pollution from Ships. The EPA has not previously established adjudicatory procedures for the assessment of civil penalties under that statute. Establishment of such procedures will provide for the efficient and effective adjudication, including administrative appeals, of such proceedings consistent with statutory requirements. This proposed rule also revises the address for the Environmental Appeals Board to reflect its relocation to the William Jefferson Clinton East Building.

In the ''Rules and Regulations'' section of this **Federal Register**, we are making this same amendment as a direct final rule. If we receive no adverse comment, the direct final rule will go into effect and we will not take further action on this proposed rule.

DATES: Written comments must be received by December 8, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OECA–2014–0551, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email:* [*docket.oeca@epa.gov.*]
3. *Fax:* (202) 566–9744.
4. *Mail:* Environmental Protection Agency, OECA Docket, Mail-Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
5. *Hand Delivery:* EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004. Attention Docket No. EPA–HQ–OECA–2014–0551. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OECA–2014–0551. The 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 the 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 the 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, the 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 the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to the **SUPPLMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or at the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004. 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 OECA Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: Meetu Kaul, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, William Jefferson Clinton Building South, Room 1117B, 1200 Pennsylvania Ave. NW., Mail Code 2242A, Washington, DC 20460, phone number (202) 564–5472 or by email at *kaul.meetu@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is the EPA issuing this proposed rule?

The EPA is proposing to revise the scope of the EPA's Consolidated Rules of Practice governing the administrative assessment of civil penalties to encompass the assessment of civil penalties under the air pollution control provisions of the Act to Prevent Pollution from Ships. Establishment of such procedures will provide for the

efficient and effective adjudication, including administrative appeals, of such proceedings consistent with statutory requirements.

We are publishing a direct final rule in the ''Rules and Regulations'' section of this **Federal Register** because we view this as a noncontroversial action and anticipate no adverse comment. We explain our reasons for this action in the preamble to the direct final rule. The regulatory text for the proposal is identical to that for the direct final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse comment, we will publish timely notice in the **Federal Register** to withdraw the direct final rule. We will address all public comments in any subsequent final rule based on this proposed rule. We do not intend to provide a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule see the **ADDRESSES** section of this document.

II. Does this action apply to me?

This action may affect parties involved in EPA administrative adjudicatory proceedings for the assessment of civil penalties under section 1908(b) of the Act to Prevent Pollution from Ships (33 U.S.C. 1908(b)). You may direct questions regarding the applicability of this action as noted in **FOR FURTHER INFORMATION CONTACT**

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

A. *Submitting CBI* Do not submit this information to the EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

B. *Tips for Preparing Your Comments*

When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- 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.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

IV. Statutory and Executive Order Reviews

A. Executive Orders 12866: Regulatory Planning and Review and 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). This action will apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this rule on small entities, I certify that this rule will not have a significant economic impact on a substantial number of small entities. This rule will not impose any additional requirements on small entities. This rule will apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The action imposes no enforceable duty on any State, local or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA.

This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. The purpose of this action is to apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and to revise the mailing and hand delivery address for the EAB to reflect the Board's relocation.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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, as specified in Executive Order 13132. This action will

apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175 Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This action will apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs the EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, the EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

The EPA has determined that this rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This action will apply the Rules of Practice to adjudicatory proceedings for the assessment of civil penalties by the EPA under its Act to Prevent Pollution from Ships authority, and will revise the mailing and hand delivery address for the EAB to reflect the Board's relocation.

V. Statutory Authority

Statutory authority for this proposed action comes from sections 1903 and 1908 of the Act to Prevent Pollution from Ships (APPS) (33 U.S.C. 1901 *et seq.*).

List of Subjects in 40 CFR Part 22

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Hazardous waste, Penalties, Pesticides and pests, Poison prevention, Water pollution control.

Dated: October 23, 2014.

Gina McCarthy,

Administrator.

[FR Doc. 2014–26318 Filed 11–5–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 202, 203, 205, 207, 211, 212, 215, 217, 218, 219, 225, 228, 234, 236, 237, 250, and 252

RIN 0750–AI43

Defense Federal Acquisition Regulation Supplement: Inflation Adjustment of Acquisition-Related Thresholds (DFARS Case 2014–D025)

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

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to further implement the U.S.C. statute on inflation adjustment of acquisition-related dollar thresholds. This statute requires an adjustment every five years of acquisition-related thresholds for inflation using the Consumer Price Index for all urban consumers, except for the Construction Wage Rate Requirements statute (Davis-Bacon Act), Service Contract Labor Standards statute, and trade agreements thresholds. DoD is also proposing to use the same methodology to adjust some nonstatutory DFARS acquisition-related thresholds in 2015.

DATES: *Comment Date:* Comments on the proposed rule should be submitted in writing to the address shown below on or before January 5, 2015, to be considered in the formation of the final rule.

ADDRESSES: Submit comments identified by DFARS Case 2014–D025, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2014–D025'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2014–D025.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2014–D025'' on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2014–D025 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Amy G. Williams, OUSD (AT&L) DPAP/DARS, Room 3B941, 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 G. Williams, Defense Acquisition Regulations System, OUSD (AT&L) DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060. Telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

This rule proposes to amend multiple DFARS parts to further implement 41 U.S.C. 1908. Section 1908 requires an adjustment every five years (on October 1 of each year evenly divisible by five) of statutory acquisition-related thresholds for inflation, using the Consumer Price Index (CPI) for all urban consumers, except for the Construction Wage Rate Requirements statute (Davis-Bacon Act), Service Contract Labor Standards statute, and trade agreements thresholds (see FAR 1.109). As a matter of policy, DoD is also proposing to use the same methodology to adjust some nonstatutory DFARS acquisition-related thresholds. All proposed threshold adjustments would become effective on October 1, 2015.

FAR case 2014–022 proposes comparable changes to acquisition-related thresholds in the FAR.

This is the third review of DFARS acquisition-related thresholds since the statute was enacted on October 28, 2004 (section 807 of the National Defense Authorization Act for Fiscal Year (FY) 2004). The last review was conducted under DFARS case 2009–D003. The final rule was published under that case in the **Federal Register** on August 2, 2010 (75 FR 45072), effective October 1, 2010.

II. Analysis

A. What is an acquisition-related threshold?

This case builds on the review of DFARS thresholds in 2005 and 2010, using the same interpretation of an acquisition-related threshold. 41 U.S.C. 1908 is applicable to ''a dollar threshold that is specified *in law* as a factor in defining the scope of the applicability of a policy, procedure, requirement, or restriction provided *in that law* to the procurement of property or services by an Executive agency, as the [FAR] Council determines.''

There are other thresholds in the DFARS that, while not specified in law, nevertheless meet all the other criteria. These thresholds may have their origin in Executive order or regulation.

Therefore, as used in this case, ''acquisition-related threshold'' has a broader meaning, i.e., a threshold that is specified *in law, Executive order, or regulation* as a factor in defining the scope of the applicability of a policy, procedure, requirement, or restriction provided *in that law, Executive order, or regulation* to the procurement of property or services by an Executive agency, as determined by the FAR Council. Acquisition-related thresholds are generally tied to the value of a contract, subcontract, or modification.

Examples of thresholds that are not ''acquisition-related,'' as defined in this case, are thresholds relating to claims, penalties, withholding, payments, required levels of insurance, small business size standards, liquidated damages, etc. This report does not address thresholds that are not acquisition-related.

B. What acquisition-related thresholds are not subject to escalation adjustment under this case?

41 U.S.C. 1908 does not permit escalation of acquisition-related thresholds established by the Construction Wage Rate Requirements statute (Davis Bacon Act), the Service Contract Labor Standards statute, or the United States Trade Representative pursuant to the authority of the Trade Agreements Act of 1979.

Also, the statute does not authorize DoD to escalate thresholds originating in Executive order or the implementing agency (such as the Department of Labor or the Small Business Administration), unless the Executive order or agency regulations are first amended.

C. How does DoD analyze escalation of a statutory acquisition-related threshold?

If an acquisition-related threshold is based on statute, the matrix at *http://www.acq.osd.mil/dpap/dars/pgi/docs/2014-D025_(p)_TAB_E_matrix_Sep_12_14.xls* identifies the statute, and the statutory threshold, including the original threshold and any subsequent revisions to it.

With the exception of thresholds set by the Construction Wage Rate Requirements statute (Davis Bacon Act), the Service Contract Labor Standards statute, and trade agreements, 41 U.S.C. 1908 requires adjustment of the acquisition-related thresholds for inflation using the Consumer Price Index (CPI) for all-urban consumers. Acquisition-related thresholds in statutes that were in effect on October 1, 2000, are only subject to escalation from that date forward. Acquisition-related thresholds in statutes that took effect after October 1, 2000, are escalated from the date that they took effect. For purposes of this proposed rule, the matrix includes calculation of escalation based on the estimated CPI value for March 2015 (currently estimated at 243.0) divided by the CPI for the date of enactment of the statute or regulation (October 2000, for statutes enacted prior to October 1, 2000). DoD will subsequently adjust as necessary before issuance of the final rule.

Once the escalation factor is applied to the acquisition-related threshold, then statutory thresholds must be rounded as follows:

< $10,000—Nearest $500
$10,000–<$100,000—Nearest $5,000
$100,000–<$1,000,000—Nearest $50,000
$1,000,000 or more—Nearest $500,000

The calculations in this proposed rule are all based on the base year amount, because escalated amounts in the 2005 rule were subject to rounding and using those amounts as the base would distort future calculations.

In 2010, some thresholds (e.g., $3,000), although subject to inflation calculation, did not actually change, because the inflation in 2010 was insufficient to overcome the rounding requirements—i.e., the escalation factor, when applied, did not cause the escalated values to be high enough to round to the next higher value. However, in FY 2015, thresholds that did not escalate in 2010 will now escalate because of five additional years of inflation. Likewise, some thresholds that were escalated in 2010 (e.g., $150,000) will not escalate in 2015.

This rule proposes to remove the major defense acquisition program thresholds (expressed in FY 1990 constant dollars) from the definition of ''major weapon system'' at DFARS 234.7001. The current major defense acquisition program thresholds in FY 2014 constant dollars are set forth in DoD Instruction 5000.02, established in accordance with the authority in 10 U.S.C. 2430(b), which allows the Secretary of Defense to adjust the amounts (and the base fiscal year) provided in subsection (a)(2) on the basis of DoD escalation rates (rather than the CPI for all urban consumers). The most recent thresholds were calculated by the DoD Comptroller, and coordinated with the Cost Assessment and Program Evaluation (CAPE) Office and the DoD General Counsel. In accordance with 10 U.S.C. 2430(b),

these thresholds were reported to Congress in December 2013. There is no need to provide these thresholds in the DFARS. The term ''major defense acquisition program'' is already defined in DFARS 202.1 and used in multiple DFARS parts (e.g., 204, 209, 215, and 216).

This proposed rule has been coordinated with the Small Business Administration in areas of the regulation for which they are the lead agency.

D. How does DoD analyze a nonstatutory acquisition-related threshold?

No statutory authorization is required to escalate thresholds that were set as policy within the DFARS. Escalation of the DoD policy acquisition-related thresholds is generally recommended using the same formula applied to the statutory thresholds, unless a reason has been provided for not doing so. Escalation is calculated using the same procedures as were explained for the statutory thresholds, to provide consistency.

However, nonstatutory thresholds that exceed $10 million may be rounded as follows:

$10 million–<$100 million—Nearest $5 million

$100 million–<$1 billion—Nearest $50 million

$1 billion or more—Nearest $500 million

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.,* because the rule maintains the status quo by adjusting thresholds for actual inflationary increases in the CPI. However, an Initial Regulatory Flexibility Analysis has been performed and is summarized as follows:

This rule proposes to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement 41 U.S.C. 1908 and to amend other acquisition-related dollar thresholds that are based on policy rather than statute in order to adjust for the changing value of the dollar. 41 U.S.C. 1908 requires adjustment every five years of statutory acquisition-related dollar thresholds, except for Construction Wage Rate Requirements statute (Davis-Bacon Act), Service Contract Labor Standards statute, and trade agreements thresholds. While reviewing all statutory acquisition-related thresholds, this case presented an opportunity to also review all nonstatutory acquisition-related thresholds in the DFARS that are based on policy.

The objective of the case is to maintain the status quo, by adjusting acquisition-related thresholds for inflation. The legal basis is 41 U.S.C. 1908. The statute does not authorize the DFARS to escalate thresholds originating in Executive orders or the implementing agency (such as the Department of Labor or the Small Business Administration), unless the Executive order or agency regulations are first amended.

This rule will likely affect to some extent all small business concerns that submit offers or are awarded contracts by the Federal Government. However, most of the threshold changes proposed in this rule are not expected to have any significant economic impact on small business concerns because any threshold changes are intended to maintain the status quo by adjusting for changes in the value of the dollar. Often any impact will be beneficial, by preventing burdensome requirements from applying to more and more acquisitions, as the dollar loses value.

The rule does not impose any new reporting, recordkeeping, or compliance requirements. Changes in thresholds for approved information collection requirements are intended to maintain the status quo and prevent those requirements from increasing over time.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no practical alternatives that will accomplish the objectives of the statute.

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 2014–D025), in correspondence.

V. Paperwork Reduction Act

The Paperwork Reduction Act does apply. The proposed changes to the FAR do not impose new information collection requirements that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.* By adjusting the thresholds for inflation, the status quo for the current information collection requirements are maintained under the following OMB clearance numbers:

OMB control No.	Title	DFARS part
0704–0187	Information Collection in Support of the DOD Acquisition Process (Solicitation Phase)	208, 209, 226, 235
0704–0229	Defense Federal Acquisition Regulation Supplement Part 225, Foreign Acquisition, and related clauses.	225
0704–0286	Defense FAR Supplement (DFARS) Part 205, Publicizing Contract Actions, and DFARS 252–205–7000, Provision of Information to Cooperative Agreement Holders.	205
0704–0477	Organizational Conflicts of Interest in Major Defense Acquisition Programs	209.5

However, the rule contains one information collection requirement that requires the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35). Accordingly, DoD has submitted to the Office of Management and Budget a request for approval of a new information collection requirement entitled ''DFARS Part 249, Termination of Contracts, and Associated DFARS Clauses at 252.249.''

A. Public reporting burden for this collection of information is estimated to average approximately .75 hours per

response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden estimated as follows:

Respondents: 42.

Responses per respondent: Approximately 6.

Total annual responses: 260.

Preparation hours per response: Approximately .75 hours

Total response Burden Hours: 193.

B. Request for Comments Regarding Paperwork Burden

Written comments and recommendations on the proposed information collection, including suggestions for reducing this burden, should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503, or email *Jasmeet_K._Seehra@omb.eop.gov,* with a copy to the Defense Acquisition Regulations System, Attn: Ms. Amy G. Williams, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060. Comments can be received from 30 to 60 days after the date of this notice, but comments to OMB will be most useful if received by OMB within 30 days after the date of this notice.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the DFARS, and will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Acquisition Regulations System, Attn: Ms. Amy G. Williams, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060, or email *osd.dfars@mail.mil.* Include DFARS Case 2014–D025 in the subject line of the message.

List of Subjects in 48 CFR Parts 202, 203, 205, 207, 211, 212, 215, 217, 218, 219, 225, 228, 234, 236, 237, 250, and 252

Government Procurement.

Manuel Quinones,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 202, 203, 205, 207, 211, 212, 215, 217, 218, 219, 225, 228, 234, 236, 237, 250, and 252 are proposed to be amended as follows:

■ 1. The authority citation for 48 CFR parts 202, 203, 205, 212, 215, 217, 225, 234, 237, and 252 continues to read as follows:

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

PART 202—DEFINITIONS OF WORDS AND TERMS

202.101 [Amended]

■ 2. Amend section 202.101 by—

■ a. Designating the definition of ''Simplified acquisition threshold'' in alphabetical order in the list of definitions; and

■ b. In the definition of ''Simplified acquisition threshold'', removing ''$300,000'' and adding $400,000'' in its place.

PART 203—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

203.1004 [Amended]

■ 3. Amend section 203.1004 in paragraph (b)(2)(ii) by removing ''$5 million'' and adding ''$5.5 million'' in its place.

PART 205—PUBLICIZING CONTRACT ACTIONS

205.303 [Amended]

■ 4. Amend section 205.303 by removing ''$6.5 million'' and adding ''$7 million'' in its place for the following—

■ a. In paragraph (a)(i) introductory text, in two places;

■ b. In paragraph (a)(i)(A); and

■ c. In paragraph (a)(i)(B), in two places.

205.470 [Amended]

■ 5. Amend section 205.470 by removing ''$1,000,000'' and adding ''$1.5 million'' in its place.

PART 207—ACQUISITION PLANNING

■ 6. The authority citation for part 207 is revised to read as follows:

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

207.170–3 [Amended]

■ 7. Amend section 207.170–3 in paragraph (a) introductory text by removing ''$6 million'' and adding ''$6.5 million'' in its place.

PART 211—DESCRIBING AGENCY NEEDS

■ 8. The authority citation for part 211 is revised to read as follows:

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

211.503 [Amended]

■ 9. Amend section 211.503 in paragraph (b) by removing ''$650,000'' and adding ''$700,000'' in its place in two places.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

212.7102–1 [Amended]

■ 10. Amend section 212.7102–1 in paragraph (c) by removing ''$50 million'' and adding ''$55 million'' in its place.

PART 215—CONTRACTING BY NEGOTIATION

215.403–1 [Amended]

■ 11. Amend section 215.403–1 in paragraphs (c)(3)(B) and (c)(4)(B) by removing ''$15,000,000'' and adding ''$20 million'' in its place.

PART 217—SPECIAL CONTRACTING METHODS

■ 12. Amend section 217.170 by—

■ a. Revising paragraph (e)(1)(iv); and

■ b. In paragraph (e)(5) by removing ''$100 million'' and adding ''$139.5 million'' in its place.

The revision reads as follows:

217.170 General.

* * * * *

(e) * * *

(1) * * *

(iv) Include a cancellation ceiling in excess of $139.5 million (see 10 U.S.C. 2306c(d)(4) and 10 U.S.C. 2306b(g)).

* * * * *

217.171 [Amended]

■ 13. Amend section 217.171 in paragraph (d) by removing ''$625.5 million'' and adding ''$698.5 million'' in its place.

217.172 [Amended]

■ 14. Amend section 217.172 in paragraphs (c), (e)(1), and (e)(2) by removing ''$500 million'' and adding ''$698.5 million'' in its place.

PART 218—EMERGENCY ACQUISITIONS

■ 15. The authority citation for part 218 is revised to read as follows:

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

218.270 [Amended]

■ 16. Amend section 218.270 by removing ''$300,000'' and adding ''$400,000'' in its place.

PART 219—SMALL BUSINESS PROGRAMS

■ 17. The authority citation for part 219 is revised to read as follows:

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

219.502–1 [Amended]

■ 18. Amend section 219.502–1 in paragraph (2) by removing ''$350,000'' and adding ''$400,000'' in its place in both places.

219.502–2 [Amended]

■ 19. Amend section 219.502–2 by—

■ a. In paragraph (a)(i), removing ''$2.5 million'' and adding ''$3 million'' in its place; and

■ b. In paragraph (a)(iii), removing ''$350,000'' and adding ''$400,000'' in its place.

PART 225—FOREIGN ACQUISITION

225.7204 [Amended]

■ 20. Amend section 225.7204 by—

■ a. In paragraphs (a) and (b), removing ''$12.5 million'' and adding ''$14 million'' it its place in both places; and

■ b. In paragraph (c), removing ''$650,000'' and adding ''$700,000'' in its place.

225.7703–2 [Amended]

■ 21. Amend section 225.7703–2 in paragraph (b)(2)(ii) by removing ''$85.5 million'' and adding ''$95.5 million'' in its place.

PART 228—BONDS AND INSURANCE

■ 22. The authority citation for part 228 is revised to read as follows:

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

228.102–1 [Amended]

■ 23. Amend section 228.102–1 by—

■ a. In the introductory text and paragraph (1), removing ''$30,000'' and adding ''$35,000'' in its place in both places; and

■ b. In paragraph (2) introductory text, removing ''$100,000'' and adding ''$150,000'' in its place.

PART 234—MAJOR SYSTEM ACQUISITION

■ 24. Revise section 234.7001 to read as follows:

234.7001 Definition.

Major weapon system, as used in this subpart, means a weapon system acquired pursuant to a major defense acquisition program.

PART 236—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

■ 25. The authority citation for part 236 is revised to read as follows:

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

236.601 [Amended]

■ 26. Amend section 236.601 in paragraph (1) by removing ''$1,000,000'' and adding ''$1.5 million'' in its place.

PART 237—SERVICE CONTRACTING

237.170–2 [Amended]

■ 27. Amend section 237.170–2 in paragraphs (a)(1) and (2) by removing ''$85.5 million'' and adding ''$95.5 million'' in its place in both places.

PART 250—EXTRAORDINARY CONTRACTUAL ACTIONS AND THE SAFETY ACT

■ 28. The authority citation for part 250 is revised to read as follows:

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

250.102–1 [Amended]

■ 29. Amend section 250.102–1 in paragraph (b) by removing ''$65,000'' and adding ''$70,000'' in its place.

250.102–1–70 [Amended]

■ 30. Amend section 250.102–1–70 in paragraph (b)(1) by removing ''$65,000'' and adding ''$70,000'' in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.203–7004 [Amended]

■ 31. Amend section 252.203–7004 by—

■ a. Removing the clause date ''DEC 2012'' and adding ''DATE'' in its place; and

■ b. In paragraph (c) introductory text, removing ''$5 million'' and adding ''$5.5 million'' in its place.

252.209–7004 [Amended]

■ 32. Amend section 252.209–7004 by—

■ a. Removing the clause date ''MAR 2014'' and adding ''DATE'' in its place; and

■ b. In paragraph (a), removing ''$30,000'' and adding ''$35,000'' in its place.

252.209–7009 [Amended]

■ 33. Amend section 252.209–7009 by—

■ a. Removing the clause date ''DEC 2012'' and adding ''DATE'' in its place; and

■ b. In paragraph (a)(ii), removing ''$50 million'' and adding ''$55 million'' in its place.

252.225–7003 [Amended]

■ 34. Amend section 252.225–7003 by—

■ a. Removing the clause date ''OCT 2010'' and adding ''DATE'' in its place;

■ b. In paragraph (b)(1), removing ''$12.5 million'' and adding ''$14 million'' in its place; and

■ c. In paragraph (b)(2)(i), removing ''$650,000'' and adding ''$700,000'' in its place.

252.225–7004 [Amended]

■ 35. Amend section 252.225–7004 by—

■ a. Removing the clause date ''OCT 2010'' and adding ''DATE'' in its place; and

■ b. In paragraph (b)(1), removing ''$650,000'' and adding ''$700,000'' in its place.

252.225–7006 [Amended]

■ 36. Amend section 252.225–7006 by—

■ a. Removing the clause date ''OCT 2010'' and adding ''DATE'' in its place; and

■ b. In paragraph (f)(1), removing ''$650,000'' and adding ''$700,000'' in its place.

252.225–7017 [Amended]

■ 37. Amend section 252.225–7017 by—

■ a. Removing the clause date ''JAN 2014'' and adding ''DATE'' in its place; and

■ b. In paragraph (c)(1), removing ''$3,000'' and adding ''$3,500'' in its place.

252.225–7018 [Amended]

■ 38. Amend section 252.225–7018 by—

■ a. Removing the clause date ''JAN 2014'' and adding ''DATE'' in its place;

■ b. In paragraph (b)(1), removing ''$3,000'' and adding ''$3,500'' in its place; and

■ c. In paragraphs (d)(1) and (2), removing ''$3,000'' and adding ''$3,500'' in both places.

252.249–7002 [Amended]

■ 39. Amend section 252.249–7002 by—

■ a. Removing the clause date ''OCT 2010'' and adding ''DATE'' in its place; and

■ b. In paragraph (d)(1), removing ''$650,000'' and adding ''$700,000'' in its place.

[FR Doc. 2014–26266 Filed 11–5–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 219, and 252

RIN 0750–AI42

Defense Federal Acquisition Regulation Supplement: Advancing Small Business Growth (DFARS Case 2014–D009)

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

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to clarify that entering into a contract award may cause a small business to eventually exceed the applicable small business size standard.

DATES: *Comment Date:* Comments on the proposed rule should be submitted in writing to the address shown below on or before January 5, 2015, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2014–D009, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2014–D009'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2014–D009.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2014–D009'' on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2014–D009 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Lee Renna, OUSD(AT&L)DPAP/DARS, Room 3B941, 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. Lee Renna, Defense Acquisition Regulations System, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060. Telephone 571–372–6095.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement policy to ensure a small business contractor is made aware that entering into a covered contract conveys its acknowledgement that doing so may cause it to eventually exceed the small business size standard of the North American Industry Classification System (NAICS) code identified in the solicitation and contract. This clarification is required by section 1611 of the National Defense Authorization Act for Fiscal Year 2014, (10 U.S.C. 2419).

A ''covered'' contract within the context of this rule means a contract that was awarded to a qualified small business concern, as defined in section 3(a) of the Small Business Act, Public Law 85–536 as amended, (15 U.S.C. 632(a)), with an estimated annual dollar value that—

- Will exceed the small business size standard (if expressed in dollars) for the North American Industry System (NAICS) code assigned by the contracting officer; or
- Will exceed $70,000,000, if the small business standard is expressed in number of employees, for the NAICS code assigned by the contracting officer.

Should this occur, the company will no longer qualify as a small business in that and other similar NAICS codes.

Section 1611 further stipulates that new language shall be added to the DFARS to encourage these companies to develop the capabilities and characteristics typically sought by DoD from contractors that are competitive as other than small businesses. To this end, small business contractors may seek out the training and counseling services available from the Procurement Technical Assistance Program (PTAP). The PTAP, through its network of over 300 Procurement Technical Assistance Centers located across the United States as well as the territories of Puerto Rico and Guam, offers a wide range of Government contracting assistance. The PTAP is administered by the Defense Logistics Agency and funded through cooperative agreements between DoD and state and local non-profit entities.

To incorporate this guidance, the rule proposes to revise 212.301(f); add a new section 219.309 entitled Solicitation provisions and contract clauses; and add a new solicitation provision at 252.219.

II. 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 a significant regulatory action and, therefore, was 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.

III. 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.,* because it does not create or alleviate any financial burden on small entities. The purpose of the rule is to advise small businesses that by entering into a DoD contract, they may eventually cause the company to exceed the size standard associated with the NAICS code identified in the contract. The rule further encourages these contractors to develop the competencies typically desired of other than small businesses. Therefore, an initial regulatory flexibility analysis has not been performed.

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 this 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 2014–D009), in correspondence.

IV. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the

Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 212, 219, and 252

Government procurement.

Manuel Quinones,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 219, and 252 are proposed to be amended as follows:

■ 1. The authority citation for parts 212 and 252 continues to read as follows:

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

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 212.301 by—

■ a. Redesignating paragraphs (f)(xxii) through (lxxiv) as (f)(xxiii) through (lxxv); and

■ b. Adding a new paragraph (f)(xxii) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

(f) * * *

(xxii) Use the provision at 252.219–XXXX, Advancing Small Business Growth, as prescribed in 219.309, to comply with 10 U.S.C. 2419.

PART 219—SMALL BUSINESS PROGRAMS

■ 3. The authority citation for part 219 is revised to read as follows:

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

■ 4. Add section 219.309 to subpart 219.3 to read as follows:

219.309 Solicitation provisions and contract clauses.

(a) Use the provision at 252.219–XXXX, Advancing Small Business Growth, as required by 10 U.S.C. 2419, in solicitations, including solicitations using FAR part 12 procedures for acquisition of commercial items, when the estimated annual value of the contract is expected to exceed—

(1) The small business size standard, if expressed in dollars, for the North American Industry Classification System (NAICS) code assigned by the contracting officer; or

(2) $70,000,000, if the small business size standard is expressed as number of employees for the NAICS code assigned by the contracting officer.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. Add section 252.219–XXXX to read as follows:

252.219–XXXX Advancing Small Business Growth.

As prescribed in 219.309, use the following provision:

Advancing Small Business Growth (Date)

(a) This provision implements 10 U.S.C. 2419.

(b) The Offeror acknowledges that by acceptance of this contract, it may exceed the applicable small business size standard of the NAICS code assigned to the contract and would no longer qualify as a small business concern for that NAICS code. (Small business size standards matched to industry NAICS codes are published by the Small Business Administration and are available at *http://www.sba.gov/content/table-small-business-size-standards*.) The Offeror is therefore encouraged to develop the capabilities and characteristics typically desired in contractors that are competitive as other-than-small contractors in this industry.

(c) For technical assistance in this regard, the Offeror may contact the nearest Procurement Technical Assistance Center (PTAC). PTAC locations are available at *http://www.aptac-us.org.*

(End of provision)

[FR Doc. 2014–26268 Filed 11–5–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 229 and 697

[Docket No. 141002823–4823–01]

RIN 0648–BE57

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Atlantic Large Whale Take Reduction Plan Regulations; Atlantic Coastal Fisheries Cooperative Management Act Provisions; American Lobster Fishery

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to amend the regulations implementing the Atlantic Large Whale Take Reduction Plan to modify the start date of the Massachusetts Restricted Area to begin on February 1, 2015, and to expand the Massachusetts Restricted Area by 912 square miles. In addition, this action also proposes to revise the Federal lobster regulations to be consistent with the revised start date of the Massachusetts Restricted Area. Recent Federal lobster regulations closed the Outer Cape Lobster Management Area to lobster trap fishing from January 15 through March 15, which is consistent with the lobster trap haul-out period in the Atlantic States Marine Fisheries Commission's Interstate Fishery Management Plan for American Lobster. This proposed rule would adjust the Outer Cape Lobster Management Area closure dates to February 1 through March 31.

DATES: Submit comments on or before November 21, 2014.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2014–0127, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal at *www.regulations.gov.*
- *Mail:* Submit written comments to Kim Damon-Randall, Assistant Regional Administrator for Protected Resources, NMFS Greater Atlantic Region, 55 Great Republic Dr., Gloucester, MA 01930, Attn: Large Whale Proposed Rule.

Instructions: 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 by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. 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, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Kate Swails, NMFS Greater Atlantic Region, 978–282–8481, *Kate.Swails@noaa.gov;* or, Kristy Long, NMFS Office of Protected Resources, 206–526–4792, *Kristy.Long@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Access

Several of the background documents for the Plan and the take reduction planning process can be downloaded from the Plan Web site at *http://www.greateratlantic.fisheries.noaa.gov/*

protected/whaletrp/index.html. The complete text of the regulations implementing the Plan can be found in the Code of Federal Regulations (CFR) at 50 CFR 229.32 or downloaded from the Web site, along with a guide to the regulations.

Background

This proposed rule combines two regulatory modifications that are authorized under different statutes. Specifically, this action proposes to amend the regulations implementing: (1) the Atlantic Large Whale Plan (Plan)_regulations found at 50 CFR part 229 under the authority of the MMPA; and (2) the Federal American lobster Fishery Management Plan regulations found at 50 CFR part 697 under the authority of the Atlantic Coastal Fisheries Cooperative Management Act.

NMFS published a final rule implementing an amendment to the Plan on June 27, 2014 (79 FR 36586) to address large whale entanglement risks associated with vertical line (or buoy lines) from commercial trap/pot fisheries. That amendment included gear modifications, gear setting requirements, a seasonal closure (Massachusetts Restricted Area) and gear marking for both the trap/pot and the gillnet fisheries. The Massachusetts Restricted Area is a seasonal closure that is effective January 1 through April 30 for all trap/pot fisheries, which accounts for the largest number of vertical lines in the water column.

In September 2010, in consultation with the Atlantic Large Whale Take Reduction Team (Team), NMFS developed protocols for considering modifications or exemptions to the regulations implementing the Plan. Following these protocols, on August 18, 2014, the Massachusetts Division of Marine Fisheries (DMF) submitted a proposal to modify the Massachusetts Restricted Area and exempt several areas from the gear setting requirements to address safety and economic concerns raised by Massachusetts fishermen.

Review of Massachusetts Restricted Area

The proposal submitted by DMF contains two components:

(1) Modify the Massachusetts Restricted Area (closure), which begins on January 1, 2015 by:

○ Modifying the timing and size of the closure.

○ Establishing gear stowage areas during a portion of the closure.

(2) Establish several exemption areas to the current minimum number of traps per trawl requirement, which take effect June 1, 2015.

○ Exemption areas would include portions of Southern New England waters (Buzzards Bay, Vineyard Sound, and Nantucket Sound) as well as state waters north and east of Cape Cod.

Given the importance of addressing the Massachusetts Restricted Area before the closure begins on January 1, 2015, and the time needed to complete the analysis of the entire suite of requests contained in the entire DMF proposal, NMFS decided to address the modifications to the Massachusetts Restricted Area and the exemption of the minimum number of traps per trawl requirements separately.

Changes Proposed to the Plan

NMFS proposes to modify the start date of the Massachusetts Restricted Area to begin on February 1, 2015 and expand the area by 912 square miles. NMFS proposes this action because it responds to comments to improve the past action while balancing risk reduction considerations. Specifically, the action decreases the number of affected vessels and results in reductions in compliance costs while maintaining the same entanglement risk reduction as provided in the June 2014 amendment to the Plan.

At its October 1, 2014 meeting, the Team discussed the requested modifications to the Massachusetts Restricted Area, as well as the creation of the trap/pot storage areas. The discussion included a review of the merits and analysis of the DMF proposal utilizing NMFS' co-occurrence model. The model incorporates information on geographic and temporal variations in fishing effort and the distribution of fishing line, as well as whale sightings per unit of survey effort, and identifies areas and times at which whales and commercial fishing gear are likely to co-occur. The model's final product is a set of indicators that provide information on factors that contribute to the risk of entanglement at various locations and at different points in time. These indicators, in particular the number of vertical lines in an area and the area's co-occurrence score, assumed to be related to the relative entanglement risk in different locations. They also provide a basis for comparing the impact of alternative management measures on the potential for entanglements to occur.

NMFS compared the impacts of the two closure areas for conservation benefit using its co-occurrence model and economic analysis. The methods and data sources used in this analysis are consistent with those applied in the Final Environmental Impact Statement (FEIS) for the 2014 Plan amendments referred above. The proposed changes to the closure would allow approximately 125 vessels to continue to fish during a lucrative time of year for the fishing industry and would require a slightly greater number of vessels to suspend activity from February through April. This is because the proposed closure area is larger than the current closure area, an increase of 912 square miles. On average, the proposed closure area offers a similar reduction in co-occurrence to that of the current closure (38.2%) while providing less of an economic burden. Therefore, this proposed action minimizes potential economic impacts without increasing risk to large whales.

At the conclusion of the October 1, 2014, meeting, the Team, by consensus, recommended that we modify the Massachusetts Restricted Area as proposed by DMF. However, the Team recommended that NMFS not act on DMF's proposed trap/pot storage areas. The remainder of DMF's proposal will be analyzed and discussed with the Team during its January 2015 meeting. The Team will provide NMFS a recommendation at that time on whether to move forward with the remaining components of the DMF proposal.

Changes to American Lobster Regulations

On April 7, 2014, NMFS published a final rule (79 FR 19015) that implemented the Outer Cape Area lobster haul-out period. In that rule, NMFS acknowledged in the preamble that it might need to adjust the closure dates if Massachusetts ultimately requested a different time period (See Response to Comment 22, 78 FR 35217, June 12, 2013). Now that Massachusetts has done so, if this proposed rule is adopted, the original Outer Cape Area lobster closure dates would become outdated and may create unintended impacts to Federal lobster fishers. For example, if NMFS does not adjust the January 15 start date, Federal lobster fishers would have to remove their traps from the Outer Cape Area two weeks earlier than the February 1 start date that exists in the Massachusetts regulations and the large whale Plan. Therefore, in this rule, NMFS proposes to change the start date of the Outer Cape Lobster Management Area closure dates from January 15 to February 1. Further, NMFS proposes to adjust the end of the Outer Cape Area haul-out period by two weeks from March 15 to March 31, to continue with a full two-month haul-out period as dictated by the Commission. NMFS considered

extending the haul-out period to April 30, to be consistent with the Plan. However, the southwestern portion of the Outer Cape Area is not included in the Plan's revised closure area, and would be closed for an additional month longer than the Commission's two-month haul-out period. Accordingly, NMFS proposes to simply shift the Outer Cape Area haul-out period dates ahead by two weeks. After March 31, lobster trap fishermen in the Massachusetts Restricted Area will be held to the more restrictive Plan dates through April 30.

Classification

The Office of Management and Budget (OMB) has determined that this action is not significant for the purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

The fisheries affected by this proposed rule are the Northeast American lobster trap/pot, Atlantic blue crab trap/pot and Atlantic mixed species trap/pot. The population of vessels that are affected by this proposed action includes commercial trap/pot vessels fishing in state and federal waters in Massachusetts. On June 12, 2014, the SBA issued an interim final rule revising the small business size standards for several industries effective July 14, 2014 (79 FR 33647). The rule increased the size standard for Finfish Fishing from $19.0 to 20.5 million, Shellfish Fishing from $5.0 to 5.5 million, and Other Marine Fishing from $7.0 to 7.5 million (79 FR 33656, 33660, 33666). Currently, the Massachusetts Restricted Area closure impacts an average of 109 vessels. All of the entities (fishing vessels) affected by this action are considered small entities under the SBA size standards for small fishing businesses.

The analysis of the economic impacts for this action were based on data from the 2014 FEIS that supported the most recent Plan amendment published as a final rule on June 27, 2014 (79 FR 36586). The number of vessels and level of overall fishing effort have remained constant since the preparation of the FEIS. Therefore, NMFS believes that these data are still relevant for the purpose of this analysis.

Currently, the Massachusetts Restricted Area closure impacts an average of 109 vessels, with $1.2 M in gross revenue potentially lost during the closure period. Relatively strong landings make this a critical time for the Massachusetts lobster fishery, especially in the northern part of the closure area. Based on an analysis of the affected number of vessels, average traps per vessel, and net revenues, NMFS estimates that by starting the closure in February, instead of January, this action would result in net revenue gains of $447,000. The net change in revenue has two components: (1) the revenue gain associated with allowing trap/pot fishing in January within the current boundaries of the Massachusetts Bay Restricted Area, and (2) the revenue loss associated with expanding the boundaries of the closure to include *all* waters within the Outer Cape Lobster Management Area, thus prohibiting trap/pot fishing in these newly-closed waters from February through April. The difference between the two is the overall net revenue gain.

This rule would result in positive economic impacts on the affected vessels by excluding the prime fishing month of January. The start date of February 1 would allow lobstermen to complete normal lobster fishing operations through the lucrative holiday months of November into January. Although the closed area is increasing by 912 square miles, the number of vessels affected by the increase in area is minimal. The average number of vessels impacted in the larger area is 106 versus the 109 vessels impacted under current regulations.

NMFS has determined that this action is consistent to the maximum extent practicable with the approved coastal management programs of Massachusetts. This determination was submitted for review by the responsible state agency under section 307 of the Coastal Zone Management Act.

This proposed rule contains policies with federalism implications as that term is defined in Executive Order 13132. Accordingly, the Assistant Secretary for Legislative and Intergovernmental Affairs will provide notice of the proposed action to the appropriate official(s) of affected state, local, and/or tribal governments.

List of Subjects

50 CFR Part 229

Administrative practice and procedure, Confidential business information, Fisheries, Marine mammals, Reporting and recordkeeping requirements.

50 CFR Part 697

Fisheries, fishing.

Dated: October 31, 2014.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 229 and 697 are proposed to be amended to read as follows:

PART 229—AUTHORIZATION FOR COMMERCIAL FISHERIES UNDER THE MARINE MAMMAL PROTECTION ACT OF 1972

■ 1. The authority citation for 50 CFR part 229 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.;* § 229.32(f) also issued under 16 U.S.C. 1531 *et seq.*

■ 2. In § 229.32, paragraph (c)(3) is revised to read as follows:

§ 229.32 Atlantic large whale take reduction plan regulations.

* * * * *

(c) * * *

(3) *Massachusetts Restricted Area*—(i) *Area.* The Massachusetts restricted area is bounded by the following points connected by straight lines in the order listed, and bounded on the west by the shoreline of Cape Cod, Massachusetts.

Point	N. Lat.	W. Long.
MRA1	42°12′	70°44′
MRA2	42°12′	70°30′
MRA3	42°30′	70°30′
MRA4	42°30′	69°45′
MRA5	41°56.5′	69°45′
MRA6	41°21.5′	69°16′
MRA7	41°15.3′	69°57.9′
MRA8	41°20.3′	70°00′
MRA9	41°40.2′	70°00′

(ii) *Closure.* From February 1 to April 30, it is prohibited to fish with, set, or possess trap/pot gear in this area unless stowed in accordance with § 229.2.

(iii) *Area-specific gear or vessel requirements.* From May 1 through January 30, no person or vessel may fish with or possess trap/pot gear in the Massachusetts Restricted Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal trap/pot gear requirements specified in paragraph (c)(1) of this section, and the area-specific requirements listed in (c)(2) of this section, or unless the gear is stowed as specified in § 229.2.

* * * * *

PART 697—ATLANTIC COASTAL FISHERIES COOPERATIVE MANAGEMENT

■ 3. The authority citation for part 697 continues to read as follows:

Authority: 16 U.S.C. 5101 *et seq.*

■ 4. In § 697.7, revise paragraph (c)(1)(xxx) introductory paragraph to read as follows:

§ 697.7 Prohibitions.

* * * * *

(c) * * *

(1) * * *

(xxx) *Outer Cape Area seasonal closure.* The Federal waters of the Outer Cape Area shall be closed to lobster fishing with traps by Federal lobster permit holders from February 1 through March 31.

* * * * *

[FR Doc. 2014–26323 Filed 11–5–14; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 79, No. 215

Thursday, November 6, 2014

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 31, 2014.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725—17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utility Service

Title: 7 CFR 1780, Water and Waste Loan and Grant Program.

OMB Control Number: 0572–0121.

Summary of Collection: Section 306 of the Consolidated Farm and Rural Development Act (CONACT), 7 U.S.C. 1926, authorizes Rural Utilities Service (RUS) to make loans and grants to nonprofit corporations, state, local and tribal governments, and public agencies for the development of water and waste disposal facilities primarily servicing rural residents with populations up to 10,000 residents.

Need and Use of the Information: Rural Development's field offices will collect information from applicants/borrowers and consultants to determine eligibility and project feasibility. The information will help to ensure borrowers operate on a sound basis and use loan funds for authorized purposes. There are agency forms required as well as other requirements that involve certifications from the borrower, lenders, and other parties. Failure to collect proper information could result in improper determinations of eligibility, use of funds and or unsound loans.

Description of Respondents: State, Local or Tribal Government; Not-for-profit institutions.

Number of Respondents: 862.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Annually and Weekly.

Total Burden Hours: 107,003.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2014–26299 Filed 11–5–14; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Agency Information Collection Activities: Revision and Extension of Approved Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

November 3, 2014.

AGENCY: The Office of the Chief Information Officer—OCIO, USDA.

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the Department of Agriculture (USDA), the Office of the Chief Information Officer (OCIO) has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.).

DATES: Comments must be submitted by December 8, 2014.

ADDRESSES: Written comments may be submitted to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Ruth Brown (202) 720–8958 or Charlene Parker (202) 720–8681.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield

quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** on July 9, 2014 (79 FR 38850). With this 30-day notice we are correcting an error that occurred in the 60-day notice with the number of burden hours. The burden hours should have been 20,000 instead of 10,000 and the time it takes to complete should have been 1 hour and not 30 minutes as stated in the **Federal Register**.

The Office of the Chief Information Officer—0503–0021

Current Actions: Revision and Extension of Currently Approved Collection.

Type of Review: Revision and Extension.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of Activities: 20.

Respondents: 20,000.

Annual Responses: 20,000.

Frequency of Response: Once per request.

Average Minutes per Response: 60.

Burden Hours: 20,000.

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

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2014–26438 Filed 11–5–14; 8:45 am]

BILLING CODE 3410–KR–P

DEPARTMENT OF AGRICULTURE

Forest Service

Fremont-Winema National Forests, Chemult and Silver Lake Ranger Districts; Oregon; Antelope Grazing Allotments AMP Analysis

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Fremont-Winema National Forest is preparing an environmental impact statement (EIS) to document the analysis of grazing management within all or portions of three allotments on the Fremont-Winema National Forests. This project, initially documented with an environmental assessment, has had one scoping period (11/2010) and two comment periods (11/2012 and 04/2014). The allotments are the Antelope Cattle & Horse Allotment on the Chemult Ranger District (RD), the Antelope Grazing Allotment on the Silver Lake RD, and a portion of the Jack Creek Sheep and Goat Allotment also on the Chemult RD. The proposed action would reauthorize term grazing permit and a term private land permit to graze cattle for an appropriate season of use (May 15–September 30) within the approximately 169,599 acre project area using an adaptive management strategy, modification of allotment boundaries, and a change in the number of total allotments and pastures. Associated activities would include fence construction, reconstruction, and removal; and spring protection/development and water infrastructure improvements.

DATES: The draft environmental impact statement is expected November 2014 and the final environmental impact statement is expected February 2015.

ADDRESSES: Documents related to this project can be viewed at the Fremont-Winema National Forests Supervisor Office, 1301 South G Street, Lakeview, Oregon 97640.

FOR FURTHER INFORMATION CONTACT: Lucas Phillips, Forest Range Program Lead, at 1301 South G Street, Lakeview, Oregon 97630; or phone at 541–947–6251.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Project Analysis Background

The Antelope Grazing Allotment Project was first presented to the public in 2010. Analysis of the project area began that year and an environmental assessment was released in 2012. A decision notice, signed February 11, 2013, was withdrawn for administrative reasons. Another environmental assessment was completed and publicized December 21, 2013. After review of comments and objections received, the Forest Supervisor decided the analysis would be better documented in an environmental impact statement than using an environmental assessment.

Purpose and Need for Action

This project is being analyzed to determine whether or not the Forest Service should reauthorize livestock grazing, and if so, the appropriate level to reauthorize within the Antelope Grazing Allotments project area. There are needs to update Allotment Management Plans to incorporate best available science that applies to the landscape within these allotments; refine allotment management strategies, systems, and boundaries to better distribute livestock and forage utilization across the allotment, consistent with Forest Plan standards; ensure compliance with the Rescission Act of 1995 (Pub. L. 104–19, Section 504) that requires the Forest Service to establish and adhere to a schedule for completion of NEPA analyses and decisions on all grazing allotments; meet Congressional intent to allow grazing on suitable lands as identified in the Forest Plans and where consistent with other multiple use goals and objectives; and, contribute to the economic and social well-being of the area by providing opportunities for economic diversity and promoting

stability for communities dependent on range resources.

Proposed Action

The Proposed Action was developed to provide grazing opportunities that meet multiple use objectives while reducing the impacts to important botanical and wildlife resource. One herd, a total of 494 cow/calf pairs per month, which includes the 75 cow/calf pair being grazed on private lands, would be authorized to graze from May 20 to October 15. Grazing would be allowed in some fenced riparian areas, additional acreage identified in the Jack Creek Sheep and Goat Allotment, and grazing of the private parcels along Jack Creek known as Upper Jamison, and Lower Jamison under a term private land grazing permit. This would facilitate coordinated management of Oregon spotted frog habitat across ownerships. The North Sheep Pasture would be added to the Antelope Grazing Allotment. The grazing system in the Chemult pasture would be a deferred rotation system made possible by allowing use of additional acreage in some of the existing fenced riparian areas and the North Sheep Pasture.

Possible Alternatives

In addition to the proposed action, the project interdisciplinary team will analyze the effects of:

No Action Alternative (Alternative 1): No livestock grazing would be authorized within the existing Allotments nor would coordinated management of grazing on private lands within the Antelope Allotments occur. Continuance or establishment of grazing on all private lands within the Antelope Allotments, including lands within Oregon spotted frog habitat, would be at stockings, rate, timings, and utilizations of the private landowners' choosing. Cattle would be removed from all allotments within two years.

Current Management Alternative (Alternative 2): Permits would be reauthorized as have been over the last three to five years; two herds at 419 cow/calf pair per month with permitted grazing from May 15 to September 30. The Antelope and Antelope Cattle & Horse Allotments would remain two separate administrative allotments and retain their existing boundaries. Approximately 3.6 miles of fence would be constructed to reinforce the Chemult Pasture boundary at the northeast corner.

Alternative 4: This alternative was developed to provide grazing opportunities while addressing concerns relating to the protection of important botanical and wildlife resources in the Chemult RD. The Chemult portion of the allotments would be administratively closed to grazing, grazing would not expand into the North Sheep Pasture, and fencing would be constructed along active allotment boundaries. New exclosure/protection fences would be constructed around sensitive springs and fens on the Silver Lake side of the allotments. Grazing would be permitted for one herd at 419 cow/calf pair per month from May 20 to July 30 without using the Chemult RD portion of the allotments.

Alternative 5: This incorporates concepts that may result in better success in allotment management and livestock needs. A two herd grazing system on the Chemult District would be used with a deferred rotation pattern involving three of the pastures. Two of these pastures would have a one-year rest during the three-year cycle. The North Sheep Pasture would be added to the Antelope Grazing Allotment. The two-herd system would incorporate the 75 cow/calf pair currently grazed on the private lands withing Jack Creek as part of a term/private permit. Private inholdings along Jack Creek would be brought under allotment management throught a term private permit to enable coordinated management of Oregon spotted frog habitat across ownerships. New exclosure/protection fences would be constructed around sensitive springs and fens. The Rock Springs area would not be included in the Tobin Cabin Allotment. The season of use in the Antelope 3 and 4 holding pastures would be extended to October 15 to facilitate movement of livestock off the Allotments at the end of the grazing season.

Responsible Official

The responsible official will be Forest Supervisor, Fremont-Winema National Forests, 1301 South G Street, Lakeview, OR 97630

Nature of Decision To Be Made

Given the purpose of and need for the proposal, the deciding official will review the proposed action, the other alternatives, and the environmental consequences to make the following decisions:

- Whether or not to authorize livestock grazing on the identified allotments and if so, the appropriate level and grazing system to use.
- If an action alternative is selected, that it is consistent with the Fremont and Winema Land and Resource Management Plans, as amended.

Preliminary Issues

Preliminary issues identified include:

- Grazing within meadows and riparian areas, including fens
- Grazing within occupied and potential habitat for Oregon spotted frog
- Proposed grazing strategies including animal unit months, rotations, and number of herds
- Overutilization, underutilization, and uneven distribution of utilization of forage that may be addressed by inclusion of acquired lands, fenced meadows, and adjacent unused grazing lands as part of the grazing strategy
- Proposed fencing strategies including construction, reconstruction, and fences to maintain or remove
- Expansion of the allotment boundaries, specifically at Cannon Well and the addition of the North Sheep Pasture.

Dated: October 28, 2014.

Constance Cummins,

Forest Supervisor.

[FR Doc. 2014–26394 Filed 11–5–14; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

Notice of Intent To Request Approval To Establish a New Information Collection

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Office of Management and Budget (OMB) Paperwork Reduction Act of 1995, this notice announces the National Institute of Food and Agriculture's (NIFA) intent to establish a new information collection of Letters of Intent (LOIs).

DATES: Submit comments on or before January 5, 2015.

ADDRESSES: Written comments concerning this notice and requests for copies of the information collection may be submitted by any of the following methods to Robert Martin, Records Officer, Information Policy, Planning and Training Mail: NIFA/USDA; Mail Stop 2216; 1400 Independence Avenue SW.; Washington, DC 20250–2216; Hand Delivery/Courier: 800 9th Street SW., Waterfront Centre, Room 4206, Washington, DC 20024; or Email: *rmartin@nifa.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Robert Martin, Records Officer, Information Policy, Planning and

Training; Office of Information Technology; NIFA;USDANIFA, Email: *rmartin@nifa.NIFA.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Letter of Intent.

OMB Number: 0524–New.

Type of Request: Intent to establish a new information collection for three years.

Abstract: NIFA sponsors ongoing agricultural research, extension, and education programs under which competitive, formula, and special awards of a high-priority nature are made. The nature of the competitive, peer-reviewed process makes it important that information from applicants be available in a standardized format to ensure equitable treatment. The LOI is used to ensure applicants adhere to program guidelines and goals and provides useful information for peer review panel planning. Applicants with relevant LOIs will be encouraged to submit a full application to the program while those that do not conform to program goals are discouraged to submit a full application. Many competitive programs currently require a LOI as a prerequisite for submission of an application. To reduce an applicant's administrative burden, NIFA may expand the use of LOIs for more of its competitive programs. Electronic submission via email in an attached PDF formatted document collects the following information:

Page 1:

a. Name of lead Project Director (PD)
b. Professional Title of lead PD
c. Department of lead PD
d. Institution of lead PD
e. Email of lead PD
f. Name of all collaborating PDs
g. Professional Title of all collaborating PDs
h. Department of all collaborating PDs
i. Institution of all collaborating PDs
j. Program Area
k. Priority Area

Page 2:

a. Descriptive Title
b. Rationale
c. Overall Hypothesis or Goal
d. Specific Objectives
e. Approach
f. Potential Impact and Expected Outcomes

The information collection will collect the same information in a fillable PDF document provided by NIFA.

Respondents: Universities, non-profit institutions, State, local, or Tribal governments, and a limited number of for-profit institutions and individuals.

Estimation of Responses: The individual form burden is as follows (calculated based on a survey of LOI applicants conducted by NIFA): 1–2 hours.

Frequency of Respondents: Annually, for those that submit LOIs to required programs.

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, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments should be sent to the address stated in the preamble. All responses to this notice will be summarized and included in the request for OMB approval. All comments also will become a matter of public record.

Done in Washington, DC, this 30th day of October 2014.

Sonny Ramaswamy,

Director, National Institute of Food and Agriculture.

[FR Doc. 2014–26404 Filed 11–5–14; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–844]

Steel Concrete Reinforcing Bar From Mexico: Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on an affirmative final determination by the Department of Commerce (the Department) and the International Trade Commission (ITC), the Department is issuing an antidumping duty (AD) order on steel concrete reinforcing bar (rebar) from Mexico.

DATES: *Effective Date:* November 6, 2014.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore or Joy Zhang, Office III, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3692 or (202) 482–1168.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 735(d) and 777(i)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(c), on September 15, 2014, the Department published its affirmative final determination of sales at less-than-fair-value (LTFV) in the antidumping duty investigation of rebar from Mexico.[1] On October 28, 2014, the ITC notified the Department of its final determination, pursuant to sections 735(b)(1)(A)(i) and section 735(d) of the Act, that an industry in the United States is materially injured by reason of LTFV imports of rebar from Mexico.[2] The ITC also determined that critical circumstances do not exist.[3]

Scope of the Order

The merchandise subject to this order is steel concrete reinforcing bar imported in either straight length or coil form (rebar) regardless of metallurgy, length, diameter, or grade. The subject merchandise is classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) primarily under item numbers 7213.10.0000, 7214.20.0000, and 7228.30.8010.

The subject merchandise may also enter under other HTSUS numbers including 7215.90.1000, 7215.90.5000, 7221.00.0015, 7221.00.0030, 7221.00.0045, 7222.11.0001, 7222.11.0057, 7222.11.0059, 7222.30.0001, 7227.20.0080, 7227.90.6085, 7228.20.1000, and 7228.60.6000. Specifically excluded are plain rounds (*i.e.,* non-deformed or smooth rebar). Also excluded from the scope is deformed steel wire meeting ASTM A1064/A1064M with no bar markings (*e.g.,* mill mark, size or grade) and without being subject to an elongation test. HTSUS numbers are provided for convenience and customs purposes; however, the written description of the scope remains dispositive.

Antidumping Duty Order

As stated above, on October, 28, 2014, in accordance with section 745(d) of the Act, the ITC notified the Department of

[1] *See Steel Concrete Reinforcing Bar From Mexico: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 79 FR 54967 (September 15, 2014) (*Final Determination*).

[2] *See* Steel Concrete Reinforcing Bar From Mexico and Turkey, Investigation Nos. 701–TA–502 and 731–TA–1227 (Final), USITC Publication 4496, (October 2014).

[3] *Id.*

its final determination in which it found that an industry in the United States is materially injured by reason of imports of rebar from Mexico.[4] Therefore, in accordance with section 735(c)(2) of the Act, we are publishing this AD order.

Further, pursuant to section 736(a) of the Act, the Department will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by the Department, AD duties equal to the amounts listed below for all relevant entries of rebar from Mexico entered, or withdrawn from warehouse, for consumption on or after April 24, 2014, the date of publication of the *Preliminary Determination,*[5] but will not include entries occurring after the expiration of the provisional measures period and before the publication of the ITC's final injury determination as further described below.

Continuation of Suspension of Liquidation

In accordance with section 736 of the Act, we will instruct CBP to continue to suspend liquidation on all entries of rebar from Mexico. We will also instruct CBP to require cash deposits at rates equal to the estimated weighted-average dumping margins indicated below. These instructions suspending liquidation will remain in effect until further notice.

Accordingly, effective on the date of publication of the ITC's final affirmative injury determination, CBP will require, at the same time as importers would normally deposit estimated duties on this subject merchandise, a cash deposit at rates equal to the estimated weighted-average dumping margins listed below.[6] The relevant all-others rate applies to all producers or exporters not specifically listed.

Provisional Measures

Section 733(d) of the Act states that instructions issued pursuant to an affirmative preliminary determination may not remain in effect for more than four months except where exporters representing a significant proportion of exports of the subject merchandise request the Department to extend that four-month period to no more than six months. At the request of exporters that account for a significant proportion of rebar from Mexico, we extended the four-month period to no more than six months.[7] The Department published the *Preliminary Determination* in the underlying investigation on April 24, 2014. Therefore, the six-month period beginning on the date of publication of the preliminary determination ended on October 21, 2014. Furthermore, section 737(b) of the Act states that definitive duties are to begin on the date of publication of the ITC's final injury determination.

Therefore, in accordance with section 733(d) of the Act and our practice, we will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of rebar from Mexico, entered, or withdrawn from warehouse, for consumption on or after October 21, 2014, the date the provisional measures expired, until and through the day preceding the date of publication of the ITC's final injury determination in the **Federal Register**. Suspension of liquidation will resume on or after the date of publication of the ITC's final injury determination in the **Federal Register**.

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

Producer or exporter	Estimated weighted-average dumping margin (percent)
Deacero S.A.P.I. de C.V	20.58
Grupo Acerero S.A. de C.V	66.70
Grupo Simec	66.70
All Others	20.58

Critical Circumstances

With regard to the ITC's negative critical circumstances determination on imports of rebar from Mexico, the Department will instruct CBP to lift suspension and refund any cash deposit made to secure payment of estimated antidumping duties with respect to entries of the merchandise entered, or withdrawn from warehouse, for consumption on or after January 24, 2014, (*i.e.,* 90 days prior to the publication date of the *Preliminary Determination*) but before April 24, 2014, the publication date of the *Preliminary Determination.*

Notification to Interested Parties

This notice constitutes the antidumping duty order with respect to rebar from Mexico pursuant to section 736(a) of the Act. Interested parties can find a list of antidumping duty orders currently in effect at *http://enforcement.trade.gov/stats/iastats1.html.*

This order is issued and published in accordance with section 736(a) of the Act and 19 CFR 351.211(b).

Dated: October 31, 2014.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014–26411 Filed 11–5–14; 8:45 am]

BILLING CODE 3510–DS–P

[4] *Id.*

[5] *See Steel Concrete Reinforcing Bar From Mexico: Preliminary Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances, and Postponement of Final Determination,* 79 FR 22802 (April 24, 2014) (*Preliminary Determination*).

[6] *See* section 736(a)(3) of the Act.

[7] *See* letter from Deacero S.A.P.I. de C.V. and Deacero USA, Inc., titled, ''Steel Concrete Reinforcing Bar (''Rebar'') From Mexico: Request To Postpone the Final Determination,'' dated April 15, 2014.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–819]

Steel Concrete Reinforcing Bar From the Republic of Turkey: Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce (the Department) and the International Trade Commission (ITC), the Department is issuing a countervailing duty (CVD) order on steel concrete reinforcing bar (rebar) from the Republic of Turkey (Turkey).

DATES: *Effective Date:* November 6, 2014.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson, Office III, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4793.

SUPPLEMENTARY INFORMATION:

Background

On September 15, 2014, the Department published the final determination in the CVD investigation of rebar from Turkey.[1] On October 28, 2014, the ITC notified the Department of its final determination pursuant to sections 705(b)(1)(A)(i) and section 705(d) of the Tariff Act of 1930, as

[1] *See Steel Concrete Reinforcing Bar from the Republic of Turkey: Final Affirmative Countervailing Duty Determination and Final Affirmative Critical Circumstances Determination,* 79 FR 54963 (September 15, 2014) (*Final Determination*).

amended (the Act), that an industry in the United States is materially injured by reason of subsidized imports of subject merchandise from Turkey.[2] The ITC also determined that critical circumstances do not exist.[3]

Scope of the Order

The merchandise subject to this investigation is steel concrete reinforcing bar imported in either straight length or coil form (rebar) regardless of metallurgy, length, diameter, or grade. The subject merchandise is classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) primarily under item numbers 7213.10.0000, 7214.20.0000, and 7228.30.8010. The subject merchandise may also enter under other HTSUS numbers including 7215.90.1000, 7215.90.5000, 7221.00.0015, 7221.00.0030, 7221.00.0045, 7222.11.0001, 7222.11.0057, 7222.11.0059, 7222.30.0001, 7227.20.0080, 7227.90.6085, 7228.20.1000, and 7228.60.6000. Specifically excluded are plain rounds (*i.e.,* non-deformed or smooth rebar). Also excluded from the scope is deformed steel wire meeting ASTM A1064/A1064M with no bar markings (*e.g.,* mill mark, size, or grade) and without being subject to an elongation test. The HTSUS numbers are provided for convenience and customs purposes; however, the written description of the scope remains dispositive.

Countervailing Duty Order

In accordance with sections 705(b)(1)(A)(i) and 705(d) of the Act, the ITC notified the Department of its final determination that the industry in the United States producing rebar is materially injured by reason of subsidized imports of rebar from Turkey. Therefore, in accordance with section 705(c)(2) of the Act, we are publishing this CVD order.

Further, pursuant to 706(a) of the Act, the Department will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by the Department, countervailing duties on unliquidated entries of rebar entered, or withdrawn from warehouse, for consumption on or after September 15, 2014, the date on which the Department published its final CVD determination in the **Federal Register**. With regard to the ITC's negative critical circumstances determination, the Department will instruct CBP to lift suspension and refund any cash deposits of estimated countervailing duties for entries on or after June 17, 2014, (*i.e.,* 90 days prior to the date of the *Final Determination*), but before September 15, 2014.

Suspension of Liquidation

In accordance with section 706 of the Act, the Department will direct CBP to continue the suspension of liquidation of rebar from Turkey, effective the date of publication of the Department's notice of final determination in the **Federal Register**, and to assess, upon further advice by the Department, pursuant to section 706(a)(1) of the Act, countervailing duties for each entry of the subject merchandise in an amount based on the net countervailable subsidy rates for the subject merchandise, except for subject merchandise entered by Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S. (Habas), whose net subsidy rate is *de minimis* and, hence, is excluded from this order. This exclusion will apply only to subject merchandise both produced and exported by Habas.

CBP must require, at the same time as importers would normally deposit estimated duties on this merchandise, as cash deposit equal to the rates noted below:

Company	Subsidy rate
Icdas Celik Enerji Tersane ve Ulasim Sanayi A.S..	1.25 percent
All Others	1.25 percent

This notice constitutes the CVD order with respect to rebar from Turkey, pursuant to section 706(a) of the Act. Interested parties may contact the Department's Central Records Unit, Room 7046 of the main Commerce Building, for copies of an updated list of countervailing duty orders currently in effect.

This order is issued and published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: October 31, 2014.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014–26414 Filed 11–5–14; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See Steel Concrete Reinforcing Bar from Mexico and Turkey*, Investigation Nos. 701–TA–502 and 731–TA–1227 (Final), USITC Publication 4496, October 2014).

[3] *Id.*

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning its proposed renewal of Day of Service project promotion tool. Individuals organizing a volunteer event will be able to register their projects. This group includes national service grantees, corporations, volunteer organizations, and individuals. The Corporation wants to help promote activities across the country and also to be able to assess impact of the Corporation's initiatives. Information provided is purely voluntary and will not be used for any grant or funding support.

Copies of the information collection request can be obtained by contacting the office listed in the **ADDRESSES** section of this Notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 5, 2015.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, Office of External Affairs; Attention: David Premo, Program Support Specialist, Room 10302–C; 1201 New York Avenue NW., Washington, DC, 20525.

(2) By hand delivery or by courier to the CNCS mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through *www.regulations.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: David Premo, 202–606–6717, or by email at *dpremo@cns.gov.*

SUPPLEMENTARY INFORMATION: CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including 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).

Background

CNCS seeks to support volunteer projects through service initiatives. The initiatives include Martin Luther King Jr. Day of Service, September 11th Day of Service and Remembrance, United We Serve, Let's Read-Let's Move, AmeriCorps Week, Senior Corps Week, and other public engagement and education efforts. To help promote activities and to ascertain impact of our initiatives, it is important to be aware of activities and projects taking place. Anyone participating in, or organizing project will be encouraged to register their project on our Web site. The information will be collected and stored securely on our computer network.

Current Action

CNCS seeks to renew the current information collection.

The information collection will also be used in the same manner as the existing application. CNCS also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on March 31, 2015.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: Day of Service Project Promotion Tool.

OMB Number: 3045–0122.

Agency Number: None.

Affected Public: Any person or group organizing a service project in conjunction with a Corporation Initiative.

Total Respondents: 100,000.

Frequency: 6 times annually.

Average Time per Response: Averages 10 minutes.

Estimated Total Burden Hours: 66,667.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: October 31, 2014.

Theodore Miller,

Office of External Affairs.

[FR Doc. 2014–26384 Filed 11–5–14; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2014–HA–0146]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Assistant Secretary of Defense for Health Affairs announces a proposed public information collection and seeks public comment on the provisions thereof. 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 5, 2015.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Mail: Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title 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. Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Health Agency (DHA), Public Health Division, Health Care Operations Directorate, 7700 Arlington Blvd., Falls Church, VA 22042, ATTN: Lt Col Brian Blalock, Falls Church, VA 80045–6900, or call 703–681–6880.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Screening and Monitoring of DoD Personnel Deployed to Ebola Outbreak Areas; DD Form 2990, DD Form 2991; OMB Control Number 0720–0056.

Needs and Uses: The information collection requirement is necessary to ensure DoD personnel deployed in support of Operation UNITED ASSISTANCE are promptly evaluated for possible exposure(s) to the Ebola virus during deployment to, and within 12 hours prior to departing from, an Ebola outbreak country or region (West Africa). Ebola is a Quarantinable Communicable Disease as named in Executive Order 13295 and supported by several DoD regulations and Federal laws. This information will be used by DoD medical and public health officials to (1) ensure Ebola exposure risk is evaluated, (2) proper prevention and quarantine efforts are implemented, (3) appropriate medical care is provided, (4) medical surveillance programs are robust and (5) the spread of Ebola beyond West Africa is minimized. The DoD has consulted with the Centers for Disease Control and Prevention, the Department of State, the Agency for

International Development, and several Defense Agencies regarding disease control efforts and health surveillance in response to the public health emergency in West Africa. DoD has also specifically discussed these new information collections with representatives of the various Military Services, representing deploying military members who have participated in the development of the content of these forms.

Affected Public: Individuals or Households.

Annual Burden Hours: 480.

Number of Respondents: 1,200.

Responses per Respondent: 2.

Average Burden per Response: 24 minutes.

Frequency: On occasion.

Respondents are DoD personnel (active duty service members, federal civilian employees and contractors). Using the DD2990 and DD2991, information will be collected from respondents during deployment and just prior to redeployment (return from deployment). This information will provide for health surveillance while deployed, removal from duty if representing a health risk to self or others, apprehension and detention, or conditional release of individuals to prevent the introduction, transmission, or spread of suspected communicable diseases, pursuant to section 361(b) of the Public health Service Act (42 U.S.C. 264), UCMJ, DoD Directive 6490.02E, DoD Instruction 6490.03, 5 CFR 339.301. The information will also be collected in order to identify any health concerns and to refer individuals for additional assessment and/or care. The overall intent is to protect the health of the individual and public from EBV. This information will also be included in deployers' medical records.

Dated: November 3, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–26369 Filed 11–5–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP14–112–000, PF13–12–000]

Empire Pipeline, Inc., National Fuel Gas Supply Corporation; Notice of Availability of the Environmental Assessment for the Proposed Tuscarora Lateral Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Tuscarora Lateral Project, proposed by Empire Pipeline, Inc. and National Fuel Gas Supply Corporation (collectively known as National Fuel) in the above-referenced dockets. National Fuel requests authorization to construct and operate natural gas pipeline facilities in New York and Tioga County, Pennsylvania.

The EA assesses the potential environmental effects of the construction and operation of the Tuscarora Lateral Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The New York Department of Agriculture and Markets participated as a cooperating agency in the preparation of the EA. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by a proposal and participate in the NEPA analysis.

The proposed Tuscarora Lateral Project includes the following facilities:

- 17.2 miles of 12.75- and 16-inch-diameter natural gas pipeline and interconnection facilities running from the existing Tuscarora Gas Compressor Station near Tuscarora, New York to the existing Tioga Pipeline Extension in Tioga County, Pennsylvania;
- an expansion of the existing Tuscarora Compressor Station by installing an additional 1,384 horsepower of compression; and
- replacement of the compressor wheels in the existing turbine-powered compressors at Empire's existing Oakfield Compressor Station in the Town of Oakfield, Genesee County, New York.

The FERC staff mailed copies of the EA to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the Project area; and parties to this proceeding. In addition, the EA is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Any person wishing to comment on the EA may do so. 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 the Commission has the opportunity to consider your comments prior to making its decision on this project, it is important that we receive your comments in Washington, DC on or before December 1, 2014.

For your convenience, there are three methods you can use to file your comments to the Commission. In all instances, please reference the project docket number (CP14–112–000) 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 submitting brief, text-only comments on a project;

(2) You can also 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.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments

[1] See the previous discussion on the methods for filing comments.

will not give you intervenor status, but you do not need intervenor status to have your comments considered.

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 (*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., CP14–112). 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 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/docs-filing/esubscription.asp.*

Dated: October 31, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–26390 Filed 11–5–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP14–539–000]

Ozark Gas Transmission, LLC; Supplemental Notice of Intent To Prepare an Environmental Assessment for the Proposed Ozark Abandonment Project and Request for Comments on Environmental Issues

On October 7, 2014, the Commission issued a ''*Notice of Intent to Prepare an Environmental Assessment for the Ozark Abandonment Project, And Request for Comments on Environmental Issues''* (NOI). It has come to our attention that the environmental mailing list was not provided copies of the NOI; therefore we are issuing this Supplemental NOI to extend the scoping period and provide additional time for interested parties to file 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 Ozark Abandonment Project (Project) involving abandonment of facilities by Ozark Gas Transmission, LLC (Ozark). The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

The Commission and cooperating agencies continue to gather input from the public and interested agencies on the Project. This process is referred to as scoping. Your input will help the Commission staff determine what issues they need to evaluate in the EA. The original NOI identified November 6, 2014 as the close of the scoping period. Please note that the scoping period is now extended and will close on December 1, 2014.

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 the Project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the proposed facilities. Ozark 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 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

Ozark proposes to abandon in place and remove from service approximately 159 miles of mainline natural gas pipeline facilities between Sebastian and White Counties, Arkansas. In addition, Ozark would disconnect and abandon 29 associated metering and regulating facilities and other appurtenant facilities, as necessary. Ozark is proposing to abandon the aforementioned facilities due to underutilization and lack of market interest.

Specifically, Ozark would abandon in place the following facilities:

- 127.5 miles of 20-inch-diameter Line 1 in Franklin, Johnson, Pope, Conway, Faulkner, and White Counties from mile post (MP) 127.52 to MP 0.00;
- 26.4 miles of 10-inch-diameter Line 2 in Sebastian, Franklin, and Logan Counties From MP 0.00 to MP 26.37;
- 4.8 miles of 12-inch-diameter Line 1–A in White County from MP 0.00 to MP 4.75;
- 29 associated metering and regulating facilities, located along Line 1, 2, and 1–A, in Franklin, Logan, Johnson, Pope, Conway, Faulkner, and White Counties; and other appurtenant facilities, as necessary.

The general location of the facilities to be abandoned is shown in appendix 1.[1]

Land Requirements for Abandonment

The abandonment activities, including excavation and ground disturbance, would disturb about 23.6 acres of land, of which 22.7 acres would be within existing facility sites operated by Ozark. The remaining acreage of impact would be within Ozark's existing easements, pipeline right of way, or original construction corridor. Following construction, only existing sites at Noark and Searcy Compressor Stations and the existing permanent pipeline right-of-way would continue to be maintained. All land disturbed outside of existing sites or permanent pipeline right of way would be restored and return to former uses.

Future Use of the Abandoned Pipeline Facilities

Following the abandonment, Ozark indicates that several parties would perform activities that are not under the jurisdiction of the FERC. In the EA, we will provide available descriptions of the non-jurisdictional facilities and include them under our analysis of cumulative impacts.

After abandonment, Ozark would transfer the assets to an affiliate, which would lease the facilities to Magellan Pipeline Company, L.P (Magellan) for refined petroleum products transportation service. The affiliate and Magellan would undertake conversion work on the abandoned lines to prepare them for refined petroleum transportation.

Additionally, after abandonment, Ozark's existing customer, SourceGas, would construct, install, and operate about 6.3 miles of new 2-inch- and 6-inch-diameter pipeline laterals and perform a meter station upgrade in Logan County in order to transfer SoureGas' existing firm service on the abandoned facilities to an economically viable transportation alternative. Furthermore, Ozark Gas Gathering, LLC (OGG) would make reconnections on

[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.

their system to continue service at two locations.

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 abandonment of facilities 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 the FERC's eLibrary system. 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 of this NOI.

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 Arkansas 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. Our EA for the Project will document our findings on the impacts on historic properties and summarize the status of consultations under Section 106.

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 1, 2014.

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 (CP14–539–000) 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; environmental and public interest groups; Indian Tribes; other interested parties and non-governmental organizations; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for abandonment purposes, or who own homes within certain distances of aboveground facilities. 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 EAs coping 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

[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, Part 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 of Historic Places.

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., CP14–539). 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/docs-filing/esubscription.asp.*

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: October 30, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–26388 Filed 11–5–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF14–19–000]

Downeast Liquefaction, LLC; Supplemental Notice of Intent To Prepare an Environmental Impact Statement for the Planned Downeast LNG Import-Export Project and Request for Comments on Environmental Issues

On October 3, 2014, the Commission issued a ''*Notice of Intent to Prepare an Environmental Impact Statement for the Planned Downeast LNG Import-Export Project, Request for Comments on Environmental Issues, and Notice of Public Scoping Meeting''* (NOI). It has come to our attention that the environmental mailing list was not provided copies of the NOI; therefore, we are issuing this Supplemental NOI to extend the scoping period and provide additional time for interested parties to file comments on environmental issues.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental impact statement (EIS) that will discuss the environmental impacts of the Downeast LNG Export Project involving construction and operation of facilities by Downeast Liquefaction, LLC (Downeast Liquefaction) in Washington County, Maine. The Commission will use this EIS in its decision-making process to determine whether the project is in the public convenience and necessity.

The Commission and its cooperating agencies continue to gather input from the public and interested agencies on the project. This process is referred to as scoping. Your input will help the Commission staff determine what issues they need to evaluate in the EIS. The NOI identified November 3, 2014 as the close of the scoping period. Please note that the scoping period is now extended and will close on December 1, 2014.

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 planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned pipeline facilities associated with the project. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain for parcels crossed by the pipeline. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site (*www.ferc.gov*). 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.

Summary of the Planned Project

Downeast Liquefaction plans to develop, construct, and operate liquefied natural gas (LNG) terminal facilities that would convert the proposed Downeast LNG Import Project (Docket Nos. CP07–52–000, CP07–53–000, and CP07–53–001) into a bidirectional import-export LNG terminal and pipeline capable of producing 3 million metric tonnes per annum (mtpa) of LNG and 100 million standard cubic feet per day (mmscfd) of regasified LNG.

The Downeast LNG Import-Export Project would consist of the following facilities:

Marine Facilities and Transfer Lines:

- The Import-Export Project would involve no changes to the marine facilities and transfer lines that were proposed and evaluated for the Import Project.

LNG Storage and Regasification:

- The Import-Export Project would include a single LNG storage tank with a nominal usable storage capacity of 160,000 cubic meters. The storage tank design and location would be the same as the southern-most LNG storage tank proposed for the Import Project. The northern-most LNG storage tank proposed for the Import Project would not be required for the Import-Export Project.
- The Import-Export Project would include two Submerged Combustion Vaporizers used for regasification of LNG during import mode, of which one would be used during operation while the second would be a backup.

LNG Liquefaction Facilities:

- Feed gas pretreatment systems;
- one LNG liquefaction train with a nominal design capacity of 3 mtpa;
- refrigerant storage and handling;
- refrigerant compression systems; and
- refrigerant cooling system.

Pipeline Facilities:

- The pipeline for the Import-Export Project would be 24 inches in diameter, a change from 30 inches in diameter as proposed for the Import Project. The pipeline route and construction work areas would remain the same as proposed for the Import Project.

Ancillary Facilities:

- Onsite power generation to support operation of the terminal in export mode; and
- utilities, infrastructure, and support systems within the terminal site would be revised for the Import-Export Project to accommodate addition of liquefaction capabilities.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

The planned LNG Export Project facilities would be constructed entirely within the 80-acre site of the proposed Downeast LNG Import Project, at Mill Cove in Robbinston, Maine.

The EIS Process

The Commission intends to publish its review of the Downeast LNG Export Project as a supplement to the previous review of the Downeast LNG Import Project (Docket Nos. CP07–52–000, CP07–53–000, and CP07–53–001), to be considered together as the Downeast LNG Import-Export Project.

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 EIS on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EIS. We will consider all filed comments during the preparation of the EIS. However, comments should focus on issues specific to the Downeast LNG Export Project and not issues previously addressed for the Downeast LNG Import Project.

In the EIS, we will discuss impacts that could occur as a result of the construction and operation of the planned project under these general headings:

- Geology and soils;
- water resources, fisheries, and wetlands;
- vegetation and wildlife;
- endangered and threatened species;
- cultural resources;
- land use;
- socioeconomics;
- air quality and noise;
- reliability and safety;
- engineering and design material; and
- direct, indirect, and cumulative environmental impacts.

We will also evaluate possible alternatives to the planned project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, we have already initiated our NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives an application. As part of our pre-filing review, we have begun to contact some federal and state agencies to discuss their involvement in the scoping process and the preparation of the EIS.

The Supplemental draft EIS will present our independent analysis of the issues. We will publish and distribute the Supplemental draft EIS for public comment. After the comment period, we will consider all timely comments and revise the document, as necessary, before issuing a Supplemental final EIS. 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 6.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this project to formally cooperate with us in the preparation of the EIS.[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. Currently, the U.S. Army Corps of Engineers (COE), U.S. Environmental Protection Agency, National Oceanic and Atmospheric Administration National Marine Fisheries Service, and Maine Department of Environmental Protection are participating as cooperating agencies in the preparation of the EIS to satisfy their NEPA responsibilities related to this project. Also, in accordance with the 2004 Interagency Agreement on the safety and security review of waterfront import/export LNG facilities, the U.S. Coast Guard and U.S. Department of Transportation participate as cooperating agencies.

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 applicable State Historic Preservation Office(s) (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 EIS for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on our previous review of the Downeast LNG Import Project, a preliminary review of the planned Export Project facilities, and the environmental information provided by Downeast Liquefaction. This preliminary list of issues may change based on your comments and our analysis. Issued identified include:

- Potential impacts on wetlands and other aquatic resources within the LNG terminal site;
- potential impacts from release of ballast water from LNG carriers during the loading of LNG cargo;
- potential visual effects on surrounding areas;
- potential noise and air emissions impacts from the addition of natural gas liquefaction facilities; and
- public safety and hazards associated with the liquefaction and transport of LNG.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. Since Commission staff will issue a supplement to the previous environmental documents for the Downeast LNG Import Project, we do not intend to re-evaluate issues previously addressed for the LNG

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the 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.

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[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation 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 of Historic Places.

Import Project; therefore, comments are requested on issues specific to the LNG Export 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 1, 2014. This is not your only public input opportunity; please refer to the Environmental Review Process flowchart in appendix 2.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please reference the project docket number (PF14–19–000) 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 located 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 located 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; environmental and public interest groups; 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 potential 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 planned project.

Copies of the completed Supplemental draft EIS 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 3).

Becoming an Intervenor

Once Downeast Liquefaction files its application with the Commission, 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. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project.

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 (*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., PF14–19–000). 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 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/docs-filing/esubscription.asp.*

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: October 29, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–26392 Filed 11–5–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TS13–4–000]

Hudson Transmission Partners, LLC; Notice of Filing

Take notice that on October 29, 2014, Hudson Transmission Partners, LLC filed a supplement to its July 12, 2013 request for exemption from, or waiver of, the standards of conduct set forth in Part 358 of the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR 358.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC.

There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on November 19, 2014.

Dated: October 30, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–26389 Filed 11–5–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14642–000]

San Diego County Water Authority; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On October 16, 2014, the San Diego County Water Authority, California, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the San Vicente Pumped Storage Project (Project) to be located at San Vicente reservoir, in Lakeside, California. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The lower reservoir portion of the proposed project would consist of the following: (1) The existing San Vicente reservoir with a storage capacity of 246,000 acre-feet and a surface area of 1,600 acres at a normal maximum operating elevation of 766 feet above mean sea level (msl); (2) the existing 1,430-foot-long, 337-foot-high San Vicente roller compacted concrete (RCC) gravity dam; (3) a lower reservoir inlet/outlet structure equipped with trash racks and one or two slide gates; (4) a 230-kilovolt (kV) substation containing step-up transformers, circuit breakers, and disconnect switches; (5) a switchyard constructed at the point of interconnection; (6) an approximately 5-mile-long, 230-kV overhead or underground transmission line that would extend from the northern end of San Vicente reservoir to the 230-kV Sycamore substation and interconnect with San Diego Gas and Electric's 500-kV Sunrise Powerlink; and (7) appurtenant facilities.

The upper reservoir portion of the proposed project would include one of the following four alternatives.

Alternative A—Iron Mountain

Alternative Site A, located near Iron Mountain, approximately 3 miles northwest of the San Vicente reservoir, would consist of: (1) A reservoir with a storage capacity of 6,100 acre-feet and a surface area of 93 acres at a full pond elevation of 2,110 feet msl; (2) three RCC saddle dams measuring respectively: (i) 1,425 feet long and 35 feet high, (ii) 1,340 feet long and 75 feet high, and (iii) 838 feet long and 15 feet high; (3) a 235-foot-long, 85-foot wide, 131-foot-tall subsurface powerhouse containing two 250–MW vertical Francis variable speed reversible pump/turbine/generator units; (4) a 1,358-foot-long, 12-foot-diameter concrete-lined tailrace tunnel; (5) an upper reservoir inlet/outlet structure; (6) two 171-foot-long, 16-foot-diameter steel-lined penstocks; (7) a 1,350-foot-long, 230-kV, underground transmission line extending from the upper reservoir to the northern end of San Vicente reservoir; and (8) appurtenant facilities. This alternative would annually generate an estimated 1,022 gigawatt-hours (GWh).

Alternative B—Foster Canyon

Alternative Site B, located near Foster Canyon, approximately one-half mile northwest of the San Vicente reservoir, would consist of: (1) A reservoir with a storage capacity of 7,800 acre-feet and a surface area of 100 acres at a full pond elevation of 1,490 feet msl; (2) five RCC saddle dams measuring, respectively: (i) 1,760 feet long and 160 feet high, (ii) 838 feet long and 80 feet high, (iii) 838 feet long and 80 feet high, (iv) 1,006 feet long and 240 feet high, and (v) 3,100 feet long and 30 feet high; (3) a 235-foot-long, 88-foot-wide, 147-foot-tall subsurface powerhouse containing two 250–MW vertical Francis variable speed reversible pump/turbine/generator units; (4) a 2,244-foot-long, 18-foot-diameter concrete-lined tailrace tunnel; (5) an upper reservoir inlet/outlet structure; (6) two 326-foot-long, 22-foot-diameter steel-lined penstocks; (7) a 2,200-foot-long, 230-kV, underground transmission line extending from the upper reservoir to the northern end of San Vicente reservoir; and (8) appurtenant facilities. This alternative would annually generate an estimated 1,022 GWh.

Alternative Site C—Northeast

Alternative Site C, located 0.8 mile northeast of the San Vicente reservoir, would consist of: (1) A reservoir with a storage capacity of 7,700 acre-feet and a surface area of 60 acres at a full pond elevation of 1,600 feet msl; (2) four RCC saddle dams measuring, respectively: (i) 1,176 feet long and 260 feet high, (ii)1,508 feet long and 20 feet high, (iii) 2,500 feet long and 20 feet high, and (iv) 2,700 feet long and 20 feet high; (3) a 267-foot-long, 93-foot-wide, 179-foot-high subsurface powerhouse, containing two 250–MW vertical Francis variable speed reversible pump/turbine-motor/generator units; (4) a 1,252-foot-long, 17-foot-diameter, concrete-lined tailrace tunnel connecting the pump/turbine draft tubes with the lower reservoir inlet/outlet structure; (5) an upper reservoir inlet/outlet structure equipped with trash racks and one or two slide gates; (6) two 297-foot-long, 22-foot-diameter steel-lined penstocks; (7) a 1,200-foot-long, 230-kV, underground transmission line from the upper reservoir to the northern end of San Vicente reservoir; and (8) appurtenant facilities. This alternative would annually generate an estimated 1,022 GWh.

Alternative Site D—Southeast

Alternative Site D, located 1.8 miles southeast of the San Vicente reservoir, would include: (1) A reservoir with a storage capacity of 4,500 acre-feet and a surface area of 80 acres at a full pond elevation of 1,800 feet msl; (2) a 2,263-foot-long, 285-foot-high RCC dam; (3) a 235-foot-long, 85-foot-wide, 131-foot-tall subsurface powerhouse containing two 250–MW vertical Francis variable speed reversible pump/turbine-motor/generator units; (4) a 1,415-foot-long, 13-foot-diameter concrete-lined tailrace tunnel; (5) an upper reservoir inlet/outlet structure; (6) two 180-foot-long, 17-foot-diameter steel-lined penstocks; (7) a 1,400-foot-long, 230-kV, underground transmission line extending from the upper reservoir to the northern end of San Vicente reservoir; and (8) appurtenant facilities. This alternative would annually generate an estimated 715 GWh.

Applicant Contact: Ms. Maureen Stapleton, General Manager, San Diego County Water Authority, 4677 Overland Avenue, San Diego, California 92123; phone: (858) 522–6781.

FERC Contact: Joseph Hassell, phone: (202) 502–8079.

Deadline for filing comments, motions to intervene, competing applications

(without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *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,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14642–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14642) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: October 30, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–26391 Filed 11–5–14; 8:45 am]

BILLING CODE 6717–01–P

FARM CREDIT ADMINISTRATION

Sunshine Act Meetings

AGENCY: Farm Credit Administration Board; Farm Credit Administration.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the regular meeting of the Farm Credit Administration Board (Board).

DATE AND TIME: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on November 13, 2014, from 9:00 a.m. until such time as the Board concludes its business.

FOR FURTHER INFORMATION CONTACT: Dale L. Aultman, Secretary to the Farm Credit Administration Board, (703) 883–4009, TTY (703) 883–4056.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090. Submit attendance requests via email to *VisitorRequest@FCA.gov.* See **SUPPLEMENTARY INFORMATION** for further information about attendance requests.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. Please send an email to *VisitorRequest@FCA.gov* at least 24 hours before the meeting. In your email include: name, postal address, entity you are representing (if applicable), and telephone number. You will receive an email confirmation from us. Please be prepared to show a photo identification when you arrive. If you need assistance for accessibility reasons, or if you have any questions, contact Dale L. Aultman, Secretary to the Farm Credit Administration Board, at (703) 883–4009. The matters to be considered at the meeting are:

Open Session

A. *Approval of Minutes*

- October 9, 2014

B. *Reports*

- Ethics Update

Closed Session*

Reports

- Office of Secondary Market Oversight Quarterly Report

Date: November 4, 2014.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

*Session Closed—Exempt pursuant to 5 U.S.C. Section 552b(c)(8) and (9).

[FR Doc. 2014–26518 Filed 11–4–14; 4:15 pm]

BILLING CODE 6705–01–P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act; Technological Advisory Council

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC) Technological Advisory Council will hold a meeting on Thursday, December 4, 2014 in the Commission Meeting Room, from 1 p.m. to 4 p.m. at the Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

DATES: Thursday December 4, 2014.

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

FOR FURTHER INFORMATION CONTACT: Walter Johnston, Chief, Electromagnetic Compatibility Division, 202–418–0807; *Walter.Johnston@FCC.gov.*

SUPPLEMENTARY INFORMATION: The FCC Technological Advisory Council will discuss progress on its work program for 2014. The FCC will attempt to accommodate as many people as possible. However, admittance will be limited to seating availability. Meetings are also broadcast live with open captioning over the Internet from the FCC Live Web page at *http://www.fcc.gov/live/.* The public may submit written comments before the meeting to: Walter Johnston, the FCC's Designated Federal Officer for Technological Advisory Council by email: *Walter.Johnston@fcc.gov* or U.S. Postal Service Mail (Walter Johnston, Federal Communications Commission, Room 7–A224, 445 12th Street SW., Washington, DC 20554). Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Office of Engineering and Technology at 202–418–2470 (voice), (202) 418–1944 (fax). Such requests should include a detailed description of the accommodation needed. In addition, please include your contact information. Please allow at least five days advance notice; last minute requests will be accepted, but may be impossible to fill.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2014–26431 Filed 11–5–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Senior Executive Service; Performance Review Board

AGENCY: Federal Mine Safety and Health Review Commission.

ACTION: Notice.

SUMMARY: This notice announces the appointment of the members of the Performance Review Board (PRB) for the Federal Mine Safety and Health Review Commission. The PRB reviews the performance appraisals of career and non-career senior executives. The PRB makes recommendations regarding proposed performance appraisals, ratings, bonuses, pay adjustments, and other appropriate personnel actions.

DATES: Effective on November 6, 2014.

FOR FURTHER INFORMATION CONTACT: Lisa Boyd, Executive Director, Federal Mine Safety and Health Review Commission, (202) 434–9910.

SUPPLEMENTARY INFORMATION: This Notice announces the appointment of the following primary and alternate members to the Federal Mine Safety and Health Review Commission PRB:

Primary Members

Cynthia Z. Springer, Deputy Commissioner, Accounting and Shared Services, Bureau of the Fiscal Service

Matthew J. Miller, Acting Assistant Commissioner, Governmentwide Accounting, Bureau of the Fiscal Service

D. Michael Linder, Deputy Assistant Commissioner, Fiscal Accounting, Bureau of the Fiscal Service

Douglas Anderson, Assistant Commissioner, Office of Shared Services, Bureau of the Fiscal Service

Donald Keith Rake, Deputy Assistant Commissioner, Office of Shared Services, Bureau of the Fiscal Service

Alternate Members

None.

Authority: 5 U.S.C. 4313(c)(4)

Lisa M. Boyd,

Executive Director, Federal Mine Safety and Health Review Commission.

[FR Doc. 2014–26416 Filed 11–5–14; 8:45 am]

BILLING CODE 6735–01–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1500]

Federal Reserve Bank Services

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) has approved the private sector adjustment factor (PSAF) for 2015 of $18.0 million and the 2015 fee schedules for Federal Reserve priced services and electronic access. These actions were taken in accordance with the requirements of the Monetary Control Act of 1980, which requires that, over the long run, fees for Federal Reserve priced services be established on the basis of all direct and indirect costs, including the PSAF.

DATES: The new fee schedules become effective January 2, 2015.

FOR FURTHER INFORMATION CONTACT: For questions regarding the fee schedules: Susan V. Foley, Associate Director, (202) 452–3596; Samantha J. Pelosi, Manager, Retail Payments, (202/530–6292); Linda S. Healey, Senior Financial Services Analyst, (202) 452–5274, Division of Reserve Bank Operations and Payment Systems. For questions regarding the PSAF: Gregory L. Evans, Deputy Associate Director, (202) 452–3945; Brenda L. Haase, Manager, Financial Accounting, (202) 452–2753; or Manuel Garcia, Senior Financial Analyst, (202) 452–3480), Division of Reserve Bank Operations and Payment Systems. For users of Telecommunications Device for the Deaf (TDD) *only,* please call (202) 263–4869. Copies of the 2015 fee schedules for the check service are available from the Board, the Federal Reserve Banks, or the Reserve Banks' financial services Web site at *www.frbservices.org.*

SUPPLEMENTARY INFORMATION:

I. Private Sector Adjustment Factor, Priced Services Cost Recovery, and Overview of 2015 Price Changes

A. Overview—Each year, as required by the Monetary Control Act of 1980, the Reserve Banks set fees for priced services provided to depository institutions. These fees are set to recover, over the long run, all direct and indirect costs and imputed costs, including financing costs, taxes, and certain other expenses, as well as the return on equity (profit) that would have been earned if a private business firm provided the services. The imputed costs and imputed profit are collectively referred to as the PSAF. From 2004 through 2013, the Reserve Banks recovered 102.0 percent of their total expenses (including imputed costs) and targeted after-tax profits or return on equity (ROE) for providing priced services.[1]

Table 1 summarizes 2013 actual, 2014 estimated, and 2015 budgeted cost-recovery rates for all priced services. Cost recovery is estimated to be 100.8 percent in 2014 and budgeted to be 101.9 percent in 2015.

TABLE 1—AGGREGATE PRICED SERVICES PRO FORMA COST AND REVENUE PERFORMANCE [a]

[Dollars in millions]

YEAR	1 [b] Revenue	2 [c] Total expense	3 Net income (ROE) [1 – 2]	4 [d] Targeted ROE	5 [e] Recovery rate after targeted ROE [1/(2+4)]
2013 (actual)	441.3	409.3	32.0	4.2	106.7%
2014 (estimate)	429.0	419.9	9.1	5.5	100.8
2015 (budget)	414.4	401.0	13.4	5.6	101.9

[a] Calculations in this table and subsequent pro forma cost and revenue tables may be affected by rounding.

[b] Revenue includes imputed income on investments when equity is imputed at a level that meets minimum capital requirements and, when combined with liabilities, exceeds total assets (attachment 1).

[c] The calculation of total expense includes operating, imputed, and other expenses. Imputed and other expenses include taxes, FDIC insurance, Board of Governors' priced services expenses, the cost of float, and interest on imputed debt, if any. Credits or debits related to the accounting for pension plans under FAS 158 [ASC 715] are also included.

[d] Targeted ROE is the after-tax ROE included in the PSAF.

[e] The recovery rates in this and subsequent tables do not reflect the unamortized gains or losses that must be recognized in accordance with FAS 158 [ASC 715]. Future gains or losses, and their effect on cost recovery, cannot be projected.

[1] The ten-year recovery rate is based on the pro forma income statement for Federal Reserve priced services published in the Board's *Annual Report.* Effective December 31, 2006, the Reserve Banks implemented Statement of Financial Accounting Standards (SFAS) No. 158: *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans* [Accounting Standards Codification (ASC) 715 *Compensation—Retirement Benefits*], which resulted in recognizing a cumulative reduction in equity related to the priced services' benefit plans. Including this cumulative reduction in equity from 2006 to 2013 results in cost recovery of 95.9 percent for the ten-year period. This measure of long-run cost recovery is also published in the Board's *Annual Report.*

Table 2 provides an overview of cost-recovery performance for the ten-year period from 2004 to 2013, 2013 actual, 2014 budget, 2014 estimate, and 2015 budget by priced service.

TABLE 2—PRICED SERVICES COST RECOVERY

[Percent]

Priced service	2004–2013	2013 Actual	2014 Budget [a]	2014 Estimate	2015 Budget [b]
All services	102.0	106.7	102.3	100.8	101.9
Check	102.0	115.4	108.8	114.2	105.4
FedACH	102.1	101.2	99.2	86.5	100.0
Fedwire Funds and NSS	101.5	98.6	98.0	101.3	100.8
Fedwire Securities	102.2	105.0	98.0	100.1	96.5

[a] The 2014 budget figures reflect the final budgets as approved by the Board in December 2013.
[b] The 2015 budget figures reflect preliminary budget information from the Reserve Bank. The Reserve Banks will submit final budget data to the Board in November 2014, for Board consideration in December 2014.

1. *2014 Estimated Performance*—The Reserve Banks estimate that they will recover 100.8 percent of the costs of providing priced services in 2014, including total expense and targeted ROE of $5.5 million, compared with a budgeted recovery rate of 102.3 percent, as shown in table 2. Overall, the Reserve Banks estimate that they will fully recover actual and imputed costs and earn net income of $9.1 million, compared with budgeted net income of $15.0 million. Although the check service, the Fedwire® Funds and National Settlement Services, and the Fedwire Securities Service are expected to achieve full cost recovery, the FedACH® Service is expected to recover 86.5 percent of its costs because of a $31.6 million charge related to its investment associated with a multiyear technology initiative to modernize its processing platform.[2] Greater-than-expected check volume processed by the Reserve Banks has been the single most significant factor influencing priced services cost recovery.

2. *2015 Private Sector Adjustment Factor*—The 2015 PSAF for Reserve Bank priced services is $18.0 million. This amount represents a decrease of $5.4 million from the 2014 PSAF of $23.4 million. This decrease is primarily the result of a reduction in the assets to be financed on the imputed priced-services balance sheet and an associated decline in the cost of debt and equity.

3. *2015 Projected Performance*—The Reserve Banks project a priced services cost-recovery rate of 101.9 percent in 2015, with net income of $13.4 million, compared to a targeted ROE of $5.6 million. The Reserve Banks project that the check service, the FedACH Service, and the Fedwire Funds and National Settlement Service will fully recover their costs; however, the Reserve Banks project that the Fedwire Securities Service will not achieve full-cost recovery because of investment costs associated with multiyear technology initiatives to modernize its processing platform. These investments are expected to enhance efficiency, the overall quality of operations, and the Reserve Banks' ability to offer additional services to depository institutions.

The primary risks to the Reserve Banks' ability to achieve their targeted cost recovery rates are unanticipated volume and revenue reductions and the potential for cost overruns with the technology modernization initiatives. In light of these risks, the Reserve Banks will continue to refine their business and operational strategies to manage aggressively operating costs, to increase product revenue, and to leverage efficiencies gained from technology initiatives.

4. *2015 Pricing*—The following summarizes the Reserve Banks' changes in fee schedules for priced services in 2015:

Check

- In October, the Reserve Banks announced a 12:00 noon ET deadline (but not the associated fee schedules) for the FedForward® product line, specifically, Mixed, Select Mixed, and Premium Mixed D products, which will provide the Reserve Banks an opportunity to present forward items to paying banks one day earlier.[3] [4] [5]
- In conjunction with the noon deadline, the Reserve Banks will reduce the per-item fees for tiers 1, 2, 3, and 4 within the current Mixed deposit option. For the Select Mixed option, the Reserve Banks will increase the per-item fees for non-eligible items from $0.10 to $0.35 and to implement a $25 image cash letter (ICL) surcharge. For the Premium Mixed D option, the Reserve Banks will charge per-item fees $0.002 higher than the per-item fees at the current 1:00 a.m. deadline (with the exception of the substitute check fee, which will be $0.20 higher) and a $25 ICL surcharge.
- The Reserve Banks will introduce two new deposit options to the FedForward Premium Mixed ICL products and to expand the list of eligible endpoints to the Select Mixed ICL products.
- The Reserve Banks will increase the FedForward Deferred Mixed ICL product per-item fees at the 5:00 a.m. and 10:00 a.m. deadlines by $0.002 and $0.004, respectively. The Reserve Banks will increase the FedForward Deferred Fine Sort ICL product per-item fees at the 5:00 a.m. and 10:00 a.m. deadlines by $0.001 and $0.002, respectively. The Reserve Banks hope to encourage depositors to shift volume from the deferred availability product to one of the immediate-availability options at 12:00 noon.

FedACH

- The Reserve Banks will modify the FedACH Minimum Origination Fee calculation to include fees associated

[2] The Reserve Banks have been engaged in a multiyear technology initiative to modernize the FedACH processing platform by migrating the service from a mainframe system to a distributed computing environment. In late 2013, the Reserve Banks conducted an assessment focused on the viability and cost-effectiveness of the program. As a result, the Reserve Banks in 2014 suspended the program and began to investigate the use of other technology solutions.

[3] All times are stated in the Eastern Time Zone (ET).

[4] Depository institutions may deposit image cash letters using nine deposit options within the FedForward product line; the options vary in price structure and funds availability. A current list of FedForward deposit options can be found at *http://frbservices.org/servicefees/check_services_2014.html.*

[5] The Reserve Banks announced the new deadline in October, effective January 2, 2015, to provide both collecting banks and paying banks sufficient time to modify their processes to deposit and receive items at 12:00 noon and 2:00 p.m., respectively. The announcement can be found at *http://www.frbservices.org/files/communications/pdf/check/100314_updated_new_fedforward_deposit_deadline.pdf.*

with SameDay and FedGlobal® origination transactions in the computation.

• The Reserve Banks will reduce the volume tier thresholds for the FedACH Risk Management Services from 500,000 to 100,000 items monitored per month.[6]

Fedwire Funds and National Settlement

• The Reserve Banks will reduce the per-item fee on all transfers that exceed $10 million (high-value transfer surcharge) from $0.15 to $0.14. The Reserve Banks will increase the monthly fee for the usage of the FedPayments® Manager import/export tool from $45 to $50. In addition, the Reserve Banks will increase the surcharge for offline transactions from $45 to $50.[7]

• The Reserve Banks will increase the Tier 1 per-item pre-incentive fee from $0.69 to $0.73 per transaction, increase the Tier 3 per-item pre-incentive fee from $0.14 to $0.15, and leave Tier 2 per-item pre-incentive fees unchanged.[8]

Fedwire Securities

• The Reserve Banks will increase the online transfer fee from $0.54 to $0.65.

• The Reserve Banks will increase the monthly account maintenance fee from $40 to $48 per account, and increase the monthly issue maintenance fee from $0.54 to $0.65 per issue.

• The Reserve Banks will increase the Joint Custody origination surcharge from $40 to $44.

FedLine® Access Solutions

• The Reserve Banks will increase the fees on legacy services, such as an additional $10 per month for FedMail® Fax and $300 per month for FedLine Direct® (56K). The Reserve Banks also will raise the monthly fee for the 56K additional dedicated electronic access connection by $400 and to introduce a legacy device VPN surcharge of $2,500 per month.[9]

• The Reserve Banks will add a new package called FedLine Advantage® Premier to the FedLine packaged solutions that will be priced at $500 per month with FedTransaction Analyzer and a secondary VPN device.[10]

• The Reserve Banks will introduce two new tiers to the FedComplete® package solutions called FedComplete 100 Premier, priced at $850 per month, and FedComplete 200 Premier, priced at $1,375 per month, with FedLine Advantage Premier included.

• The Reserve Banks will change the name of the FedMail Email package to FedLine Exchange; there is no change to the published fee.

5. *2015 Price Index*—Figure 1 compares indexes of fees for the Reserve Banks' priced services with the GDP price index starting in 2005, which is the first full year the Reserve Banks offered Check 21 services. The price index for Reserve Bank priced services is projected to increase approximately 1 percent in 2015 from the 2014 level. The price index for Check 21 services is projected to decrease approximately 3 percent. The price index for the FedACH Service is projected to decrease nearly 1 percent. The price index for the Fedwire Funds and National Settlement Services is projected to increase approximately 5 percent. The price index for the Fedwire Securities Services is projected to increase approximately 15 percent. For the period 2005 to 2014, the price index for total priced services is expected to decrease 32 percent. In comparison, for the period 2005 to 2013, the GDP price index increased 16 percent.

[6] The FedACH Risk Management Services includes FedACH Risk Origination Monitoring Service, FedACH Risk RDFI Alert Service, and FedACH Risk Returns Reporting Service. For more information, refer to *http://frbservices.org/files/serviceofferings/pdf/FedACHRiskServices.pdf.*

[7] The monthly fee is charged to any Fedwire Funds participant that originates a Fedwire Funds transfer message via the FedPayments Manager (FPM) Funds tool and has the import/export processing option setting active at any point during the month.

[8] The per-item pre-incentive fee is the fee that the Reserve Banks charge for transfers that do not qualify for incentive discounts. The Tier 1 per-item pre-incentive fee applies to the first 14,000 transfers, the Tier 2 per-item pre-incentive fee applies to the next 76,000 transfers, and the Tier 3 per-item pre-incentive fee applies to any additional transfers. The Reserve Banks apply an 80 percent incentive discount to every transfer over 60 percent of a customer's historic benchmark volume.

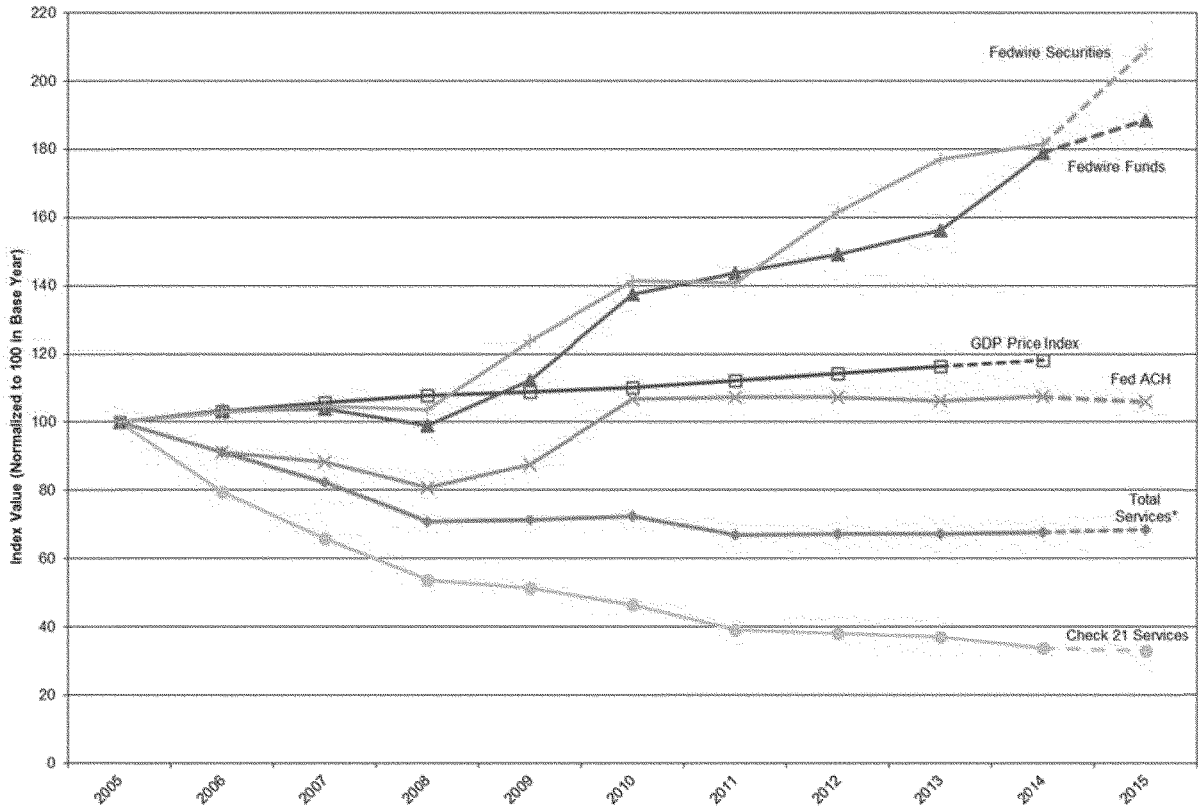
[9] Effective February 1, 2015. Price will increase to $5,000 on May 1, 2015 and $7,500 on September 1, 2015.

[10] All customers, regardless of their chosen electronic access channel, are responsible for the purchase and installation of each VPN device.

FIGURE 1

2015 Price Index

PRICE INDEXES FOR FEDERAL RESERVE PRICED SERVICES



* Total Services excludes legacy paper services, which now have minimal volume and are expected to generate less than $12 million in revenue in 2015.

B. Private Sector Adjustment Factor—The imputed debt financing costs, targeted ROE, and effective tax rate are based on a U.S. publicly traded firm market model.[11] The method for calculating the financing costs in the PSAF requires determining the appropriate imputed levels of debt and equity and then applying the applicable financing rates. In this process, a pro forma balance sheet using estimated assets and liabilities associated with the Reserve Banks' priced services is developed, and the remaining elements that would exist are imputed, as if these priced services were provided by a private business firm. The same generally accepted accounting principles that apply to commercial-entity financial statements apply to the relevant elements in the priced services pro forma financial statements.

The portion of Federal Reserve assets that will be used to provide priced services during the coming year is determined using information about actual assets and projected disposals and acquisitions. The priced portion of these assets is determined based on the allocation of depreciation and amortization expenses of each asset class. The priced portion of actual Federal Reserve liabilities consists of postemployment and postretirement benefits, accounts payable, and other liabilities. The priced portion of the actual net pension asset or liability is also included on the balance sheet.[12]

The equity financing rate is the targeted ROE produced by the capital asset pricing model (CAPM). In the CAPM, the required rate of return on a firm's equity is equal to the return on a risk-free asset plus a market risk premium. The risk-free rate is based on the three-month Treasury bill; the beta is assumed to be equal to 1.0, which approximates the risk of the market as a whole; and the market risk premium is based on the monthly returns in excess of the risk-free rate over the most recent 40 years. The resulting ROE reflects the return a shareholder would expect when investing in a private business firm.

For simplicity, given that federal corporate income tax rates are graduated, state income tax rates vary, and various credits and deductions can apply, an actual income tax expense is not explicitly calculated for Reserve Bank priced services. Instead, the Board targets a pre-tax ROE that would provide sufficient income to fulfill the priced services' imputed income tax obligations. To the extent that performance results are greater or less

[11] Data for U.S. publicly traded firms is from the Standard and Poor's Compustat® database. This database contains information on more than 6,000 U.S. publicly traded firms, which approximates the entirety of the U.S. market.

[12] The pension assets are netted with the pension liabilities and reported as a net asset or net liability as required by ASC 715 *Compensation—Retirement Benefits.*

than the targeted ROE, income taxes are adjusted using the effective tax rate.

Capital structure. The capital structure is imputed based on the imputed funding need (assets less liabilities), subject to minimum equity constraints. Short-term debt is imputed to fund the imputed short-term funding need. Long-term debt and equity are imputed to meet the priced services long-term funding need at a ratio based on the capital structure of the U.S. publicly traded firm market. The level of equity must meet the minimum equity constraints, which follow the FDIC requirements for a well-capitalized institution. The priced services must maintain equity of at least 5 percent of total assets and 10 percent of risk-weighted assets.[13] Any equity imputed that exceeds the amount needed to fund the priced services' assets and meet the minimum equity constraints is offset by a reduction in imputed long-term debt. When imputed equity is larger than what can be offset by imputed debt, the excess is imputed as investments in Treasury securities; income imputed on these investments reduces the PSAF.

Application of the Payment System Risk (PSR) Policy to the Fedwire Services. The Board recently approved revisions to the PSR policy to reflect the new international standards for financial market infrastructures (FMIs) developed by the Committee on Payment and Settlement Systems and the Technical Committee of the International Organization of Securities Commissions in the *Principles for Financial Market Infrastructures.* The revised policy retains the expectation that the Fedwire Services will meet or exceed the applicable risk-management standards. Principle 15 states that an FMI should identify, monitor, and manage general business risk and hold sufficient liquid net assets funded by equity to cover potential general business losses so that it can continue operations and services as a going concern if those losses materialize. Further, liquid net assets should at all times be sufficient to ensure a recovery or orderly wind-down of critical operations and services. The Fedwire Services do not face the risk that a business shock would cause the service to wind down in a disorderly manner and disrupt the stability of the financial system. In order to foster competition with private-sector FMIs, however, the Reserve Banks' priced services will hold six months of the Fedwire Funds Service's current operating expenses as liquid net financial assets and equity on the pro forma balance sheet.[14] Current operating expenses are defined as normal business operating expenses on the income statement less depreciation, amortization, taxes, and interest on debt. The Fedwire Funds Service's six months of operating expenses are computed based on its 2015 budget at $47.7 million.[15] The revised PSR policy requirement is met in 2015 by the investments and equity imputed to the priced services balance sheet; therefore, there is no need to impute additional assets or equity.

Effective tax rate. As with the imputed capital structure, the effective tax rate is calculated based on data from U.S. publicly traded firms. The tax rate is the mean of the weighted average rates of the U.S. publicly traded firm market over the past 5 years.

Debt and equity financing. The imputed short- and long-term debt financing rates are derived from the nonfinancial commercial paper rates from the Federal Reserve Board's H.15 Selected Interest Rates release (AA and A2/P2) and the annual Merrill Lynch Corporate & High Yield Index rate, respectively. The rates for debt and equity financing are applied to the priced services estimated imputed short-term debt, long-term debt, and equity needed to finance short- and long-term assets and meet equity requirements.

The decrease in the 2015 PSAF is primarily due to lower financing costs as a result of fewer priced services assets to be financed than in 2014. Debt and equity financing rates declined and less debt and equity was imputed to fund priced services assets.

Projected 2015 Federal Reserve priced-services assets, reflected in table 3, have decreased $107.3 million from 2014, which is primarily the result of a decline in the deferred tax asset. As shown in table 3, the amount of long-term debt for the 2015 PSAF is $81.9 million, a decline of $37.4 million from $119.3 million in 2014. Imputed equity for 2015 is $71.9 million, a decrease of approximately $10.4 million from the equity imputed for 2014. In accordance with FAS 158 [ASC 715], this amount includes an accumulated other comprehensive loss of $523.7 million.

Table 4 reflects the portion of short- and long-term assets that must be financed with actual or imputed liabilities and equity. Debt and equity imputed to fund the 2015 priced services assets within the observed market leverage ratio produced an equity level that did not meet the FDIC minimum equity requirements. As a result, additional equity was imputed to meet the FDIC requirements and imputed long-term debt was reduced. The ratio of capital to risk-weighted assets meets the required 10 percent of risk-weighted assets and equity exceeds 5 percent of total assets (table 6). In 2014, long-term debt and equity was imputed to meet the asset funding requirements and reflects the leverage ratio observed in the market; no additional equity was required (table 5).

Table 5 shows the derivation of the 2015 and 2014 PSAF. Financing costs for 2015 are $4.3 million lower than in 2014. In addition to the decline in the levels of debt and equity mentioned above, the long-term debt and cost of equity declined 9 basis points and 5 basis points, respectively. The reduced equity balance and the lower cost of equity result in a pre-tax ROE that is $1.4 million lower than the 2014 pre-tax ROE. Imputed sales taxes declined to $3.3 million in 2015 from $3.5 million in 2014. The priced services portion of the Board's expenses decreased $0.8 million to $3.3 million in 2015 from $4.1 million in 2014. The effective income tax rate used in 2015 decreased to 22.4 percent from 37.2 percent in 2014.

[13] The FDIC rule, which was adopted as final on April 8, 2014, requires that well-capitalized institutions meet or exceed the following standards: (1) total capital to risk-weighted assets ratio of at least 10 percent, (2) tier 1 capital to risk-weighted assets ratio of at least 8 percent, (3) common equity tier 1 capital to risk-weighted assets ratio of at least 6.5 percent, and (4) a leverage ratio (tier 1 capital to total assets) of at least 5 percent. Since all of the Federal Reserve priced services' equity on the pro forma balance sheet qualifies as tier 1 capital, only requirements 1 and 4 are binding. The FDIC rule can be located at *https://www.fdic.gov/news/board/2014/2014-04-08_notice_dis_c_fr.pdf.*

[14] This requirement, which becomes effective on December 31, 2015, does not apply to the Fedwire Securities Service. There are no competitors to the Fedwire Securities Service that will face such a requirement, and imposing such a requirement when pricing securities services could artificially increase the cost of these services.

[15] 2015 budget pro forma as of October 8, 2014 based on initial transmission data.

TABLE 3—COMPARISON OF PRO FORMA BALANCE SHEETS FOR BUDGETED FEDERAL RESERVE PRICED SERVICES

[Millions of dollars—projected average for year]

	2015	2014	Change
Short-term assets:			
Receivables	34.5	35.8	(1.3)
Materials and supplies	0.6	0.7	(0.1)
Prepaid expenses	11.0	11.1	(0.1)
Items in process of collection [16]	151.0	200.0	(49.0)
Total short-term assets	197.2	247.7	(50.5)
Imputed investments [17]	$600.0	$600.0	$0.0
Long-term assets:			
Premises [18]	$116.2	$123.6	$(7.4)
Furniture and equipment	39.9	37.6	2.3
Leasehold improvements and long-term prepayments	91.5	103.3	(11.7)
Net pension asset	79.6	39.3	40.2
Deferred tax asset	222.8	303.1	(80.2)
Total long-term assets	550.0	606.8	(56.8)
Total assets	$1,347.2	$1,454.5	$(107.3)
Short-term liabilities:			
Deferred credit items	$751.0	$800.0	$(49.0)
Short-term debt	18.5	22.2	(3.6)
Short-term payables	27.6	25.5	2.1
Total short-term liabilities	797.2	847.7	(50.5)
Long-term liabilities:			
Long-term debt	$81.9	$119.3	$(37.4)
Postemployment/postretirement benefits and net pension liabilities [19]	396.3	405.2	(8.9)
Total liabilities	$1,275.3	$1,372.2	$(96.9)
Equity [17 20]	$71.9	$82.3	$(10.4)
Total liabilities and equity	$1,347.2	$1,454.5	$(107.3)

TABLE 4—IMPUTED FUNDING FOR PRICED-SERVICES ASSETS

[Millions of dollars]

	2015	2014
A. Short-term asset financing		
Short-term assets to be financed.		
Receivables	$34.5	$35.8
Materials and supplies	0.6	0.7
Prepaid expenses	11.0	11.1
Total short-term assets to be financed	$46.2	$47.7
Short-term payables	27.6	25.5
Net short-term assets to be financed	$18.5	$22.2
Imputed short-term debt financing [21]	$18.5	$22.2
B. Long-term asset financing		
Long-term assets to be financed.		
Premises	$116.2	$123.6

[16] Credit float, which represents the difference between items in process of collection and deferred credit items, occurs when the Reserve Banks debit the paying bank for transactions prior to providing credit to the depositing bank. Float is directly estimated at the service level.

[17] Consistent with the Federal Reserve Policy on Payment System Risk, the Reserve Banks' priced services will hold six months of the Fedwire Funds Service's current operating expenses as liquid net financial assets and equity on the pro forma balance sheet. Six months of the Fedwire Funds Service's projected operating expenses is $47.7 million. As this requirement takes effect on the last day of the year, the minimum liquid financial assets and equity requirement is $0.1 million ($47.7 million/365). The investments and equity imputed to the priced services balance sheet of $600 million and $71.9 million, respectively, are greater than the liquid financial assets and equity required; therefore no additional imputation is necessary.

[18] Includes the allocation of Board of Governors assets to priced services of $0.7 and $0.6 million for 2015 and 2014, respectively.

[19] Includes the allocation of Board of Governors liabilities to priced services of $0.6 million and $0.6 million for 2015 and 2014, respectively.

[20] Includes an accumulated other comprehensive loss of $523.7 million for 2015 and $497.5 million for 2014, which reflects the ongoing amortization of the accumulated loss in accordance with FAS 158 [ASC 715]. Future gains or losses, and their effects on the pro forma balance sheet, cannot be projected. See table 5 for calculation of required imputed equity amount.

TABLE 4—IMPUTED FUNDING FOR PRICED-SERVICES ASSETS—Continued

[Millions of dollars]

	2015	2014
Furniture and equipment	39.9	37.6
Leasehold improvements and long-term prepayments	91.5	103.3
Net pension asset	79.6	39.3
Deferred tax asset	222.8	303.1
Total long-term assets to be financed	$550.0	$606.8
Postemployment/postretirement benefits and net pension liabilities	396.3	405.2
Net long-term assets to be financed	$153.8	$201.6
Imputed long-term debt [21]	$81.9	$119.3
Imputed equity [21]	71.9	82.3
Total long-term financing	$153.8	$201.6

TABLE 5—DERIVATION OF THE 2015 AND 2014 PSAF

[Dollars in millions]

	2015			2014		
	Debt		Equity	Debt		Equity
A. Imputed long-term debt and equity:						
Net long-term assets to finance	$153.8	.....	$153.8	$201.6	.....	$201.6
Capital structure observed in market	58.2%	.....	41.8%	59.2%	.....	40.8%
Pre-adjusted long-term debt and equity	$89.5	.....	$64.3	$119.3	.....	$82.3
Equity adjustments offset by: [22]						
Imputed long-term debt	(7.6)	.....	7.6	—	.....	—
Imputed investments	—	.....	—	—	.....	—
	$81.9	.....	$71.9	$119.3	.....	$82.3
B. Cost of capital:						
Elements of capital costs.						
Short-term debt [23]	$18.5 ×	0.2% =	$0.0	$22.2 ×	0.2% =	$0.0
Long-term debt [23]	81.9 ×	5.0% =	4.1	119.3 ×	5.9% =	7.0
Equity [24]	71.9 ×	10.1% =	7.3	82.3 ×	10.6% =	8.7
	.....	.....	$11.4	.....	.....	$15.8
C. Other required PSAF costs:						
Sales taxes	.....	$3.3	.....	.....	$3.5	
Board of Governors expenses	.....	3.3	.....	.....	4.1	
	.....	.....	6.6	.....	.....	7.6
	.....	.....	$18.0	.....	.....	$23.4
D. Total PSAF:						
As a percent of assets	.....	.....	1.3%	.....	.....	1.6%
As a percent of expenses	.....	.....	4.5%	.....	.....	5.6%
E. Tax rates	.....	.....	22.4%	.....	.....	37.2%

[21] See table 5 for calculation.

[22] If minimum equity constraints are not met after imputing equity based on the capital structure observed in the market, additional equity is imputed to meet these constraints. The long-term funding need was met by imputing long-term debt and equity based on the capital structure observed in the market (see tables 4 and 6). In 2014, the amount of imputed equity was based on the minimum equity requirements for risk-weighted assets, or 10%.

[23] Imputed short-term debt and long-term debt are computed at table 4.

[24] The 2015 ROE is equal to a risk-free rate plus a risk premium (beta * market risk premium). The 2015 after-tax CAPM ROE is calculated as 0.03% + (1.0 * 7.83%) = 7.86%. Using a tax rate of 22.4%, the after-tax ROE is converted into a pretax ROE, which results in a pretax ROE of (7.86%/(1 − 22.4%)) = 10.1%. Calculations may be affected by rounding.

TABLE 6—COMPUTATION OF 2015 CAPITAL ADEQUACY FOR FEDERAL RESERVE PRICED SERVICES

[Dollars in millions]

	Assets	Risk weight	Weighted assets
Imputed investments:			
3-month Treasury bills [25]	$—		$—
Federal funds [26]	600.0	0.2	120.0
Total imputed investments	600.0		
Receivables	$34.5	0.2	$6.9
Materials and supplies	0.6	1.0	0.6
Prepaid expenses	11.0	1.0	11.0
Items in process of collection	151.0	0.2	30.2
Premises	116.2	1.0	116.2
Furniture and equipment	39.9	1.0	39.9
Leasehold improvements and long-term prepayments	91.5	1.0	91.5
Pension asset	79.6	1.0	79.6
Deferred tax asset	222.8	1.0	222.8
Total	$1,347.2		$718.8
Imputed equity			$71.9
Capital to risk-weighted assets	10.0%		
Capital to total assets	5.3%		

C. *Check Service*—Table 7 shows the 2013 actual, 2014 estimated, and 2015 budgeted cost-recovery performance for the commercial check service.

TABLE 7—CHECK SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE) [1 − 2]	Targeted ROE	Recovery rate after targeted ROE [1/(2+4)] %
	1	2	3	4	5
2013 (actual)	198.9	170.7	28.2	1.7	115.4
2014 (estimate)	172.5	149.1	23.4	1.9	114.2
2015 (budget)	151.8	142.0	9.8	2.0	105.4

1. *2014 Estimate*—The Reserve Banks estimate that the check service will recover 114.2 percent of total expenses and targeted ROE, compared with a 2014 budgeted recovery rate of 108.8 percent. Greater-than-expected check volumes processed by the Reserve Banks and lower-than-expected costs have influenced significantly the check services cost recovery.[27] [28]

The decline in Reserve Bank check volume, which is attributable to the decline in the number of checks written generally, was not as great as anticipated. Through September, total forward check volume is 4.5 percent lower and total return check volume is 12.4 percent lower than for the same period last year. For full-year 2014, the Reserve Banks estimate that their total forward check volume will decline 5.1 percent (compared to a budgeted decline of nearly 9 percent) and their total return check volume will decline 13.0 percent (compared to a budgeted decline of about 14 percent) from 2013 levels.[29]

2. *2015 Pricing*—The Reserve Banks project that the check service will recover 105.4 percent of total expenses and targeted ROE in 2015. The Reserve Banks project revenue to be $151.8 million, a decline of 12 percent from 2014. This decline is driven largely by projected reductions in both forward check and return check volume. The Reserve Banks estimate that total Reserve Bank forward check volumes will decline nearly 7 percent to 5.3 billion and return check volumes will decline approximately 14 percent to 31.3 million in 2015. Total expenses for the check service are projected to be $142.0 million, a decline of nearly 5 percent from 2014. The reduction in check costs is driven primarily by the cost savings associated with the implementation of a more efficient

[25] If minimum equity constraints are not met after imputing equity based on all other financial statement components, additional equity is imputed to meet these constraints. Additional equity imputed to meet minimum equity requirements is invested solely in Treasury securities. The imputed investments are similar to those for which rates are available on the Federal Reserve's H.15 statistical release, which can be located at *http://www.federalreserve.gov/releases/h15/data.htm.*

[26] The investments are imputed based on the amounts arising from the collection of items prior to providing credit according to established availability schedules.

[27] The greater-than-expected check volume is attributed to continued enhancements of two strategic FedForward product offerings, specifically select mixed and premium mixed.

[28] Operating costs are expected to be $2.1 million lower than the original 2014 budget due to operational efficiencies in check processing as well as lower than budgeted information technology costs. Pension costs are also projected to be $3.5 million under the original budget.

[29] Total Reserve Bank forward check volumes are expected to drop from roughly 6.0 billion in 2013 to 5.7 billion in 2014. Total Reserve Bank return check volumes are expected to drop from roughly 42.1 million in 2013 to 36.6 million in 2014.

check processing platform and the full decommissioning of the legacy platform.[30]

The Reserve Banks announced in October a 12:00 noon deadline (but not the associated fees) for three deposit options within the current FedForward product line, specifically, Mixed, Premium Mixed D, and Select Mixed products, to provide an opportunity for the bank of first deposit to present forward items to paying banks one day earlier.[31] [32] For the Mixed deposit option, the Reserve Banks will reduce the per-item fees for tiers 1, 2, 3, and 4 from the current 10:00 a.m. deposition option, as seen in table 8.[33] For the Select Mixed option, the Reserve Banks will increase the per-item fees for non-eligible items from $0.10 to $0.35 and to implement a $25 ICL surcharge.[34] For the Premium Mixed D option, the Reserve Banks will charge per-item fees $0.002 higher than the per-item fees at the current 1:00 a.m. deadline (with the exception of the substitute check fee, which will be $0.20 higher) and a $25 ICL surcharge.[35]

TABLE 8

FedForward Mixed Image Cash Letter [a] [b]

Deadline	9:00 p.m.	1:00 a.m.	5:00 a.m.	12:00 p.m.
Cash letter fee	$3.50	$4.50	$6.50	$6.50
Tier 1	0.0080	0.0230	0.0500	0.0700
Tier 2	0.0200	0.0330	0.0800	0.1000
Tier 3	0.0300	0.0500	0.2000	0.2200
Tier 4	0.0400	0.0600	0.2500	0.2700
Substitute check [e]	0.1500	0.1500	0.3000	0.3500

FedForward Premium Mixed D Image Cash Letter [a] [b]

Deadline	1:00 a.m.	12:00 p.m.
Cash letter fee [d]	$500.00	$500.00
Cash letter surcharge [c]	.....	25.00
Tier 1	0.0040	0.0060
Tier 2	0.0170	0.0190
Tier 3	0.0280	0.0300
Tier 4	0.0390	0.0410
Substitute check [e]	0.1500	0.3500

FedForward Select Mixed Image Cash Letter [a] [b]

Deadline	5:00 a.m.		12:00 p.m.	
	Level 1	Level 2	Level 1	Level 2
Daily fixed fee	$2,200.00	$900.00	$2,200.00	$900.00
Cash letter surcharge [c]	.....	.....	25.00	25.00
Tier 1	0.0020	0.0020	0.0020	0.0020
Tier 2	0.0040	0.0060	0.0040	0.0060
Tier 3	0.0060	0.0080	0.0060	0.0080
Non-eligible endpoints	0.1000	0.1000	0.3500	0.3500

[a] All deadlines are Monday through Friday.
[b] A current list of FedForward endpoint tier listings can be found at *http://www.frbservices.org/servicefees/check21_endpoint_listing.html.*
[c] The surcharge will apply to each cash letter received between 5:00 a.m. and 12:00 p.m., in addition to the daily fixed fee.
[d] Depositors who send more than the allowed maximum number of files will be charged a $35.00 file overage fee for each additional cash letter. The maximum number of cash letters per day for the Premium Mixed D product is 35.
[e] The Reserve Bank's Check 21 service fees include separate and substantially different fees for the delivery of checks to electronic endpoints versus paper substitute check endpoints.

The Reserve Banks will introduce two new deposit options to the FedForward Premium Mixed ICL products, Premium Mixed E and F, as seen in table 9.

[30] The Reserve Banks completed a multi-year check platform modernization initiative in October 2012.

[31] Depository institutions deposit image cash letters using nine deposit options within the FedForward product line, which vary in price structure and funds availability. A current list of FedForward deposit options can be found at *http://frbservices.org/servicefees/check_services_2014.html.*

[32] The Reserve Banks announced the deadline in October, effective January 2, 2015, to provide both collecting banks and paying banks enough time to modify their processes to deposit and receive items at 12:00 noon and 2:00 p.m., respectively. The announcement can be found at *http://www.frbservices.org/files/communications/pdf/check/100314_updated_new_fedforward_deposit_deadline.pdf.*

[33] The Mixed product option allows customers to send forward collection items in a mixed cash letter at various deadlines for a lower cash letter fee and higher electronic per-item fee.

[34] The Select Mixed product option allows customers to send forward collection items drawn on specific endpoints in a separate cash letter, which combines a high fixed fee with a lower per-item variable fee. All eligible items in the cash letter receive immediate availability and qualify for the special pricing while ineligible items receive deferred availability of the next business day and pay a higher per-item fee. A current list of Select Mixed endpoints can be found at *http://www.frbservices.org/servicefees/check21_endpoint_listing.html.*

[35] The Premium Mixed product option allow customers to send forward collection items within a specific number of mixed cash letters for a daily fixed fee and a lower per-item fee. A surcharge, or overage fee, is charged for each cash letter deposited over the published threshold. Premium Mixed depositors are not eligible to use Fine Sort and Deferred Fine Sort products.

TABLE 9—FEDFORWARD PREMIUM MIXED IMAGE CASH LETTER [A B]

Deadline	Premium Mixed E [c]		Premium Mixed F [c]	
	5:00 a.m.	12:00 p.m.	5:00 a.m.	12:00 p.m.
Daily fixed fee [d]	$325.00	$325.00	$650.00	$650.00
Cash letter surcharge [e]	.....	25.00	.....	25.00
Tier 1	0.0040	0.0060	0.0040	0.0060
Tier 2	0.0170	0.0190	0.0170	0.0190
Tier 3	0.0280	0.0300	0.0280	0.0300
Tier 4	0.0390	0.0410	0.0390	0.0410
Substitute Checks [f]	0.3000	0.3500	0.3000	0.3500

[a] All deadlines are Monday through Friday.
[b] A current list of FedForward endpoint tier listings can be found at *http://www.frbservices.org/servicefees/check21_endpoint_listing.html.*
[c] Premium Mixed E and Premium Mixed F products are not eligible to use Fine Sort or Deferred Fine Sort products.
[d] Depositors who send more than the allowed maximum number of files will be charged a $35.00 file overage fee for each additional cash letter. The maximum number of cash letters per day for Premium Mixed E and Premium Mixed F is 30 and 60, respectively.
[e] The surcharge will apply to each cash letter received between 5:00 a.m. and 12:00 p.m., in addition to the daily fixed fee.
[f] The Reserve Bank's Check 21 service fees include separate and substantially different fees for the delivery of checks to electronic endpoints versus paper substitute check endpoints.

The Reserve Banks will increase the FedForward Deferred Mixed ICL product per-item fees at the 5:00 a.m. and 10:00 a.m. deadlines by $0.002 and $0.004, respectively. They also will increase the FedForward Deferred Fine Sort ICL product per-item fees at the 5:00 a.m. and 10:00 a.m. deadlines by $0.001 and $0.002, respectively. The Reserve Banks hope to encourage depositors to shift volume from the deferred-availability product to one of the immediate-availability options at 12:00 noon. The Reserve Banks estimate that the price changes will result in an approximate 0.5 percent average price decrease for check customers.

Risks to the Reserve Banks' ability to achieve budgeted 2015 cost recovery for the check service include greater-than-expected check volume losses due to reductions in check writing overall and competition from correspondent banks, aggregators, and direct exchanges, which would result in lower-than-anticipated revenue, and higher-than-expected support and overhead costs.

D. *FedACH Service*—Table 10 shows the 2013 actual, 2014 estimate, and 2015 budgeted cost-recovery performance for the commercial FedACH service.

TABLE 10—FEDACH SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (Roe) [1–2]	Targeted roe	Recovery rate after targeted Roe [1/(2+4)]
	1	2	3	4	5
2013 (actual)	118.9	116.3	2.6	1.2	101.2%
2014 (estimate)	123.3	140.9	−17.6	1.7	86.5
2015 (budget)	124.4	122.6	1.8	1.7	100.0

1. *2014 Estimate*—The Reserve Banks estimate that the FedACH service will recover 86.5 percent of total expenses and targeted ROE, compared with a 2014 budgeted recovery rate of 99.2 percent. The shortfall in the FedACH Service is due to a $31.6 million charge related to its investment associated with a multiyear technology initiative to modernize its processing platform.[36] The Reserve Banks' long-term cost recovery average, from 2003 to 2014, is 102.1 percent. Through September, FedACH commercial origination and receipt volume was 4.1 percent higher than it was during the same period last year. The Reserve Banks believe that the volume growth will continue at the same pace for the full year 2014, higher than the 3.0 budgeted volume increase.

2. *2015 Pricing*—The Reserve Banks expect the FedACH service to recover 100.0 percent of total expenses and targeted ROE in 2015. FedACH commercial origination and receipt volume is projected to grow 3.5 percent contributing to an increase of $1.1 million in total revenue from the 2014 estimate. Total expenses are budgeted to decrease $900 thousand from 2014 budgeted expenses of $125.3 million, primarily because of efficiencies gained from synergies between the check and ACH operations.

The Reserve Banks will modify the FedACH Minimum Origination Fee calculation to include fees associated with SameDay and FedGlobal origination transactions in the computation.[37] The Reserve Banks will reduce the tier volume thresholds for the FedACH Risk Management Services from 500,000 to 100,000 items reviewed per month.

The primary risks to the Reserve Banks' ability to achieve budgeted 2015 cost recovery for the FedACH service are cost overruns associated with unanticipated problems related to infrastructure currency efforts and higher-than-expected support and overhead costs. Other risks include lower-than-expected volume and associated revenue due to unanticipated

[36] The Reserve Banks have been engaged in a multiyear technology initiative to modernize the FedACH processing platform by migrating the service from a mainframe system to a distributed computing environment. In late 2013, the Reserve Banks conducted an assessment focused on the viability and cost-effectiveness of the program. As a result, the Reserve Banks in 2014 suspended the program and began to investigate the use of other technology solutions.

[37] Each Originating Depository Financial Institution (ODFI) is charged a minimum of $35 per month in forward value and non-value item origination fees. The fees associated with domestic FedACH, SameDay, and FedGlobal originations are collectively subject to the minimum fee.

mergers and acquisitions and loss of market share due to direct exchanges and a shift of volume to the private-sector operator.

E. *Fedwire Funds and National Settlement Services*—Table 11 shows the 2013 actual, 2014 estimate, and 2015 budgeted cost-recovery performance for the Fedwire Funds and National Settlement Services.

TABLE 11—FEDWIRE FUNDS AND NATIONAL SETTLEMENT SERVICES PRO FORMA COST AND REVENUE PERFORMANCE

[dollars in millions]

Year	Revenue	Total expense	Net income (ROE) [1–2]	Targeted ROE	Recovery rate after targeted ROE [1/(2+4)] %
	1	2	3	4	5
2013 (actual)	96.7	97.1	−0.3	1.0	98.6
2014 (estimate)	109.5	106.6	2.9	1.5	101.3
2015 (budget)	112.2	109.8	2.4	1.5	100.8

1. *2014 Estimate* — The Reserve Banks estimate that the Fedwire Funds and National Settlement Services will recover 101.3 percent of total expenses and targeted ROE, compared with a 2014 budgeted recovery rate of 98.0 percent. The higher-than-budgeted cost recovery is primarily due to lower-than-expected operating costs, which offset weaker-than-anticipated volumes and associated revenue.

Through September, Fedwire Funds Service online volume was 0.6 percent lower than for the same period last year. For full-year 2014, the Reserve Banks estimate Fedwire Funds Service online volume to decline 1.1 percent from 2013 levels, compared to the 3.8 percent volume increase that had been budgeted. Through September, National Settlement Service settlement file volume was unchanged from the same period last year, while settlement entry volume was 5.6 percent lower. For the full year, the Reserve Banks estimate that settlement file volume will decrease 2.8 percent (same as budgeted) and settlement entry volume will decrease 7.3 percent from 2013 levels (compared to a budgeted 1.8 percent increase).

2. *2015 Pricing*—The Reserve Banks expect the Fedwire Funds Service to recover 100.8 percent of total expenses and targeted ROE. Revenue is projected to be $112.2 million, an increase of 2.5 percent from 2014. The Reserve Banks project total expenses to be $3.2 million higher than the 2014 estimate.

The Reserve Banks will adjust the incentive pricing fees for the Fedwire Funds Service by increasing the Tier 1 per item pre-incentive fee (the fee before volume discounts are applied) from $0.69 to $0.73 and increasing the Tier 3 per item pre-incentive fee from $0.14 to $0.15. The Reserve Banks intend to keep the Tier 2 per-item pre-incentive fee the same.

The Reserve Banks will decrease the surcharge for transfers exceeding $10 million from $0.15 to $0.14.

The Reserve Banks will increase the FedPayments Manager import/export monthly fee from $45 to $50. In addition, the Reserve Banks will increase the offline transaction surcharge from $45 to $50. The Reserve Banks estimate that the price changes will result in an approximate 4.7 percent average price increase for Fedwire Funds customers.

The Reserve Banks will not change National Settlement Service fees for 2015. The Reserve Banks' Fedwire Funds and National Settlement Services fees are consistent with their multi-year strategy to minimize pricing volatility while undertaking ongoing technology upgrades and related projects to further strengthen information security.

The primary risk to the Reserve Banks' ability to achieve budgeted 2015 cost recovery for these services is cost overruns and schedule delays from unanticipated problems with managing complex technology programs.

F. *Fedwire Securities Service*—Table 12 shows the 2013 actual, 2014 estimate, and 2015 budgeted cost recovery performance for the Fedwire Securities Service.[38]

TABLE 12—FEDWIRE SECURITIES SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[dollars in millions]

Year	Revenue	Total expense	Net income (ROE) [1–2]	Targeted ROE	Recovery rate after targeted ROE [1/(2+4)] %
	1	2	3	4	5
2013 (actual)	26.9	25.3	1.5	0.2	105.0
2014 (estimate)	23.8	23.4	0.4	0.3	100.1
2015 (budget)	26.0	26.5	−0.6	0.4	96.5

1. *2014 Estimate*— The Reserve Banks estimate that the Fedwire Securities Service will recover 100.1 percent of total expenses and targeted ROE, compared with a 2014 budgeted recovery rate of 98.0 percent. The

[38] The Reserve Banks provide transfer services for securities issued by the U.S. Treasury, federal government agencies, government-sponsored enterprises, and certain international institutions. The priced component of this service, reflected in this memorandum, consists of revenues, expenses, and volumes associated with the transfer of all non-Treasury securities. For Treasury securities, the U.S. Treasury assesses fees for the securities transfer component of the service. The Reserve Banks assess a fee for the funds settlement component of a Treasury securities transfer; this component is not treated as a priced service.

higher-than-expected cost recovery is primarily due to lower-than-budgeted information technology and pension costs, which offset weaker-than-anticipated volumes and associated revenue.

Through September, Fedwire Securities Service online volume was 31.5 percent lower than the same period last year. For full-year 2014, the Reserve Banks estimate Fedwire Securities Service online volume to decline 30.8 percent from 2013 levels, compared to a budgeted decline of 10.9 percent.

2. *2015 Pricing*—The Reserve Banks expect the Fedwire Securities Service to recover 96.5 percent of total expenses and targeted ROE in 2015. The Reserve Banks project that 2015 revenue and expenses will increase by $2.2 million and $3.1 million, respectively, compared to 2014 estimates.

The Reserve Banks project that online transfer activity will decline by 12.9 percent in 2015, the number of accounts maintained will decrease by 14.1 percent, and the number of agency securities maintained will increase by 0.1 percent.[39] The projected decline in account maintenance activity reflects customer closures of empty accounts to avoid unnecessary expenses and increased competition in collateral management services.[40] The Reserve Banks also estimate a decrease in online transfer activity, driven by lower expected issuance of mortgage-backed and agency debt securities. The reduction in mortgage-backed securities issuance reflects gradually increasing interest rates and lower anticipated mortgage refinancing. The reduction in agency debt issuance reflects a further required reduction in government sponsored enterprise portfolios, which has led to a reduced funding need for new debt issuance.

Expenses are budgeted to increase by $3.1 million from 2014 estimates, reflecting higher technology upgrade costs. The higher technology upgrade costs, however, are expected to be partially offset by higher Treasury reimbursements.[41]

The Reserve Banks will increase various fees for the Fedwire Securities Service. The Reserve Banks will increase the online transfer fee from $0.54 to $0.65, the monthly account maintenance fee from $40 to $48, and the monthly issue maintenance fee from $0.54 to $0.65 per issue. The Reserve Banks will also increase the Joint Custody Origination Surcharge from $40 to $44. The Reserve Banks estimate that the price changes will result in an approximate 19.1 percent average price increase for Fedwire Securities customers.

The primary risk to the Reserve Banks' ability to achieve budgeted 2015 cost recovery for these services is cost overruns and schedule delays from unanticipated problems with managing complex technology upgrades.

G. *FedLine Access*—The Reserve Banks charge fees for the electronic connections that depository institutions use to access priced services and allocate the costs and revenue associated with this electronic access to the various priced services. There are currently five FedLine channels through which customers can access the Reserve Banks' priced services: FedMail, FedLine Web®, FedLine Advantage, FedLine Command®, and FedLine Direct.[42] The Reserve Banks package these channels into ten FedLine packages, described in the two paragraphs below, that are supplemented by a number of premium (or à la carte) access and accounting information options. In addition, the Reserve Banks offer FedComplete packages, which are bundled offerings of a FedLine Advantage connection and a fixed number of FedACH, Fedwire Funds, and Check 21-enabled services.

Five attended access packages offer access to critical payment and information services via a Web-based interface. The FedLine Exchange package (formerly the FedMail Email package) provides access to basic information services via email, while two FedLine Web packages offer an email option plus online attended access to a range of services, including cash services, FedACH information services, and check services. Three FedLine Advantage packages expand upon the FedLine Web packages and offer attended access to critical transactional services: FedACH, Fedwire Funds, and Fedwire Securities.

Four unattended access packages are computer-to-computer, IP-based interfaces designed for medium- to high-volume customers. The FedLine Command package offers an unattended connection to FedACH, as well as most accounting information services. The three remaining packages are FedLine Direct packages, which allow for unattended connections at one of three connection speeds to FedACH, Fedwire Funds, and Fedwire Securities transactional and information services and to most accounting information services.[43]

Many of the FedLine access solutions fees in 2015 are designed to encourage customers to migrate to more efficient access solutions. The Reserve Banks will increase the fees on legacy services, such as an additional $10 per month for FedMail Fax, $300 per month for FedLine Direct (56K), and $400 for an additional 56K connection. The Reserve Banks also will introduce a $2,500 per month surcharge for those depository institutions that continue to use the AT&T VPN after February 1, 2015, instead of migrating to the Sprint VPN.

In addition, the Reserve Banks will make other changes to FedLine pricing for 2015 to improve contingency preparedness between Reserve Banks and depository institutions. In particular, the Reserve Banks will add to the FedLine Advantage channel a new package, FedLine Advantage Premier that will be priced at $500 per month and includes a secondary VPN device.[44] FedLine Advantage Premier will also include the FedTransaction Analyzer® tool, which enables depository institutions to streamline after-the-fact analysis of payment transactions and automate reporting processes. Depository institutions with more than 250 Fedwire transactions, or more than one routing number, will have access to the FedTransaction Analyzer tool via FedLine Advantage Premier rather than FedLine Advantage Plus package.[45]

The Reserve Banks will introduce two new tiers to FedComplete package solutions called FedComplete 100 Premier and FedComplete 200 Premier,

[39] The online transfer fee, monthly account maintenance fee, and monthly issue maintenance fee accounted for 92 percent of total Fedwire Securities Service revenue through June 2014.

[40] Specifically, collateral management services refers to the Fedwire Securities Joint Custody Service, which facilitates the collateralization of deposits made by a government entity, through the pledging of book-entry securities by its depository institution. Approximately 72 percent of Fedwire Securities priced accounts are collateral accounts related to the Joint Custody Service.

[41] Treasury reimbursement is calculated by multiplying costs by the ratio of Treasury to agency transfers. In 2015, Treasury projects its transfer volume will remain flat, while the Reserve Banks expect agency transfers to decrease. Therefore, the higher projected ratio of Treasury to agency transfers will result in Treasury reimbursing a higher portion of total costs.

[42] FedMail, FedLine Web, FedLine Advantage, FedLine Command, and FedLine Direct are registered trademarks of the Federal Reserve Banks.

[43] The FedLine Direct base-level package is available to current customers only and will be phased out in 2015 due to elimination of 56K line speed.

[44] All customers, regardless of their chosen electronic access channel, are responsible for the purchase and installation of each VPN device.

[45] Current FedTransaction Analyzer customers will be automatically moved to FedLine Advantage Premier if they originate and receive more than 250 Fedwire funds transfers or have more than one routing number in a given month. Customers can opt out of the increased fees by discontinuing their use of the FedTransaction Analyzer tool or the FedLine Advantage access solution.

which are $850 and $1,375 per month, respectively. These FedComplete packages include FedLine Advantage Premier.

II. Analysis of Competitive Effect

All operational and legal changes considered by the Board that have a substantial effect on payments system participants are subject to the competitive impact analysis described in the March 1990 policy, *The Federal Reserve in the Payments System*.[46] Under this policy, the Board assesses whether proposed changes would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services because of differing legal powers or constraints or because of a dominant market position deriving from such legal differences. If any proposed changes create such an effect, the Board must further evaluate the changes to assess whether the benefits associated with the changes—such as contributions to payment system efficiency, payment system integrity, or other Board objectives—can be achieved while minimizing the adverse effect on competition.

The changes for 2015 are limited to product enhancements and pricing modifications; no new products or pricing constructs are introduced. These changes will not have a direct and material adverse effect on the ability of other service providers to compete effectively with the Reserve Banks in providing similar services. The changes should permit the Reserve Banks to earn a ROE that is comparable to overall market returns and provide for full cost recovery over the long run.

III. 2015 Fee Schedules

FEDACH SERVICE 2015 FEE SCHEDULE

[Effective January 2, 2015. **Bold indicates changes from 2014 prices]**

	Fee
FedACH minimum monthly fee.	
Originating Depository Financial Institution (ODFI)[47]	$35.00.
Receiving Depository Financial Institution (RDFI)[48]	25.00.
Origination (per item or record)[49].	
Forward or return items in small files	0.0030.
Forward or return items in large files	0.0025.
Addenda record	0.0015.
FedLine Web®-originated returns and notification of change (NOC) fee[50]	0.35.
Facsimile exception returns/NOC[51]	45.00.
Automated NOC fee	0.20.
Volume-based discounts (based on monthly billed receipt volume)[52].	
Per item when receipt volume is 10,000,001 to 17,500,000 items per month	0.0002 discount.
Per item when receipt volume is more than 17,500,000 items per month	0.0003 discount.
Receipt (per item or record).	
Forward item	0.0025.
Return item	0.0075.
Addenda record	0.0015.
On-us receipt credit[53]	0.0025 discount.
Volume-based discounts (forward items excluding FedACH SameDay service items).	
Non-Premium Receivers—RDFIs receiving less than 90 percent of total network volume through FedACH.	
Per item when volume is 1,000,001 to 12,500,000 items per month[54]	0.0007 discount.
Per item when volume is more than 12,500,000 items per month[55]	0.0009 discount.
Premium Receivers, level one—RDFIs receiving at least 90 percent of FedACH-originated volume through FedACH.	
Per item when volume is 1,000,001 to 2,500,000 items per month[58]	0.0007 discount.
Per item when volume is 2,500,001 to 12,500,000 items per month[58]	0.0008 discount.
Per item when volume is more than 12,500,000 items per month.[59]	0.0010 discount.
Premium Receivers, level two—RDFIs receiving at least 90 percent of ACH volume originated through FedACH or EPN.	
Per item when volume is 1,000,001 to 2,500,000 items per month[58]	0.0007 discount.
Per item when volume is 2,500,001 to 12,500,000 items per month[58]	0.0009 discount.
Per item when volume is more than 12,500,000 items per month[59]	0.0011 discount.
FedACH SameDay Service.	
Origination[56 57].	
Forward item in a small file	0.0030 surcharge.
Forward item in a large file	0.0035 surcharge.
Addenda record	0.0015 surcharge.
Return item in a small file	0.0030 discount.
Return item in a large file	0.0025 discount.
Return addenda record	0.0015 discount.
Receipt[58].	
Forward item	0.0025 discount.
Return item	0.0075 discount.
Addenda record (forward/return)	0.0015 discount.
Monthly FedACH Risk® Management fees[59].	
Risk Origination Monitoring Service/RDFI Alert Service package pricing.	
For up to 5 criteria sets	35.00.
For 6 through 11 criteria sets	70.00.
For 12 through 23 criteria sets	125.00.

[46] Federal Reserve Regulatory Service (FRRS) 9–1558.

FEDACH SERVICE 2015 FEE SCHEDULE—Continued

[Effective January 2, 2015. **Bold indicates changes from 2014 prices]**

	Fee
For 24 through 47 criteria sets	150.00.
For 48 through 95 criteria sets	250.00.
For 96 through 191 criteria sets	425.00.
For 192 through 383 criteria sets	675.00.
For 384 through 584 criteria sets	850.00.
For 585+ criteria sets	1,100.00.
Risk origination monitoring batch.	
For 1 through 100,000 batches	0.007/batch.
For 100,000+ batches	0.0035/batch.
Monthly FedPayments Reporter Service.	
FedPayments Reporter Service package pricing includes.	
Standard reports [60].	
ACH volume summary by SEC code report—customer.[61]	
Daily return ratio report.	
Monthly return ratio report.	
Receiver setup report.	
Report delivery via FedLine file access solution (monthly fee).	
For up to 50 reports	35.00.
For 51 through 150 reports	55.00.
For 151 through 500 reports	100.00.
For 501 through 1,000 reports	180.00.
For 1,001 through 1,500 reports	260.00.
For 1,501 through 2,500 reports	420.00.
For 2,501 through 3,500 reports	580.00.
For 3,501 through 4,500 reports	740.00.
For 4,501 through 5,500 reports	900.00.
For 5,501 through 7,000 reports	1,100.00.
For 7,001 through 8,500 reports	1,300.00.
For 8,501+ reports	1,500.00.
Premier reports [62].	
ACH volume summary by SEC code report—depository financial institution.	
Reports 1 through 5	10.00/report.
Reports 6 through 10	6.00/report.
Reports 11+	1.00/report.
On Demand	1.00/report surcharge.
ACH volume summary by SEC code report—customer On Demand	1.00/report surcharge.
Monthly ACH routing number activity report.	
Reports 1 through 5	10.00/report.
Reports 6 through 10	6.00/report.
Reports 11+	1.00/report.
On-us inclusion.	
Participation fee	10.00/month/RTN.
Per-item fee	0.0030.
Per-addenda fee	0.0015.
Report delivery via encrypted email	0.20/email.
Other fees.	
Monthly fee (per routing number).	
Account servicing fee [63]	45.00.
FedACH settlement [64]	55.00.
Information extract file	100.00.
IAT Output File Sort	75.00.
Notification of change participation fee [65]	5.00.
Non-electronic input/output fee [66].	
CD or DVD input/output	50.00.
Paper input/output	50.00.
FedGlobal ACH Payments.	
Canada service fee.	
Item originated to Canada [67]	0.62.
Return received from Canada [68]	0.99.
Trace of item at receiving gateway	5.50
Trace of item not at receiving gateway	7.00.
Mexico service fee.	
Item originated to Mexico [67]	0.67.
Return received from Mexico [68]	0.91.
Item trace	13.50.
A2R item originated to Mexico [67 69]	3.45.
F3X item originated to Mexico [68 70]	0.67.
Panama service fee.	
Item originated to Panama [67]	0.72.
Return received from Panama [68]	1.00.
Item trace	7.00.

FEDACH SERVICE 2015 FEE SCHEDULE—Continued

[Effective January 2, 2015. **Bold indicates changes from 2014 prices]**

	Fee
NOC	0.72.
Latin America service fee.	
A2R item originated to Latin America [67 69]	4.40.
Return received from Latin America [68]	0.72.
Item trace	5.00.
Europe service fee.	
Item originated to Europe [67]	1.25.
F3X item originated to Europe [67 70]	1.25.
Return received from Europe [68]	1.35.
Item trace	7.00.

FEDWIRE FUNDS AND NATIONAL SETTLEMENT SERVICES 2015 FEE SCHEDULE

[Effective January 2, 2015. **Bold indicates changes from 2014 prices**]

	Fee
Fedwire Funds Service	
Monthly participation fee	**$90.00**
Basic volume-based pre-incentive transfer fee (originations and receipts).	
Per transfer for the first 14,000 transfers per month	**0.73**
Per transfer for additional transfers up to 90,000 per month	0.24
Per transfer for every transfer over 90,000 per month	**0.15**
Volume-based transfer fee with the incentive discount (originations and receipts) [71].	
Per eligible transfer for the first 14,000 transfers per month	**0.148**
Per eligible transfer for additional transfers up to 90,000 per month	0.048
Per eligible transfer for every transfer over 90,000 per month	**0.030**
Surcharge for offline transfers (originations and receipts)	**50.00**
Surcharge for high-value payments > $10 million	**0.14**
Surcharge for high-value payments > $100 million	0.36
Surcharge for payment notification	0.20
Surcharge for late-day transfer originations [72]	0.26
Monthly FedPayments Manager import/export fee [73]	**50.00**
National Settlement Service	
Basic	
Settlement entry fee	1.50
Settlement file fee	30.00
Surcharge for offline file origination	45.00

[47] Any ODFI incurring less than 35 in forward value and non-value item origination fees will be charged a variable amount to reach the minimum.

[48] Any RDFI not originating forward value and non-value items and incurring less than 25 in receipt fees will be charged a variable amount to reach the minimum.

[49] Small files contain fewer than 2,500 items and large files contain 2,500 or more items.

[50] The fee includes the item and addenda fees in addition to the conversion fee.

[51] The fee includes the item and addenda fees in addition to the conversion fee. Reserve Banks also assess a 30 fee for every government paper return/NOC they process.

[52] Origination discounts apply only to those items received by FedACH receiving points and are available only to Premium Receivers.

[53] Depository institutions originating and receiving items on the same routing number.

[54] This per-item discount is a reduction to the standard receipt fees listed in this fee schedule.

[55] Receipt volumes of more than 12,500,000 items per month qualify for the waterfall discount which includes all FedACH receipt items.

[56] This per-item surcharge is in addition to the standard origination fees for forward items.

[57] This per-item discount is a reduction to the standard origination fees for return items.

[58] This per-item discount is a reduction to the standard receipt fees.

[59] Criteria may be set for both the origination monitoring service and the RDFI alert service. Subscribers with no criteria set up will be assessed the 35 monthly package fee.

[60] Standard reports include Customer Transaction Activity, Death Notification, International (IAT), Notification of Change, Payment Data Information File, Remittance Advice Detail, Remittance Advice Summary, Return Item, Return Ratio, Social Security Beneficiary, and Originator Setup Reports.

[61] ACH volume summary by SEC code reports generated on demand are subject to a 1.00 per report surcharge.

[62] Premier reports generated on demand are subject to the package/tiered fees plus a surcharge.

[63] The account servicing fee applies to routing numbers that have received or originated FedACH transactions. Institutions that receive only U.S. government transactions through the Reserve Banks or that elect to use EPN exclusively are not assessed this fee.

[64] The FedACH settlement fee is applied to any routing number with activity during a month, including institutions that elect to use EPN exclusively but also have items routed to or from customers that access the ACH network through FedACH. This fee does not apply to routing numbers that use the Reserve Banks for only U.S. government transactions.

[65] The notification of change fee is applied to any routing number with activity during a month. This fee does not apply to routing numbers that use the Reserve Banks for only U.S. government transactions.

[66] Limited services are offered in contingency situations.

[67] This per-item surcharge is in addition to the standard domestic origination and input file processing fees.

[68] This per-item surcharge is in addition to the standard domestic receipt fees.

[69] Account-to-receiver (A2R) allows funds from accounts at a U.S. depository institution to be retrieved by any receiver at either a participating bank location or a trusted, third-party provider.

[70] Payments are both transferred and received in foreign currency. The foreign exchange rate and settlement is managed and processed by participating U.S. depository institutions and the respective foreign gateway operators via their foreign correspondent banks.

FEDWIRE FUNDS AND NATIONAL SETTLEMENT SERVICES 2015 FEE SCHEDULE—Continued

[Effective January 2, 2015. **Bold indicates changes from 2014 prices**]

	Fee
Minimum monthly charge (account maintenance) [74]	60.00
Special settlement arrangements [75].	
Fee per day	150.00

FEDWIRE SECURITIES SERVICE 2015 FEE SCHEDULE

[Effective January 2, 2015. **Bold indicates changes from 2014 prices**]

	Fee
Basic transfer fee	
Transfer or reversal originated or received	**$0.65**
Surcharge.	
Offline origination & receipt surcharge	66.00
Monthly maintenance fees	
Account maintenance (per account)	**48.00**
Issues maintained (per issue/per account)	**0.65**
Claim adjustment fee	0.75
Joint Custody Origination Surcharge	**44.00**

FEDLINE 2015 FEE SCHEDULE

[Effective January 2, 2015. **Bold indicates changes from 2014 prices.**]

FedComplete Packages (monthly) [76]	
FedComplete 100 Plus	$775.00.
Includes: 7,500 FedForward transactions.	
70 FedReturn® transactions.	
14,000 FedReceipt® transactions.	
35 Fedwire funds origination transfers.	
35 Fedwire funds receipt transfers.	
Fedwire participation fee.	
1,000 FedACH origination items.	
FedACH minimum fee.	
7,500 FedACH receipt items.	
FedACH receipt minimum fee.	
10 FedACH web return/NOC.	
500 FedACH addenda originated.	
1,000 FedACH addenda received.	
FedACH account servicing.	
FedACH settlement.	
FedLine Advantage Plus.	
FedLine subscriber 5-pack.	
FedLine Exchange subscriber 5-pack.	
FedComplete 100 Premier	**850.00.**
Includes: 7,500 FedForward transactions.	
70 **FedReturn transactions**.	
14,000 FedReceipt transactions.	
35 **Fedwire funds origination transfers**.	
35 Fedwire funds receipt transfers.	
Fedwire participation fee.	
1,000 FedACH origination items.	
FedACH minimum fee.	
7,500 FedACH receipt items.	
FedACH receipt minimum fee.	

[71] The incentive discounts apply to the volume that exceeds 60 percent of a customer's historic benchmark volume. Historic benchmark volume is based on a customer's average daily activity over the previous five calendar years. If a customer has fewer than five full calendar years of previous activity, its historic benchmark volume is based on its daily activity for as many full calendar years of data as are available. If a customer has less than one year of prior activity, then the customer qualifies automatically for incentive discounts for the year. The applicable incentive discounts are as follows: $0.582 for transfers up to 14,000; $0.192 for transfers 14,001 to 90,000; and $0.120 for transfers over 90,000.

[72] This surcharge applies to originators of transfers that are processed by the Reserve Banks after 5:00 p.m. ET.

[73] This fee is charged to any Fedwire Funds participant that originates a transfer message via the FedPayments Manager (FPM) Funds tool and has the import/export processing option setting active at any point during the month.

[74] This minimum monthly charge is only assessed if total settlement charges during a calendar month are less than $60.

[75] Special settlement arrangements use Fedwire Funds transfers to effect settlement. Participants in arrangements and settlement agents are also charged the applicable Fedwire Funds transfer fee for each transfer into and out of the settlement account.

FEDLINE 2015 FEE SCHEDULE—Continued

[Effective January 2, 2015. **Bold indicates changes from 2014 prices.**]

FedComplete Packages (monthly) [76]	
10 FedACH web return/NOC.	
500 FedACH addenda originated.	
1,000 FedACH addenda received.	
FedACH account servicing.	
FedACH settlement.	
FedLine Advantage Premier.	
FedLine subscriber 5-pack.	
FedLine Exchange subscriber 5-pack.	
FedComplete 200 Plus	1,300.00.
Includes: 25,000 FedForward transactions.	
225 FedReturn transactions.	
25,000 FedReceipt transactions.	
100 Fedwire funds origination transfers.	
100 Fedwire funds receipt transfers.	
Fedwire participation fee.	
2,000 FedACH origination items.	
FedACH minimum fee.	
25,000 FedACH receipt items.	
FedACH receipt minimum fee.	
20 FedACH web return/NOC.	
750 FedACH addenda originated.	
1,500 FedACH addenda received.	
FedACH account servicing.	
FedACH settlement.	
FedLine Advantage Plus.	
FedLine subscriber 5-pack.	
FedLine Exchange subscriber 5-pack.	
FedComplete 200 Premier	**1,375.00.**
Includes: 25,000 FedForward transactions.	
225 FedReturn transactions.	
25,000 FedReceipt transactions.	
100 Fedwire funds origination transfers.	
100 Fedwire funds receipt transfers.	
Fedwire participation fee.	
2,000 FedACH origination items.	
FedACH minimum fee.	
25,000 FedACH receipt items.	
FedACH receipt minimum fee.	
20 FedACH web return/NOC.	
750 FedACH addenda originated.	
1,500 FedACH addenda received.	
FedACH account servicing.	
FedACH settlement.	
FedLine Advantage Premier.	
FedLine subscriber 5-pack.	
FedLine Exchange subscriber 5-pack.	
FedComplete Excess Volume Surcharge. [77]	
FedForward	0.01/item.
FedReturn	0.7500/item.
Fedwire funds origination	0.7000/item.
FedACH origination	0.0025/item.
FedComplete package credit incentive [78]	(1,500.00).
FedLine Customer Access Solutions (monthly). [79]	
FedLine Exchange (formerly FedMail Email)	40.00.
FedLine Web	110.00.
Includes: FedLine Exchange.	
FedLine Web with no priced services subscriptions.	
FedACH information services (includes RDFI file alert service).	
Check 21 services. [80]	
Check 21 duplicate notification.	
Check adjustments.	
Service charge information.	
Account management information. [81]	
FedLine Web Plus	140.00.
Includes:FedLine Web traditional package.	
FedACH risk management services.	
FedACH FedPayments Reporter Service via secure email.	
Check large dollar return.	
Check FedImage® services.	
Account management information.	
Cash management plus service.	

FEDLINE 2015 FEE SCHEDULE—Continued

[Effective January 2, 2015. **Bold indicates changes from 2014 prices.**]

FedComplete Packages (monthly) [76]	
Various accounting and other inquiry and report services (Real-time Account Balance information, Daylight Overdraft Balance, and Available Funds Balance information; drill down and search features to view transaction details; daily Statement of Account and data files; collateral totals and details; and ex-post Daylight Overdraft reports)..	
FedLine Advantage	380.00.
Includes: FedLine Web traditional package.	
FedACH transactions.	
Fedwire funds transactions.	
Fedwire securities transactions.	
Fedwire cover payments.	
Check large dollar return.	
Check FedImage services.	
Account management information.	
Various accounting services (ABMS inquiry, IAS/PSR inquiry, IAS detailed inquiries, notifications and advices, end-of-day accounting file (PDF)).	
FedLine Advantage Plus	425.00.
Includes: FedLine Advantage traditional package.	
FedACH risk management services.	
FedACH FedPayments Reporter Service via secure email.	
Fedwire Funds FedPayments Manager import/export.	
FedTransaction Analyzer **(less than 250 FedWire transactions and one routing number per month)**.	
Account management information with intra-day search.	
FedLine Advantage Premier	**500.00.**
Includes: FedLine Advantage Plus package with no priced services subscriptions.	
FedTransaction Analyzer (more than 250 Fedwire transactions and two routing numbers per month).	
Secondary VPN device.	
FedLine Command Plus	1,000.00.
Includes: FedLine Advantage Plus package.	
FedLine Command with two certificates.	
Fedwire statement services.	
Intra-day CI file.	
Statement of account spreadsheet file (SASF).	
Financial Institution Reconcilement Data File (FIRD).	
Billing Data Format File (BDFF).	
FedLine Direct. [82]	**4,500.00.**
Includes: FedLine Advantage traditional package.	
56K Dedicated WAN Connection.	
FedLine Command with two certificates.	
FedLine Direct with two certificates.	
Fedwire statement services.	
Intra-day file (I-Day CI File).	
Statement of Account Spreadsheet File (SASF).	
Financial Institution Reconcilement Data File (FIRD).	
Billing Data Format File (BDFF).	
FedLine Direct Plus	3,600.00.
Includes: FedLine Direct traditional package.	
56K or 256K Dedicated WAN Connection.	
FedACH risk management services.	
FedACH FedPayments Reporter Service via secure email.	
Fedwire Funds FedPayments Manager import/export.	
FedTransaction Analyzer.	
FedLine Direct Premier	6,500.00.
Includes: FedLine Direct Plus package.	
T1 Dedicated WAN Connection.	
A La Carte Options (monthly). [83]	
Electronic Access.	
FedLine Exchange subscriber 5-pack [84]	10.00.
FedLine subscriber 5-pack	80.00.
Additional FedLine Command certificate [85]	100.00.
Additional FedLine Direct certificate [86]	100.00.
Maintenance of additional virtual private network device	60.00.
FedLine Advantage 800# Usage (per hour)	3.00.
Dial-Only VPN surcharge	1,000.00.
Additional dedicated connections. [87]	
56K	**3,500.00.**
256K	2,500.00.
T1	3,200.00.
FedLine international setup (one-time fee)	5,000.00.
FedLine Direct contingency solution [88]	1,000.00.
Check 21 large file delivery	various.
FedMail Fax	**70.00.**
Legacy VPN device surcharge [89]	**2,500.00.**

FEDLINE 2015 FEE SCHEDULE—Continued

[Effective January 2, 2015. **Bold indicates changes from 2014 prices.**]

FedComplete Packages (monthly) [76]	
VPN device modification	200.00.
VPN device modification emergency surcharge	200.00.
VPN device missed activation appointment	175.00.
VPN device expedited hardware surcharge	100.00.
VPN device replacement or move	300.00.
Expedited legacy VPN device order/change [90]	500.00.
Accounting Information Services.	
Cash Management System. [91]	
Plus—Own report—up to six files with no respondent/sub-account activity (per month)	60.00.
Plus—Own report—up to six files with less than 10 respondent and/or sub-accounts (per month)	125.00.
Plus—Own report—up to six files with 10–50 respondent and/or sub-accounts (per month)	250.00.
Plus—Own report—up to six files with 51–100 respondents and/or sub-accounts (per month	500.00.
Plus—Own report—up to six files with 101–500 respondents and/or sub-accounts (per month)	750.00.
Plus—Own report—up to six files with >500 respondents and/or sub-accounts (per month)	1,000.00.
End-of-day financial institution reconcilement data file (per month) [92]	150.00.
Statement of account spreadsheet file (per month) [93]	150.00.
Intra-day download search file (with AMI) (per month) [94]	150.00.
ACTS Report—<20 sub-accounts	500.00.
ACTS Report—21–40 sub-accounts	1,000.00.
ACTS Report—41–60 sub-accounts	1,500.00.
ACTS Report—> 60 sub-accounts	2,000.00.

[76] FedComplete packages are all-electronic service options that bundle payment services with an access solution for one monthly fee.

[77] Per-item surcharges are in addition to the standard fees listed in the applicable priced services fee schedules.

[78] New FedComplete package customers with a new FedLine Advantage connection are eligible for a one-time $1,500 credit applied to their Federal Reserve service charges. Customers receiving credit must continue using the FedComplete package for a minimum of six months or forfeit the $1,500 credit.

[79] VPN hardware for FedLine Advantage and FedLine Command is billed directly by the vendor. A list of fees can be found at *http://www.frbservices.org/files/servicefees/pdf/access/2013_vendor_fees.pdf.*

[80] Check 21 services can be accessed via three options: FedLine Web, an Internet connection with Axway Secure Transport Client, or a dedicated connection using Connect: Direct.

[81] Ex-post Daylight Overdraft Reports and the daily Statement of Account are available via FedMail.

[82] FedLine Direct is available to installed customer base only. The 56K option is not available for new orders.

[83] These add-on services can be purchased only with a FedLine Customer Access Service option.

[84] There are no priced subscribers contained in the FedLine Exchange or FedLine packages.

[85] Additional FedLine Command Certificates available for FedLine Command and Direct packages only.

[86] Additional FedLine Direct Certificates available for FedLine Direct packages only.

[87] Network diversity supplemental charge of $2,000 a month may apply in addition to these fees.

[88] FedLine Direct contingency solution is available only for FedLine Direct Plus & Premier packages.

[89] Effective February 1, 2015. Price will increase to $5,000 on May 1, 2015 and $7,500 on September 1, 2015.

[90] Applicable to VPN devices ordered before May 13, 2013.

[91] Cash Management Service options are limited to Plus and Premier packages.

[92] End of Day Reconcilement File option is available to FedLine Web Plus and FedLine Advantage Plus packages.

[93] Statement of Account Spreadsheet File option is available to FedLine Web Plus and FedLine Advantage Plus packages.

[94] ACTS Report options are limited to FedLine Command Plus and FedLine Direct Plus and Premier packages.

By order of the Board of Governors of the Federal Reserve System, October 31, 2014.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2014–26322 Filed 11–5–14; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 1, 2014.

A. Federal Reserve Bank of San Francisco (Gerald C. Tsai, Director, Applications and Enforcement), 101 Market Street, San Francisco, California 94105–1579:

1. *Pacific Premier Bancorp, Inc.,* Irvine, California; to acquire voting shares of Independence Bank, Newport Beach, California.

Board of Governors of the Federal Reserve System, November 3, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–26366 Filed 11–5–14; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 141 0183]

H.I.G. Bayside Debt & LBO Fund II, L.P. and Crestview Partners, L.P. ; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 2, 2014.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/higbaysidedebtconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''In the Matter of H.I.G. Bayside Debt & LBO Fund II, L.P., and Crestview Partners, L.P., Matter No. 141 0183'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/higbaysidedebtconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''In the Matter of H.I.G. Bayside Debt & LBO Fund II, L.P., and Crestview Partners, L.P., Matter No. 141 0183'' on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jill Frumin, Bureau of Competition, (202–326–2758), 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for October 31, 2014), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 2, 2014. Write ''In the Matter of H.I.G. Bayside Debt & LBO Fund II, L.P., and Crestview Partners, L.P., Matter No. 141 0183'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/higbaysidedebtconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''In the Matter of H.I.G. Bayside Debt & LBO Fund II, L.P., and Crestview Partners, L.P., Matter No. 141 0183'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 2, 2014. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Orders to Aid Public Comment

I. Introduction And Background

The Federal Trade Commission (''Commission'') has accepted for public comment, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from H.I.G. Bayside Debt & LBO Fund II, L.P. (''H.I.G.''), and Crestview Partners, L.P. (''Crestview''). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that otherwise would result from the acquisition of Symbion Holdings Corporation (''Symbion''), a Crestview subsidiary, by Surgery Center Holdings, Inc. (''Surgery Partners''), an H.I.G. subsidiary. The proposed Consent Agreement requires Surgery Partners to divest its ownership interest in the Blue Springs Surgery Center (''Blue Springs'') in Orange City, Florida, which it will acquire as part of its acquisition of Symbion, to a Commission-approved

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

acquirer, and in a manner approved by the Commission, no later than sixty (60) days after the Commission's final Decision and Order is issued. Under the proposed Consent Agreement, Surgery Partners is required to hold separate the to-be-divested interest and maintain the economic viability and competitiveness of Blue Springs until the potential acquirer is approved by the Commission and the divestiture is complete. In the event that a timely divestiture of Surgery Partners' Blue Springs interest is not accomplished, the Decision and Order provides that the Commission may appoint a trustee to divest either Surgery Partners' ownership interest in Blue Springs, or its ownership interest in Orange City Surgery Center (''OCSC''), a competing facility in Orange City in which Surgery Partners owns a controlling interest.

The proposed Consent Agreement has been placed on the public record for thirty days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission again will review the proposed Consent Agreement and comments received, and decide whether it should withdraw the Consent Agreement, modify the Consent Agreement, or make it final.

On June 13, 2014, Surgery Partners and Symbion signed a merger agreement pursuant to which Surgery Partners agreed to acquire all of the voting securities of Symbion for $792 million. The Commission's complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by eliminating actual, direct, and substantial competition between the parties for the sale and provision of outpatient surgical services to commercial health plans and commercially insured patients in the Orange City/Deltona market in Florida. The proposed Consent Agreement would remedy the alleged violations by requiring a complete divestiture of Surgery Partners' ownership interest in Blue Springs in the affected market. The divestiture will restore the competition that otherwise would be lost as a result of the proposed acquisition.

II. The Parties

H.I.G. is a private equity fund that owns 100% of Surgery Partners. Surgery Partners owns, in whole or in part, 47 ambulatory surgery centers (''ASCs'') in 17 states across the country. Surgery Partners generated approximately $280 million in revenue during 2013.

Crestview is a private equity firm that owns 100% of Symbion. Symbion owns, in whole or in part, 44 ASCs in 21 states, as well as several short-stay surgical hospitals and other clinical facilities. Symbion generated more than $535 million in revenue during 2013.

III. Outpatient Surgical Services in Orange City/Deltona, Florida

The relevant product market in which Surgery Partners' proposed acquisition of Symbion poses antitrust concerns is the sale and provision of outpatient surgical services to commercial health plans and commercially insured patients. Outpatient surgical services are sold to commercial health plans, which then sell benefit plans to commercially insured patients. Outpatient surgical procedures can be performed at an ASC, a specialty hospital, or a general acute care hospital.

When commercial health plans reimburse providers for outpatient surgical services, they pay two fees: A professional services fee to the surgeon who performed the procedure and a separate facility fee to the ASC or hospital where the procedure was performed. The facility fee covers use of the operating room as well as other costs associated with the procedure, such as nursing services or supplies. The potential anticompetitive effects of the proposed acquisition here are limited to facility fees. The acquisition is unlikely to have an anticompetitive effect on professional services fees because Blue Springs and OCSC do not employ physicians and, therefore, do not charge or compete for those fees.

Outpatient surgical services markets are local in nature. Evidence gathered during our investigation of the proposed acquisition establishes that patients have a strong preference for receiving outpatient surgical services within the area where they live or work. Accordingly, the proposed acquisition raises serious antitrust concerns for patients seeking outpatient surgical services in the southwestern Volusia County, Florida, area, which includes the cities of Orange City and Deltona, Florida (the ''Orange City/Deltona Area''). The evidence indicates that commercially insured patients who reside in the Orange City/Deltona Area are unlikely to seek outpatient surgical services from more distant providers, even in response to a small but significant and non-transitory increase in price.

The proposed acquisition would combine the only two multi-specialty ASCs in the Orange City/Deltona Area, Symbion's Blue Springs and Surgery Partners' OCSC, and, post-merger, would leave commercial health plans and commercially insured patients in the Orange City/Deltona Area with only one meaningful alternative to Surgery Partners for outpatient surgical services. Absent relief, the proposed acquisition would substantially increase concentration in the Orange City/Deltona Area market for outpatient surgical services. Using the Herfindahl-Hirschman Index (''HHI''), the standard measure of market concentration under the 2010 Department of Justice and Federal Trade Commission Merger Guidelines (''Merger Guidelines''), the proposed acquisition would result in a post-merger HHI of greater than 2,500 and a delta of greater than 1,000, thus creating a presumption under the Merger Guidelines that the transaction will result in competitive harm.

IV. Competitive Effects of the Proposed Acquisition

The evidence gathered in staff's investigation establishes that Symbion's Blue Springs and Surgery Partners' OCSC are each other's closest competitors, competing head-to-head on a number of price and non-price factors. By eliminating this close competition between Surgery Partners and Symbion, the proposed acquisition is likely to increase Surgery Partners' bargaining leverage in post-merger negotiations with commercial health plans in the Orange City/Deltona Area and result in higher reimbursement rates. Absent relief, the proposed acquisition would also reduce Surgery Partners' competitive incentives to maintain and improve the quality of care of its ASCs in the Orange City/Deltona Area. Ultimately, these effects would be felt by local patients in the form of higher health insurance premiums and out-of-pocket costs, as well as reduced access to high quality care.

New entry or expansion is unlikely to deter or counteract the anticompetitive effects of the proposed acquisition in the Orange City/Deltona Area. Significant entry barriers include the time and costs associated with constructing or expanding an ASC or hospital-based outpatient surgical services facility, regulatory and licensing requirements that govern the provision of outpatient surgical services, and the need to recruit a sufficient number of physicians to staff an ASC in order to restore the competition lost as a result of the proposed acquisition. Several market-specific factors, including a lack of sufficient demand and the potential inability to recruit qualified personnel to the area, also reduce the likelihood of new entry in the Orange City/Deltona Area. For these

reasons, it is unlikely that new entry or expansion sufficient to achieve a significant market impact will occur in a timely manner.

V. The Proposed Consent Agreement

The proposed Consent Agreement remedies the concerns about the effect of the transaction on competition in the Orange City/Deltona Area. The proposed Consent Agreement would maintain competition in the area by requiring Surgery Partners to fully divest its newly acquired ownership interest in Blue Springs in a manner approved by the Commission. The parties have indicated they will propose to divest this interest in Blue Springs to Dr. Mark Hollmann, one of Blue Springs' other current owners, who is actively involved in Blue Springs' operations and a physician at the ASC. Any potential buyer for this ownership interest is subject to the prior approval of the Commission. The proposed Consent Agreement requires Surgery Partners to provide transitional services to the approved acquirer for a period of up to six months, renewable for an additional six months at the option of the acquirer, to assist the acquirer in operating Blue Springs as a viable and ongoing business. Until the divestiture is completed, Surgery Partners is required to hold its interest in Blue Springs separate, subject to the standard terms of the Order to Hold Separate and Maintain Assets (''Hold Separate Order''). Additionally, the Commission has appointed Richard Shermer as the Hold Separate Monitor to oversee compliance with the Hold Separate Order. If, for any reason, Surgery Partners fails to divest its interest in Blue Springs within sixty (60) days after entry of the final Decision and Order, the Commission has the right to appoint a divestiture trustee to divest Surgery Partners' interest in either Blue Springs or OCSC, expeditiously and at no minimum price.

The sole purpose of this analysis is to facilitate public comment on the Consent Agreement. This analysis does not constitute an official interpretation of the Consent Agreement or modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2014–26433 Filed 11–5–14; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Electronic Government Office, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for a 3-year renewal of a previously approved information collection assigned OMB control number 4040–0008—SF–424 C Budget Information for Construction Programs, which expired on June 30, 2014. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *ed.calimag@hhs.gov* or by calling (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–EGOV–21479–60D for reference.

Information Collection Request Title: SF–424 C Budget Information for Construction Programs.

Abstract: SF–424 C Budget Information for Construction Programs is used to request funds for construction grant programs.

Need and Proposed Use of the Information: The SF–424 C Budget Information for Construction Programs is used to request funds for construction grant programs. The Federal awarding agencies use information submitted on this form for award determination of the Federal assistance awards programs.

Likely Respondents: Federal grant applicants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	1,254	1	1	1,254
Total	1,254	1	1	1,254

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26377 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–20883–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before December 8, 2014.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990-new 30D for reference.

Information Collection Request Title: Tissue and Organ Donor epidemiology Study (TODES).

Abstract: This Study is a request for a new data collection OMB Number: 0990-new TODES is being conducted in order to better understand the impact of donor screening and selection procedures, and to determine the extent of donor-donation level data that are collected for organ and tissue (including ocular) donors. The data that are obtained from Organ Procurement Organizations (OPOs) and Eye Banks will provide a better characterization of the deceased donor pool; information regarding data management and storage practices; and a measure of the degree of standardization of data collected by various organizations across the U.S. TODES may provide better estimates of the risk of HIV, HBV and HCV infections associated with organ and tissue transplantation and the potential for disease transmission; illustrate differences in laboratory screening methods and the impact of protocol variations; and serve as a pilot for future studies. This retrospective study will provide a framework for future, prospective studies of organ and tissue donors that could inform policy decisions regarding donor qualification procedures and, potentially, increase the donor pool.

Need and Proposed Use of the Information: A workshop in June 2005 (''Preventing Organ and Tissue Allograft-Transmitted Infection: Priorities for Public Health Intervention'') identified gaps in organ and tissue safety in the United States. Participants developed a series of allograft safety initiatives, assessed progress, and identified priorities for future interventions. Despite progress, improved recognition and prevention of donor-derived transmission events is needed. It was concluded that this requires systems integration across the organ and tissue transplantation communities including organ procurement organizations, eye and tissue banks, and transplant infectious disease experts. Commitment of resources and improved coordination of efforts are required to develop essential tools to enhance safety for transplant recipients.

Likely Respondents: organ procurement organizations, tissue banks, eye banks

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
OPOs	17	1	85/60	24.1
Eye Banks	7	1	55/60	6.4
Total				30.5

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26359 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Electronic Government Office, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Electronic Government Office (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is to reinstate the use of the previously approved information collection, Project Abstract Summary, assigned OMB control number 0980–0204 which expired on 11/30/2011, and to reinstate this information collection to 4040–0010 with a 3 year clearance. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *ed.calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: Project Abstract Summary.

OMB No.: 4040–0010.

Abstract: The Project Abstract Summary provides the Federal grant-making agencies a simplified alternative to the Standard Form 424 data set and form. Agencies may use the Project Abstract Summary for grant programs not required to collect all the data that

is required on the SF–424 core data set and form.

Need and Proposed Use of the Information: The Project Abstract Summary is used by the public to apply for Federal financial assistance in the forms of grants. These forms are submitted to the Federal grant-making agencies for evaluation and review.

Likely Respondents: Organizations and institutions seeking grants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours for the Department of Health and Human Services estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN FOR HHS—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Project Abstract Summary	4,270	1	1	4,270
Total	4,270	1	1	4,270

EGOV specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26378 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Electronic Government Office, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for reinstatement of a previously-approved information collection assigned OMB control number 4040–0012—SF–270: Request for Advance or Reimbursement, which expired on October 31, 2013. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *Ed.calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: Request for Advance or Reimbursement.

Abstract: The SF–270 is used to request funds for all non-construction grant programs when letters of credit or predetermined advance methods are not used.

Need and Proposed Use of the Information: The SF–270 is used to request funds for all non-construction grant programs when letters of credit or predetermined advance methods are not used. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. The Federal awarding agencies and OMB use information reported on this form for general management of the Federal assistance awards programs.

Likely Respondents: Federal grant award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	100,000	1	1	100,000

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Total	100,000	1	1	100,000

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26380 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for issuance of a new expiration date of a previously-approved information collection assigned OMB control number 4040–0014–SF–425 Federal Financial Report, which expires on February 28, 2015. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *Ed.calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: SF–425 Federal Financial Report.

Abstract: The SF–425 Federal Financial Report is used by persons who request or receive a Federal contract, grant, cooperative agreements, loan or a Federal commitment to insure or guarantee a loan for financial reporting to the awarding agency.

Need and Proposed Use of the Information: The SF–425 Federal Financial Report is used by persons who request or receive a Federal contract, grant, cooperative agreements, loan or a Federal commitment to insure or guarantee a loan. The Federal awarding agencies and OMB use information reported on this form for general management of the Federal assistance awards programs.

Likely Respondents: Federal grant award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	100,000	1	1	100,000
Total	100,000	1	1	100,000

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26382 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for a 3 year renewal of a previously-approved information collection assigned OMB control number 4040–0006—SF–424 A Budget Information for Non-Construction Programs, which expired on June 30, 2014. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR. Additionally, Grants.gov requests a change to the Application Instructions for this form. Application instructions are available from the Grants.gov program management office. The point of contact is Ed Calimag (*ed.calimag@hhs.gov*).

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *Ed.Calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: SF–424 A Budget Information for Non-Construction Programs.

Abstract: SF–424 A Budget Information for Non-Construction Programs is used to request funds for non-construction grant programs.

Need and Proposed Use of the Information: The SF–424 A Budget Information for Non-Construction Programs is used to request funds for construction grant programs. The Federal awarding agencies use information submitted on this form for award determination of the Federal assistance awards programs.

Likely Respondents: Federal grant applicants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	40000	1	1	40000
Total	40000	1	1	40000

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26374 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Electronic Government Office, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for reinstatement of a previously-approved information collection assigned OMB control number 4040–0011—SF–271 Outlay Report and Request for Reimbursement for Construction Programs, which expired on October 31, 2013. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *ed.calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: SF–271 Outlay Report and Request for Reimbursement for Construction Programs.

Abstract: The SF–271 Outlay Report and Request for Reimbursement for Construction Programs is used to request funds for all non-construction grant programs when letters of credit or predetermined advance methods are not used.

Need and Proposed Use of the Information: The SF–271 is used to request reimbursement for all construction programs. The Federal awarding agencies and OMB use information reported on this form for general management of the Federal assistance awards programs.

Likely Respondents: Federal grant award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time

needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	40,000	1	1	40,000
Total	40,000	1	1	40,000

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26379 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Electronic Government Office, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for reinstatement of a previously-approved information collection assigned OMB control number 4040–0016—SF–429 Real Property Status Report, which expired on July 31, 2014. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *Ed.calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: SF–429 Real Property Status Report.

Abstract: SF–429 Real Property Status Report standard disclosure reporting form for lobbying paid for with non-Federal funds.

Need and Proposed Use of the Information: This is a standard report to be used by recipients of Federal financial assistance to report real property status (Attachment A) or to request agency instructions on real property (Attachments B, C) that was/will be provided as Government Furnished Property (GFP) or acquired (i.e., purchased or constructed) in whole or in part under a Federal financial assistance award (i.e., grant, cooperative agreement, etc.). This includes real property that was improved using Federal funds and real property that was donated to a Federal project in the form of a match or cost share donation. This report is to be used for awards that establish a Federal Interest on real property.

Likely Respondents: Federal grant award recipients

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	100,000	1	1	100,000
Total	100,000	1	1	100,000

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26383 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Electronic Government Office, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for reinstatement of a previously-approved information collection assigned OMB control number 4040–0013—SF–LLL—Disclosure of Lobbying Activities, which expired on December 31, 2013. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *Ed.calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: Disclosure of Lobbying Activities.

Abstract: The SF–LLL is the standard disclosure reporting form for lobbying paid for with non-Federal funds, as required by the Byrd Amendment, as amended by the Lobbying Disclosure Act of 1995.

Need and Proposed Use of the Information: The SF–LLL is the standard disclosure reporting form for lobbying paid for with non-Federal funds, as required by the Byrd Amendment, as amended by the Lobbying Disclosure Act of 1995. The form is used by persons who request or receive a Federal contract, grant, cooperative agreements, loan or a Federal commitment to insure or guarantee a loan. The Federal awarding agencies and OMB use information reported on this form for general management of the Federal assistance awards programs.

Likely Respondents: Federal grant award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	17,144	1	.25	4,286
Total	17,144	1	.25	4,286

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26381 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for reinstatement of a previously-approved information collection assigned OMB control number 4040–0002—SF424—Mandatory, which expired on May 31, 2014. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *Ed.Calimag@hhs.gov* or (202) 690–7569

FOR FURTHER INFORMATION CONTACT: *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: SF–424 Mandatory Form.

Abstract: The SF–424 Mandatory Form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use the SF–424 Mandatory Form for grant programs not required to collect all the data that is required on the SF–424 core data set and form.

Need and Proposed Use of the Information: To obtain Federal grants funds, applicant organizations must apply to the Federal agency or organization responsible for administering the grant program. The SF–424 Mandatory Form will be used by applicants to apply for Federal grants and for Federal agencies to review submissions for Federal grants funds.

Likely Respondents: Federal grant applicants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	8388	1	1	8388
Total	8388	1	1	8388

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26371 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for reinstatement of a previously-approved information collection assigned OMB control number 4040–0003—SF424—Short Organizational, which expired on July 30, 2011. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *Ed.Calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: SF–424 Short Organizational Form.

Abstract: The SF–424 Short Organizational Form provides the Federal grant-making agencies a simplified alternative to the Standard Form 424 data set and form. Agencies may use the SF–424 Short Organizational Form for grant programs not required to collect all the data that is required on the SF–424 core data set and form.

Need and Proposed Use of the Information: To obtain Federal grants funds, applicant organizations must apply to the Federal agency or organization responsible for administering the grant program. The SF–424 Short Organizational Form will be used by applicants to apply for Federal grants and for Federal agencies to review submissions for Federal grants funds.

Likely Respondents: Federal grant applicants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden Hours
	8388	1	1	8388
Total	8388	1	1	8388

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26373 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for a 3 year renewal of a previously-approved information collection assigned OMB control number 4040–0007—SF–424 B Assurances for Non-Construction Programs, which expired on June 30, 2014. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *Ed.Calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: Form is available upon request.

Information Collection Request Title: SF–424 B Assurances for Non-Construction Programs.

Abstract: SF–424 B Assurances for Non-Construction Programs is used as by the grant applicant when requesting funds for non-construction grant programs.

Need and Proposed Use of the Information: The SF–424 B Assurances for Non-Construction Programs form is used as by the grant applicant when requesting funds for non-construction grant programs. The Federal awarding agencies use information submitted on this form for award determination of the Federal assistance awards programs.

Likely Respondents: Federal grant applicants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	40000	1	1	40000
Total	40000	1	1	40000

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26375 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, Grants.gov (EGOV), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for a 3 year renewal of a previously-approved information collection assigned OMB control number 4040–0006–SF–424 D Assurances for Construction Programs, which expired on June 30, 2014. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Prior to submitting that ICR to OMB, EGOV seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 5, 2015.

ADDRESSES: Submit your comments to *ed.calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: *Ed.Calimag@hhs.gov* or (202) 690–7569.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–EGOV–21478–60D for reference.

Information Collection Request Title: SF–424 D Assurances for Construction Programs.

Abstract: SF–424 D Assurances for Construction Programs is used as certification of assurances by the grant applicant when requesting funds for construction grant programs. Need and Proposed Use of the Information: The SF–424 D Assurances for Construction Programs form is used as certification of assurances by the grant applicant when requesting funds for non-construction grant programs. The Federal awarding agencies use information submitted on this form for award determination of the Federal assistance awards programs.

Likely Respondents: Federal grant applicants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	5,694	1	1	5,694
Total	5,694	1	1	5,694

Grants.gov specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (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.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–26376 Filed 11–5–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination Concerning a Petition to Add a Class of Employees to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a determination concerning a petition to add a class of employees from the Simonds Saw and Steel Company in Lockport, New York, to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA).

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 1090 Tusculum Avenue, MS C–47, Cincinnati, OH 45226–1938, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION:

Authority: [42 U.S.C.7384q].

On October 9, 2014, the Secretary of HHS determined that the following class of employees does not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

All Atomic Weapons Employer employees who worked at Simonds Saw and Steel Co. in Lockport, New York, from January 1, 1958, through December 31, 2006.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2014–26425 Filed 11–5–14; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15DA]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public 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. To request more information on the below

proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. 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; (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. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

''Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics''—American Society for Microbiology—NEW—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention is funding three 5-year projects collectively entitled ''Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics''. An ''LPG'' is defined as written recommendations for voluntary, standardized approaches for medical laboratory testing that takes into account processes for test selection, sample procurement and processing, analytical methods, and results reporting for effective diagnosis and management of disease and health conditions. LPGs may be disseminated to, and used by, laboratorians and clinicians to assist with test selection and test result interpretation. The overall purpose of these cooperative agreements is to increase the effectiveness of LPGs by defining measures and collecting information to inform better LPG creation, revision, dissemination, promotion, uptake and impact on clinical testing and public health. The project will explore how these processes and their impediments and facilitators differ among various intended users of LPGs. Through this demonstration project, CDC seeks to understand how to customize LPG creation and promotion to better serve these intended users of LPGs. An important goal is to help organizations that sponsor the development of LPGs create a sustainable approach for continuous quality improvement to evaluate and improve an LPG's impact through better collection of information.

The CDC selected three organizations that currently create and disseminate LPGs to support activities under a cooperative agreement funding mechanism to improve the impact of their LPGs. The American Society for Microbiology (ASM), the Clinical and Laboratory Standards Institute, and the College of American Pathologists, will each use their LPGs as models to better understand how to improve uptake and impact of these and future LPGs. Only the ASM submission will be described in this notice.

The ASM project will address four LPGs that are important to clinical testing and have a high public health impact: Reducing blood culture contamination (BCC), rapid diagnosis of blood stream infections (BSI), proper collection and transport of urine (UT), and microbiological practices to improve the diagnosis and management of patients with *Clostridium difficile* (*C. difficile*) infection (CDI). The BCC LPG was published and it includes recommendations for the use of: (1) Venipuncture over catheters as the preferred technique for sample collection in a clinical setting, and (2) phlebotomy teams over non-phlebotomist staff for collecting blood for culture. The BSI report examines the effectiveness of rapid diagnostic tests to promote more accurate and timely administration of targeted antibiotic therapy for patients with bloodstream infections. This report will be published and recommendations will be developed based on additional information collected. Practices related to the collection, storage and preservation of urine for microbiological culture that improve the diagnosis and management of patients with urinary tract infections were analyzed and approved recommendations will be published. Microbiological practices related to improving diagnosis and management of patients with *C. difficile* infection will be collected and analyzed, and recommendations will also be developed and published.

The intended respondents of ASM's surveys will include microbiology supervisors, laboratory directors, and laboratory managers. For this request for OMB approval of a new information collection, we will be requesting approval to collect baseline and post-dissemination information for the BCC LPG. Because the BSI, UT and CDI reports are not yet published, ASM will conduct a baseline survey to determine current practices prior to dissemination of the LPGs.

On behalf of the ASM and the CDC, the Laboratory Response Network (LRN), which was founded by the CDC, will recruit laboratories that perform the kinds of testing affected by these LPGs to take the surveys. Messages regarding ASM surveys will be worded as an invitation, not as a coercive request. Some states may opt not to recruit LRN laboratory participation, but because the issues are important to clinical and public health, we expect good participation by most states. This mechanism will assure the best response rate of all the options we considered.

The CDC LRN Coordinator will email a letter to the Laboratory Director of the LRN Reference Laboratories, (i.e., 50 State Public Health Laboratories, the New York City Public Health Laboratory and the Los Angeles County Public Health Laboratory). These 52 LRN Reference Laboratory Directors will be asked to then email the sentinel laboratories, which include hospital and independent laboratories, in their states, and provide a hyperlink to access the survey tool on-line via a landing page provided by ASM through their Clinical Microbiology portal. Survey Monkey will be used as the data collection instrument and responses will be collected and maintained by ASM. We anticipate that a maximum of 4,200 sentinel laboratories will be contacted and asked to complete the survey on-line. ASM anticipates achieving an 80% response rate with their information collections, or 3,360 out of ~4,200 aggregate responses for each of the 5 different surveys.

For burden calculations, we assume one respondent per laboratory and we also assume respondents will include microbiology supervisors, laboratory directors, and laboratory managers, approximately in a 50%:25%:25% distribution, respectively. According to ASM, the burden hours per respondent who will be invited to participate in the BCC baseline and post-dissemination surveys and the BSI, UT and CDI baseline surveys will be 20 minutes. This time frame was specified based on ASM's previous experiences conducting laboratory surveys. Each survey will be pilot tested with 9 or fewer respondents before dissemination to assure that completing the surveys does not extend past 20 minutes.

CDC is requesting a three-year OMB approval to collect this information. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Microbiology Supervisors	BCC	2,100	2	20/60	1,400
	BSI	2,100	1	20/60	700
	UT	2,100	1	20/60	700
	CDI	2,100	1	20/60	700
Laboratory Directors	BCC	1,050	2	20/60	700
	BSI	1,050	1	20/60	350
	UT	1,050	1	20/60	350
	CDI	1,050	1	20/60	350
Laboratory Managers	BCC	1,050	2	20/60	700
	BSI	1,050	1	20/60	350
	UT	1,050	1	20/60	350
	CDI	1,050	1	20/60	350
Total					7,000

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–26354 Filed 11–5–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–0931]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public 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. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. 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; (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. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Healthy Homes and Lead Poisoning Surveillance System (HHLPSS) (OMB No. 0920–0931, expires 04/30/2015)—Extension—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The overarching goal of the Healthy Homes and Lead Poisoning Surveillance System (HHLPSS) is to support healthy homes surveillance activities at the state and national levels. CDC is requesting a three-year extension of Office of Management and Budget (OMB) approval for up to 40 state and local Healthy Homes Childhood Lead Poisoning Prevention Programs (CLPPP) and the state-based Adult Blood Lead Epidemiology and Surveillance (ABLES) programs. The programs will report information (e.g., presence of lead paint, age of housing, occupation of adults and type of housing) to the CDC. They will use the system as designed.

Over the last three years, 7 states have adopted the HHLPPS and 13 are in beta-testing. In October 2014, CDC began funding 40 state and local blood lead surveillance programs. Many of these programs and their subcontractors at the local level will come on line with HHLPSS in the next year.

The objectives for this surveillance system are two-fold. First, the HHLPSS allows CDC to systematically track how the state and local programs conduct case management and follow-up of residents with housing-related health outcomes. Second, the system allows for identification and collection of information on other housing-related risk factors. Childhood and adult lead poisoning is just one of many adverse health conditions that are related to common housing deficiencies. Multiple hazards in housing (e.g., mold, vermin, radon and the lack of safety devices) continue to adversely affect the health of residents. HHLPSS offers a coordinated, comprehensive, and systematic public health approach to eliminate multiple housing-related health hazards.

HHLPSS enables flexibility to evaluate housing where the risk for lead poisoning is high, regardless of whether children less than 6 years of age currently reside there. Thus HHLPSS supports CDC efforts for primary prevention of childhood and adult lead poisoning. Over the past several decades there has been a remarkable reduction in environmental sources of lead, improved protection from occupational lead exposure, and an overall decreasing trend in the prevalence of elevated blood lead levels (BLLs) in U.S. adults. As a result, the U.S. national BLL geometric mean among adults was 1.2 μg/dL during 2009–2010. Nonetheless, lead exposures continue to occur at unacceptable levels. Current research continues to find that BLLs previously considered harmless can have harmful effects in adults, such as decreased renal function and increased risk for hypertension and essential tremor at BLLs <10 μg/dL.

There is no cost to respondents other than their time. The total estimated annual burden hours is 640.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
State, Local, and Territorial Health Departments.	Healthy Homes and Lead Poisoning Surveillance System (HHLPSS) Variables.	40	4	4	640
Total					640

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–26355 Filed 11–5–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–15–14HW]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) 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; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluating the Effectiveness of Interventions for Airplane Cargo Baggage Handling—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 worker safety and health through research and prevention. Under Public Law 91–596, sections 20 and 22 (Section 20–22, Occupational Safety and Health Act of 1970), NIOSH has the responsibility to conduct research to advance the health and safety of workers. In this capacity, NIOSH is seeking a three-year approval from the Office of Management and Budget (OMB) to conduct a study to assess the effectiveness and cost-benefit of engineering interventions for reducing musculoskeletal disorders (MSDs) among baggage handlers working at airports.

In recent years (2009–2012), the overall annual incidence rate of work-related injuries resulting in days away from work, job transfer, or restricted work in the airport passenger transportation industry was approximately 7%. This is one of the highest rates in all job categories tracked by the Bureau of Labor Statistics (BLS). A very large proportion of the injury cases in the airport passenger transportation industry are musculoskeletal disorders (MSDs), especially low back disorders, which were found primarily in baggage handlers working in the ramp or tarmac

area, where airplanes are parked for services.

Two interventions to be evaluated are the power stow (PS) and the vacuum lift (VL) systems. The PS is a semi-automatic conveyor to assist the user in transferring bags. The VL is a lifting assist hoist to assist in manual lifting. The PS will be used in the cargo compartments in the airplane, while the VL will be used for tasks required for transferring bags from a baggage cart to the conveyor connected to the cargo compartments. The systems will be evaluated through a prospective study design with a control group.

An estimate of 960 ramp workers are planned to be recruited into the study. Stratified by their crew units (5 workers per crew), 60 of 960 ramp workers will be randomly chosen to use the interventions (30 in each intervention group). The remainder of 900 will serve as the control group. MSD risk and incidence data will be collected by a self-reported questionnaire at baseline, one and two years after implementation of the two interventions. Additional MSD symptoms and intervention compliance information will be requested monthly by a short mail-in questionnaire. The effectiveness of the interventions will be assessed by a reduction in MSD risks or incidence rates at the end of the two follow-up periods. The primary health outcomes from the questionnaires include self-reported musculoskeletal symptoms in multiple body regions (neck, shoulders, low back and knees), sickness, absence, and medical attention due to the symptoms. The annual questionnaire will be used to collect additional information (demographics, alcohol consumption, health problems, etc.), job demands (work method, time spent on each job position, etc.), and psychosocial job characteristics (perceived job stress, coworker support, etc.). The annual estimated time for completing the yearly questionnaire is 30 minutes per person.

Between the baseline and the second follow-up, a monthly mail-in short survey will be self-administered to collect additional information on participants' work methods/postures and health outcomes in the preceding month. The effectiveness of the interventions will be evaluated by several health outcome measures including self-reported musculoskeletal pain symptoms in multiple body regions (neck, shoulders, low back and knees), sickness absence, and worker compensation costs in a two-year study period. The estimated time for completing the monthly questionnaire is 10 minutes per person.

A small portion of the study population (30 from the control, 30 from the PS and VL intervention groups, respectively) will be sampled for their work using a video task analysis method. Hand forces required for the recorded tasks will be measured by NIOSH to estimate operational hand forces for the tasks. WMSD risk data for each task will be determined by estimated working posture in the video recording and measured hand force data using a biomechanical model. Baggage weight information in the airline company baggage record system will be used to estimate the number of baggage handling operations per flight/day to estimate a cumulative risk. Through the prospective study design, a potential exposure-response relationship between the WMSD risk factors and WMSD incidence, adjusted for personal and psychosocial factors, will be evaluated for airport baggage handlers. There is no burden to respondents during video recording and hand force sampling because the video and force data collections will be conducted by NIOSH investigators without respondents' involvement.

An informed consent form will be collected one time during the initial enrollment period. Annualized, over the course of the three year study, this will be 320 participants completing the informed consent. An early exit phone interview will be conducted if the respondent decides to leave the study before the end date. A 20% early exit study rate during the entire study period of three years is estimated. This amounts to 64 participants completing the early exit interview annually. The number of respondents with missing data (approximately 5 questionnaire items across the annual and monthly questionnaires per respondent) is estimated to be 5% annually. Based on the above information and the frequencies of the annual and monthly surveys, the total estimated annualized burden is 2,436 hours.

Once the study is completed, results will be made available through the NIOSH Internet site, trade journals and peer-reviewed publications. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Airline baggage handlers in the ramp area	Self-reported annual questionnaire survey for MSD symptoms and risk factors.	960	1	30/60
	Self-reported monthly questionnaire for MSD symptoms and work method.	960	12	10/60
	Informed Consent Form	320	1	5/60
	Follow-up on missing questionnaire data	48	5	1/60
	Early Exit Interview	64	1	5/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–26353 Filed 11–5–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–15–14CP]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) 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; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Monitoring and Reporting System for the State Public Health Actions Cooperative Agreement—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2013, CDC initiated a new cooperative agreement program: ''State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors and Promote School Health,'' under Funding Opportunity Announcement (FOA) DP13–1305. The new program, commonly referred to as the State Public Health Actions program, provides funding for integrated approaches to preventing and managing chronic conditions that share common risk factors. Cooperative agreement awards were made to all 50 states and the District of Columbia. Thirty-two (32) awardees were funded at the Enhanced level to implement evidence-based environmental approaches that address the underlying causes of chronic diseases, and interventions that strengthen systems and resources for early detection and better management of chronic diseases. Nineteen (19) awardees were initially funded at the Basic level for health promotion, epidemiology, and surveillance activities. In 2014, all awardees received supplemental funding to increase program activities. Basic-level awardees received supplemental funding to incorporate a number of additional interventions also being implemented by awardees funded at the Enhanced level. Enhanced-level awardees received additional funds to increase the number and intensity of activities occurring within already selected interventions.

CDC requests OMB approval to collect performance monitoring information from all awardees participating in the State Public Health Actions program. Annually, each awardee will submit a Work Plan, Budget, and Evaluation Plan. The Work Plan and Budget information will be submitted to CDC by completing a spreadsheet template, and uploading the information to a secure, password-protected FTP site. Evaluation Plans will also be submitted to CDC via the secure FTP site, but will be based on commonly available word processing software. CDC initially considered collecting information through a customized, Web-based management information system (MIS), but has decided to implement a revised information collection plan utilizing commonly available commercial software. By developing user-friendly templates (tools) for this software, CDC anticipates that the reporting and tracking burden for awardees will be reduced due to: (1) Awardees' familiarity with the software, which reduces training burden; and (2) the compatibility of the templates with other record keeping processes that are already in place for many awardees. CDC staff and contractors will be responsible for converting each awardee's submissions into a secure MIS for reporting and analysis.

CDC anticipates that respondent burden will be greatest for the initial Work Plan, Budget, and Evaluation Plan submissions. A separate allocation for the burden associated with initial population of the reporting tools is provided, and is annualized over the three-year clearance period. Burden per response for routine annual reporting is lower since annual Work Plan, Budget, and Evaluation progress reports will be limited to entering changes, updates, and new activities. Overall, CDC anticipates that burden will be lower for awardees funded at the Basic level (including the 2014 supplement) than for awardees funded at the Enhanced level.

The information to be collected will help CDC and awardees assure compliance with cooperative agreement requirements, support program evaluation efforts, and obtain information needed to respond to inquiries about program activities and effectiveness from Congress and other sources. Budget information will be collected and tracked to assure proper disbursement of, and accounting for, funds awarded.

OMB approval is requested for three years. Participation is required as a condition of cooperative agreement funding. There are no costs to respondents other than their time. The total estimated burden hours are 665.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
FOA 1305 Program Awardees Basic Level Supplement	Initial Work Plan	6	1	6

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
FOA 1305 Program Awardees Enhanced Level	Initial Budget	6	1	4
	Initial Evaluation Plan	6	1	4
	Annual Work Plan Progress Report	19	1	1
	Annual Budget Progress Report	19	1	1
	Annual Evaluation Report	19	1	2
	Initial Work Plan	11	1	12
	Initial Budget	11	1	9
	Initial Evaluation Plan	11	1	6
	Annual Work Plan Progress Report	32	1	2
	Annual Budget Progress Report	32	1	1.5
	Annual Evaluation Report	32	1	3

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–26352 Filed 11–5–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Proposed Healthy Marriage and Responsible Fatherhood performance measures and additional data collection (part of the Fatherhood and Marriage Local Evaluation and Cross-site (FaMLE Cross-site) Project).

OMB No.: New Collection.

Background

For decades various organizations and agencies have been developing and operating programs to strengthen families through healthy marriage and relationship education and responsible fatherhood programming. The Administration for Children and Families (ACF), Office of Family Assistance (OFA), has had administrative responsibility for federal funding of such programs since 2006 through the Healthy Marriage (HM) and Responsible Fatherhood (RF) Grant Programs. The authorizing legislation for the programs may be found in Section 403(a)(2) of the Social Security Act [1]. Responsible Fatherhood grantees provide a comprehensive set of services designed to promote responsible fatherhood including activities related to promoting economic stability, fostering responsible parenting, and promoting healthy marriage. Grantees receiving funding for Healthy Marriage offer a broad array of services designed to promote healthy marriage.

The federal government currently collects a set of performance measures from HM and RF grantees. The purpose of this previously approved information collection is to allow OFA and ACF to carry out their responsibilities for program accountability. Descriptions of the information collection may be found at *http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201206-0970-005;* all measures may be found at *http://www.reginfo.gov/public/do/PRAICList?ref_nbr=201206-0970-005.*

The Fatherhood and Marriage Local Evaluation (FaMLE) Cross-Site Project

The Offices of Family Assistance (OFA) and Planning, Research and Evaluation (OPRE) in the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) are proposing new data collection activities to replace existing performance measures as part of the Fatherhood and Marriage Local Evaluation and Cross-site (FaMLE Cross-site) Project. The purpose of the FaMLE Cross-site Project is to support high quality data collection, strengthen local evaluations, and conduct cross-site analysis for the Responsible Fatherhood and Healthy Marriage grantees.

The FaMLE Cross-site project will answer three main research questions: (1) What strategies did grantees use to design well-conceived programs? (2) What strategies did grantees use to successfully implement well-conceived programs? (3) What were the reported outcomes for participants in the programs? In order to answer these questions, we are considering a new set of data collection activities.

Current Request

ACF is engaged in a learning agenda to increase our understanding of Healthy Marriage and Responsible Fatherhood programs. This means that we incorporate multiple opportunities and options for learning throughout a program's implementation that provide a range of insights and perspectives. These opportunities help programming constantly develop and advance. For example, data provide the opportunity to feed information back to decision-makers and leaders—both those on the ground and those in management—to inform program design, operation, and oversight.

ACF is requesting comment on the following:

Performance measures. ACF is proposing a new set of performance measures to be collected by all grantees, beginning with the next round of HMRF grants. These measures will collect standardized information in the following areas:

- Applicant characteristics;
- Program operations (including program characteristics and service delivery); and
- Participant outcomes (will be measured both at initiation of program services (pre-test) and completion (post-test)).

These draft measures were developed per extensive review of the research literature and grantees' past measures.

The next set of grantees will be required to submit data on a set of standardized measures covering these areas on a regular basis (e.g., quarterly). In addition to the performance measures mention above, ACF seeks comment on draft instruments for these data submissions:

- Quarterly Performance Report (QPR), and
- Semi-annual Performance Progress Report (PPR).

A new management information system is being developed which would improve efficiency and the quality of data, and make reporting easier.

Standardized measures and reporting in these areas will enable ACF to track programming outputs and outcomes across programs, and will allow grantees to self-monitor progress.

Additional data collection. As an additional component of the learning agenda, the FaMLE Cross-Site contractor will collect information from a sub-set of grantees on how they designed and implemented their programs (information on outcomes associated with programs will also be assessed). This sub-set of grantees will be required to participate in the additional data collection noted below. The following protocols have been developed:

- Staff interview protocol on program design (will be collected from about half of all grantees);
- Staff interview protocols on program implementation (will be collected from about 10 grantees); and
- Program participant focus group protocol (will be conducted with about 10 grantees).

ACF also seeks comment on these draft protocols.

Respondents

The respondents to the data collection instruments include Responsible Fatherhood and Healthy Marriage Program grantees (e.g., grantee staff) and program participants.

Annual Burden Estimates

The table below is required by law for **Federal Register** notices like this one. The federal government's Office of Management and Budget requires federal agencies, including ACF, to estimate how many hours it will take respondents to complete data collection, and to publish these estimates in the **Federal Register**. The following table provides our estimates.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Applicant characteristics (applicant burden)	157,500	52,500	1	0.25	13,125
Applicant characteristics (staff burden)	1080	360	146	0.25	13,140
Program operations (related to program characteristics)	360	120	1	0.75	90
Program operations (related to service delivery)	432	144	257	0.50	18,504
Participant outcomes (pre-test)	110,700	36,900	1	0.42	15,498
Participant outcomes (post-test)	84,600	28,200	1	0.42	11,844
Data entry (for grantees that do not use new management information system, includes applicant characteristics and participant outcomes)	144	48	274	0.21	2,762
Quarterly Performance Form (QPR)	72	24	1	1	24
Semi-annual Performance Progress Report (PPR)	360	120	2	3.2	768
Staff interview protocol on program design	60	20	1	1	20
Staff interview protocol on program implementation	300	100	1	1	100
Program participant focus group protocol	200	67	1	1.50	101

Estimated Total Annual Burden Hours: 75,976.

Note: The annual number of hours shown for ''applicant characteristics (staff burden)'' (13,140) is slightly higher than the annual number of hours shown for ''applicant characteristics (applicant burden)'' (13,125) due to rounding up the average number of responses per staff to the nearest whole number (146).

How To Obtain Copies of the Data Collection Instruments

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *RFHM.FRN.response@acf.hhs.gov.* All requests should be identified by the title of the information collection.

Specific Areas for Comment

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Reference

[1] *http://www.ssa.gov/OP_Home/ssact/title04/0403.htm.*

Karl Koerper,

OPRE Reports Clearance Officer.

[FR Doc. 2014–26320 Filed 11–5–14; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.612]

Proposed Adoption of Administration for Native Americans Program Policies and Procedures

AGENCY: Administration for Native Americans, ACF, HHS.

ACTION: Notice for public comment.

SUMMARY: The Administration for Native Americans (ANA) invites public comment pursuant to Section 814 of the Native American Programs Act of 1974

(NAPA), as amended, which requires ANA to provide members of the public with the opportunity to comment on proposed changes in interpretive rules, general statements of policy, and rules of agency procedure or practice that affect programs, projects, and activities authorized under the NAPA, and to give notice of the final adoption of such changes at least 30 days before the changes become effective. In accordance with notice requirements of NAPA, ANA herein describes its proposal to fund projects, beginning in Fiscal Year (FY) 2015, under Alaska-Specific SEDS.

DATES: Submit written or electronic comments on this Notice, on or before December 8, 2014.

ADDRESSES: Send comments in response to this notice via email to Lillian A. Sparks, Commissioner, Administration for Native Americans, at *ANACommissioner@acf.hhs.gov.* Comments will be available for inspection by members of the public at the Administration for Native Americans, 901 D Street SW., Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT: Carmelia Strickland, Director, Division of Program Operations, ANA, (877) 922–9262.

SUPPLEMENTARY INFORMATION:

A. Funding Opportunity Announcements

Beginning in FY 2015, ANA proposes to re-establish publishing a separate Alaska-Specific SEDS Funding Opportunity Announcement (FOA) to target support and attention to core capacity building at the Alaska Native Village level. This Alaska-Specific SEDS FOA, Social and Economic Development Strategies for Alaska-SEDS–AK (HHS–2015–ACF–ANA–NK–0960) is intended to respond to the unique governmental structures in Alaska. Re-establishment of Alaska-Specific SEDS, is designed to provide targeted support for Village-specific projects to improve and strengthen the administrative and management capacity of Alaska Native Village governments, governments that are central to social and economic self-sufficiency in Alaska. From FYs 1984 through 2009, ANA funded Alaska-Specific SEDS projects under 45 CFR 1336.33 (a)(2) and (b)(4). In 2009, ANA stopped funding projects under Alaska-Specific SEDS and, from FYs 2010 through 2014, projects that had previously been funded under Alaska-Specific SEDS were funded under the general Social and Economic Development Strategies (SEDS) FOAs. This approach precluded implementation of 45 CFR 1336.33 (b)(4), a special provision applicable only to projects funded under Alaska-Specific SEDS, under which funding for core administrative capacity building projects at the Village government level is allowable, if the village does not have governing systems in place. Based on review of historical data covering the period from FYs 1984 through 2014, ANA has decided to re-establish Alaska-Specific SEDS in order to emphasize improving and strengthening the capacity of Alaska Native Village governments; focusing on the strengths present in Native Villages to generate evidence-based practices and sustainable approaches demonstrated to be effective at the Village level.

In an effort to meaningfully create opportunities to build and strengthen core governmental capacity in the areas of administration and project management at the Alaska Native Village level, ANA will make up to $1,000,000 available for Alaska-Specific SEDS funding in FY 2015 for new, community-based Village-level projects that will be available through competition under Social and Economic Development Strategies for Alaska-SEDS–AK (HHS–2015–ACF–ANA–NK–0960).

All language in the standing FOA, Social and Economic Development Strategies—SEDS (HHS–2014–ACF–ANA–NA–0776) available at *http://www.acf.hhs.gov/grants/open/foa/index.cfm?switch=foa&fon=HHS-2014-ACF-ANA-NA-0776,* will apply to the Alaska-Specific SEDS FOA, Social and Economic Development Strategies for Alaska-SEDS–AK (HHS–2015–ACF–ANA–NK–0960), except as follows:

B. Alaska-Specific SEDS Program Areas of Interest

ANA has identified the following program areas of interest for the Alaska-Specific SEDS FOA, however funding is not restricted to those listed below:

(a) *Governance:* Governance is defined as increasing the ability of tribal and Alaska Native Village governments to exercise local control and decision-making, and to develop and enforce laws, regulations, codes, and policies that reflect and promote the interests of community members. ANA recognizes the structure of governance that controls Native lands and communities in Alaska are more complex than in the lower 48 states. With some exceptions, most tribes in the lower 48 states escape the complicated jurisdictional and administrative situation that prevails in rural Alaska, where powers over lands, other resources, and relevant governmental programs are fragmented and widely dispersed among tribes, corporations, municipalities, governmental agencies, and other bodies. Examples of Alaska-Specific program areas of interest are:

- *Administrative and program management capacity building*—Planning and financial management capacity building to strengthen effective and accountable planning and management of Village-level government operations.
- *Governmental administration*—Improving Village-level capacity related to regulatory, judicial, and administrative infrastructure, including clarifying jurisdiction, developing or amending codes and procedures, enforcing contracts and property rights, and addressing family and child welfare issues.
- *Comprehensive strategies*—Developing Village-level strategies to assess and address the needs of children, youth, and community members.
- *Emergency Preparedness/Disaster Recovery/Disaster Preparedness*—Planning, analysis, and mitigation efforts to ensure needed services to better communicate and coordinate preparedness, response, and recovery efforts.
- *Adaptation and mitigation of impacts of climate change*—Assessment, planning, and implementation of efforts to adapt to climate change and to effectively respond to its impacts at the Village level, including efforts to address the effects of climate change on local fisheries and fresh water supplies, effects that increase the risk of flooding and wildfires, assessment and planning for relocation, and mitigation of impacts of erosion and permafrost melt.
- *Technology infrastructure*—Establishing and implementing Village-level systems to address internet connectivity and broadband planning as well as technology upgrades at the Village level.

(b) *Economic Development:* Projects that support the creation of sustainable local economies and promote self-sufficiency. Examples of Alaska-Specific program areas of interest are:

- *Economic stability*—Conducting the necessary planning and/or research to support achievement of long-range economic development goals at the Village level. Examples may include performing gap or value-added analyses to identify strengths and weaknesses in the local Village economy, strengthening Village capacity to deliver programs that promote economic development and security.

• *Energy-related activities*—Projects that promote traditional energy activities and practices that support conservation and help to mitigate the high costs of the purchase, transportation, and storage of fuel in Alaskan Villages, especially strategic energy plans that have been identified in tribally approved strategic energy plans. Examples include projects to implement renewable energy resources at the Village level such as bio-energy, geothermal, hydropower, solar, wind, or other methods appropriate to the geographical location.

• *Infrastructure*—Developing Village-level infrastructure (transportation systems, communication, distribution networks, financial institutions, etc.) to support the Village workforce and to make sustainable business activity possible.

• *Subsistence*—Enhancing subsistence and agricultural activities to retain or revitalize traditional food sources and practices at the Village-level.

(c) *Social Development:* Projects that develop and implement culturally appropriate strategies to meet the social service needs of Alaska Natives. Examples of Alaska-Specific program areas of interest are:

• *Community living*—Development and coordination of services to assist people with disabilities by helping them reach their maximum potential through increased independence, productivity, and integration within the Village community.

• *Early childhood education and development*—Supporting stable and high-quality, culturally responsive early childhood programs, creating early childhood education and development jobs, and improving Village level planning and coordination of early childhood education and development programs.

• *Youth development*—Improving the well-being of youth through life skills training at the Village level, workforce development, mentoring programs, substance abuse programs, and preventing suicides and juvenile crime.

• *Community Health*—Promoting improved access to health care and quality of care through coordinated Village and regional approaches, expanding access to healthy foods available in Native Villages, and supporting environmental health.

• *Arts and culture*—Developing or enhancing activities, at the Village level that promote, preserve, or restore Native Village culture and arts.

• *Rescue archaeology*—Recovery of cultural material due to climate change such as exposure of cultural artifacts due to permafrost melting.

• *Organizational Development*—Increasing organizational capacity at the Village level to successfully implement mission and goals.

• *Nutrition and Fitness*—Promoting increased knowledge and participation in activities that promote healthy foods, active lifestyles, the reduction of obesity, and other healthy-living habits

• *Strengthening Families*—Incorporating culturally relevant strategies to strengthen families and promote family preservation, responsible parenting, and healthy relationship skills; and to foster the well-being of children residing in Villages

• *Responsible Fatherhood*—Supporting responsible fatherhood through activities such as counseling, mentoring, marriage education, enhancing relationship skills, parenting, and activities to foster economic stability

• *Suicide Prevention*—Promoting safety, resilience, and protective factors necessary to foster mental health and reduce incidences of suicide and suicidal ideation

• *Human Trafficking*—Development of Village-level assessments and strategies to address human trafficking, including efforts to bring awareness of human trafficking to the public, development of prevention strategies to address the needs of victims, and establishment of collaborative partnerships including those that train public safety officials to recognize traffickers and their victims.

C. Eligible Applicants

Applicants eligible under the Alaska-Specific SEDS FOA are those listed in 45 CFR 1336.33(a)(2): that is, ''(i) Federally recognized Indian tribes in Alaska; (ii) Alaska Native villages as defined in the Alaska Native Claims Settlement Act (ANSCA) and/or non-profit village consortia; (iii) Incorporated nonprofit Alaska Native multi-purpose community-based organizations; (iv) Nonprofit Alaska Native Regional Corporations/Associations in Alaska with village specific projects; and (v) Nonprofit Native organizations in Alaska with village specific projects.'' As this listing already appears in our regulations we are not seeking comment on this aspect of the Alaska-Specific SEDS Projects.

Statutory Authority: This notice for public comment is required by Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

Kimberly Romine,

Deputy Commissioner, Administration for Native American.

[FR Doc. 2014–26426 Filed 11–5–14; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0509]

Agency Information Collection Activities; Proposed Collection; Comment Request; Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for appeals of science-based decisions above the division level at the Center for Veterinary Medicine (CVM).

DATES: Submit electronic or written comments on the collection of information by January 5, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the

Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Appeals of Science-Based Decisions Above the Division Level at CVM—21 CFR Part 10.75 (OMB Control Number 0910–0566)—Revision

Respondents: Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

CVM's Guidance for Industry #79—''Dispute Resolution Procedures for Science-based Decisions on Products Regulated by the Center for Veterinary Medicine,'' describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the guidance details information on how the Agency intends to interpret and apply provisions of the existing regulations regarding internal Agency review of decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established Agency channels of supervision for review.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.75	2	4	8	10	80

CVM encourages applicants to begin the resolution of science-based disputes with discussions with the review team/group, including the Team Leader or Division Director. The Center prefers that differences of opinion regarding science or science-based policy be resolved between the review team/group and the applicant. If the matter is not resolved by this preferred method, then CVM recommends that the applicant follow the procedure in Guidance for Industry #79. Of the two respondents who were advised on the procedure during the past 3 years, one has not followed up to initiate it and the other is working with the review team/group to resolve the issue(s). Therefore, this estimated annual reporting burden is based on CVM's previous experience in handling formal appeals for scientific disputes.

Dated: October 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26307 Filed 11–5–14; 8:45 am]

BILLING CODE 4164–01–P

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0984]

Specification of the Unique Facility Identifier System for Drug Establishment Registration; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration.'' This guidance specifies the UFI system for registration of domestic and foreign drug establishments. The guidance addresses provisions set forth in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). This guidance finalizes the draft guidance issued on September 6, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the

Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2262, Silver Spring, MD 20993–0002, *edrls@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration.'' In July 2012, FDASIA was signed into law (Pub. L. 112–144). Sections 701 and 702 of FDASIA direct the Secretary of Health and Human Services (and by delegation, FDA) to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the FD&C Act (21 U.S.C. 360), as amended, requires that each initial and annual drug establishment registration include a UFI (21 U.S.C. 360(b), (c), and (i)). This guidance is intended solely to address sections 701 and 702 of FDASIA. Although section 703 of FDASIA mandates the use of the same UFI system (specified for drug establishment registration) to identify excipient manufacturers in product listings, this guidance does not address implementation of section 703 of FDASIA.

This guidance specifies the UFI system for registration of domestic and foreign drug establishments. At this time, FDA's preferred UFI for a drug establishment is the Data Universal Numbering System (DUNS) number, assigned and managed by Dun and Bradstreet. The DUNS number is available free of charge to all drug establishments and may be obtained by visiting Dun and Bradstreet's Web site at *http://www.dnb.com/*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) This guidance reflects the Agency's current thinking in light of data standards, information technology, and information management resources. As these variables change over time, FDA may revisit the guidance.

In the **Federal Register** of September 6, 2013 (78 FR 54899), FDA announced the availability of the draft guidance entitled ''Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration.'' The notice gave the public an opportunity to comment by November 5, 2013. FDA carefully considered all comments received in preparing the guidance. No substantive changes were made in finalizing the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the Agency's current thinking on specification of the UFI system for drug establishment registration. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control number 0910–0045.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *http://www.regulations.gov*.

Dated: November 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26397 Filed 11–5–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369, formerly 2007D–0168]

Bioequivalence Recommendations for CONCERTA (Methylphenidate Hydrochloride) Extended-Release Tablets; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for CONCERTA (methylphenidate hydrochloride) Extended-Release Tablets.'' The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) that reference the listed drug CONCERTA (methylphenidate hydrochloride (HCl)) extended-release tablets (new drug application (NDA) 021121). The draft guidance is a revised version of a previously issued draft guidance on the same subject.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 5, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kris André, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4726, Silver Spring, MD 20993–0002, 240–402–7959.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry, ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for CONCERTA (methylphenidate HCl) extended-release tablets. This draft guidance revises and replaces the draft guidance for industry entitled ''Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability,'' issued on September 14, 2012 (77 FR 56851), which provided recommendations to establish BE to CONCERTA (methylphenidate hydrochloride) (NDA 021121).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for CONCERTA (methylphenidate HCl) extended-release tablets. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/*Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or *http://www.regulations.gov.*

Dated: October 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26306 Filed 11–5–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, Program on Biosecurity and Biosafety Policy; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the National Science Advisory Board for Biosecurity (NSABB).

Name of Committee: National Science Advisory Board for Biosecurity.

Date: November 25, 2014.

Time: 11:00 a.m.–1:00 p.m. Eastern. The teleconference line will be open at 10:30 a.m. to allow for check-in with the operator. (Times are approximate and subject to change.)

Agenda: Discussion regarding: (1) Finalization of draft NSABB statement regarding gain-of-function research; and (2) other business of the Board. Time will be allotted on the agenda for oral public comment, with presentations limited to three minutes per speaker.

Place: National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland. (Telephone Conference call only; No in-person meeting.)

Call-in Information: Toll-Free Number: 1–888–469–1981. Participant Passcode: NSABB. The line will be open 30 minutes in advance of the meeting to allow time for operator-assisted check-in.

Contact Person: Carolyn Mosby, NSABB Program Assistant, NIH Program on Biosecurity and Biosafety Policy, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, (301) 435–5504, *carolyn.mosby@nih.gov.*

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the NSABB to provide advice regarding federal oversight of dual use research, defined as biological research that generates information and technologies that could be misused to pose a biological threat to public health and/or national security.

Please Note: The teleconference meeting agenda, draft statement, and other information about the NSABB will be available at *http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb.* Please check this Web site for updates.

The meeting will be open to the public through a teleconference call phone number. Members of the public who participate in the teleconference will be able to listen to the meeting but will not be heard apart from during the public comment session. If you experience any technical problems with the conference call, please send an email to *carolyn.mosby@nih.gov.*

Public Comments: The teleconference will include opportunity for public comment. In addition, any interested person may file written comments with the committee via email to *nsabb@od.nih.gov* with ''NSABB Public Comment'' as the subject line or by regular mail to 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, *Attention:* Carolyn Mosby. Comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the commenter. Written comments received by 5:00 p.m. (Eastern) on Sunday November 23, 2014, will be provided to NSABB members prior to the teleconference.

Accommodations Statement: Individuals who participate by using this teleconference call service and who need special assistance such as captioning or other reasonable accommodations should submit a request to the Contact Person listed on this notice as soon as possible.

Dated: November 3, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–26422 Filed 11–5–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0025]

Agency Information Collection Activities: Waiver of Rights, Privileges, Exemptions and Immunities, Forms I–508 and I–508F; Revision of a Currently Approved Collection.

ACTION: 60-day notice.

SUMMARY: Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information or new collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e. the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until January 5, 2015.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0025 in the subject box, the agency name and Docket ID USCIS–2008–0015. To avoid duplicate submissions, please use only one of the following methods to submit comments:

(1) *Online.* You may access the **Federal Register** Notice and submit comments via the Federal eRulemaking Portal Web site by visiting *www.regulations.gov.* In the search box either copy and paste, or type in, the e-Docket ID number USCIS–2008–0015. Click on the link titled Open Docket Folder for the appropriate Notice and supporting documents, and click the Comment Now tab to submit a comment;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

SUPPLEMENTARY INFORMATION:

Comments

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at: *https://egov.uscis.gov/cris/Dashboard.do,* or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Waiver of Rights, Privileges, Exemptions and Immunities.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–508 and Form I–508F. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This form is used by the USCIS to determine eligibility of an applicant to retain the status of an alien lawfully admitted to the United States for permanent residence.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

- Form I–508: 1,728 responses at .33 hours (20 minutes) per response, and
- Form I–508F: 200 responses at .33 hours (20 minutes) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 636.24 hours.

If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: *http://www.regulations.gov.* We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number 202–272–8377.

Dated: November 3, 2014.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2014–26423 Filed 11–5–14; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2014–N232; FXIA16710900000–156–FF09A30000]

Endangered Species; Marine Mammals; 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, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit 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 8, 2014. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by December 8, 2014.

ADDRESSES: Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281; or email *DMAFR@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (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.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *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. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

A. Endangered Species

Applicant: Arizona Turtle Compound, Surprise, AZ; PRT–71315A

The applicant requests to amend their captive-bred registration under 50 CFR 17.21(g) to add the following species 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.

Species

Aquatic box turtle (*Terrapene Coahuila*)
Galapagos tortoise (*Chelonoidis nigra*)
Bolson tortoise (*Gopherus flavomarginatus*)
Yellow-spotted side-necked turtle (*Podocnemis unifilis*)
Giant Amazon river turtle (*Podocnemis expansa*)
Spotted pond turtle (*Geoclemys hamiltonii*)
Cuban rock iguana (*Cyclura nubila*)
Grand Cayman iguana (*Cyclura lewisi*)
Cayman Brac ground iguana (*Cyclura nubila caymanensis*)
San Esteban Island chuckwalla (*Sauromalus varius*)

Applicant: Binder Park Zoo, Battle Creek, MI; PRT–701789

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following families and species to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Species

Bontebok (*Damaliscus pygargus dorcas*)
Cheetah (*Acinonyx jubatus*)
African wild dog (*Lycaon pictus*)
Panamanian golden frog (*Atelopus varius zeteki*)
Red-Necked gazelle (*Nanger dama ruficollis*)
White handed gibbon (*Hylobates lar*)
Przewalski's wild horse (*Equus przewalskii*)
Snow leopard (*Uncia uncia*)
Parma wallaby (*Macropus parma*)
Mexican gray wolf (*Canis lupus baileyi*)
Ring-tailed lemur (*Lemur catta*)
Black-and-white ruffed lemur (*Varecia variegate*)
Cotton-topped tamarin (*Saguinus oedipus*)

Applicant: The Institute of Greatly Endangered and Rare Species, Myrtle Beach, SC; PRT–36398B

The applicant requests a permit to export and re-import 18 captive-born tigers (*Panthera tigris*) for the purpose of enhancement of the survival of the species to Cancun, Quintana Roo, Mexico. This notification covers activities to be conducted by the applicant over a 3-year period.

Applicant: Jerry Fife, Laveen, AZ; PRT–833285

The applicant requests renewal of a captive-bred wildlife registration under 50 CFR 17.21(g) for the Galapagos tortoise (*Chelonoidis nigra*) and the radiated tortoise (*Astrochelys radiata*) to enhance the species' survival through captive propagation. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Potter Park Zoo, Lansing, MI; PRT–672455

The applicant requests renewal of a captive-bred wildlife registration under 50 CFR 17.21(g) for the following families and species to enhance the species survival through captive propagation. This notification covers activities to be conducted by the applicant over a 5-year period.

Family

Bovidae
Callithricidae
Canidae
Cebidae
Cercopithecidae
Cervidae
Elephantidae
Felidae

Hominidae
Hylobatidae
Lemuridae
Macropodidae
Tapiridae
Accipitridae
Anatidae
Falconidae
Struthionidae
Sturnidae
Alligatoridae

Applicant: Animals of Montana, Bozeman, MT; PRT–36691B

The applicant requests renewal of a captive-bred wildlife registration under 50 CFR 17.21(g) for the African hunting dog (*Lycaon pictus*), clouded leopard (*Neofelis nebulosa*), snow leopard (*Uncia uncia*), and spotted leopard (*Panthera pardus*) to enhance the species' survival through captive propagation. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Los Angeles Zoo and Botanical Gardens, Los Angeles, CA; PRT–45687B

The applicant requests a permit to import two female mandrills (*Mandrillus sphinx*) from Zoo La Palmyre, France, 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: Los Angeles Zoo and Botanical Gardens, Los Angeles, CA; PRT–43317B

The applicant requests a permit to import one male mandrill (*Mandrillus sphinx*) from Tierpark Ueckermunde, Germany, 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: Close-Up Creatures, LLC, Naples, FL; PRT–19478A

The applicant requests amendment of their captive-bred wildlife registration under 50 CFR 17.21(g) for the clouded leopard (*Neofelis nebulosa*) and cheetah (*Acinonyx jubatus*) to enhance the species' propagation or survival. The notification covers activities to be conducted by the applicant over the remainder of the 5-year period for which the permit would be valid.

Applicant: Wildlife Conservation Society, Bronx, NY; PRT–45536B

The applicant requests a permit to import two female captive-born southern pudus (*Pudu puda)* from Africam Safari, Mexico, for the purpose of enhancement of the survival of the species.

Applicant: Corey Knowlton, Royse City, TX; PRT–33291B

The applicant requests a permit to import the sport-hunted trophy of one male black rhinoceros (*Diceros bicornis*) taken from the wild in Namibia, for the purpose of enhancement of the survival of the species.

Applicant: Michael Luzich, Las Vegas, NV; PRT–33743B

The applicant requests a permit to import the sport-hunted trophy of one male black rhinoceros (*Diceros bicornis*) taken from the wild in Namibia, 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: Denis Ksarnosky, Burlington, WI; PRT–47740B; Applicant: Robert Patton, Fort Worth, TX; PRT–46007B; Applicant: Austin Pipkin, Houston, TX; PRT–48390B; Applicant: Albert Seeno, Concord, CA; PRT–46538B; Applicant: Don Byrne, Montgomery, TX; PRT–47538B;

B. Endangered Marine Mammals and Marine Mammals

Applicant: National Marine Mammal Laboratory, NOAA, Seattle, WA; PRT–212570

The applicant requests renewal of the permit to harass walrus (*Odobenus rosmarus*) and polar bear (*Ursus maritimus*) during aerial surveys in Alaska for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2014–26357 Filed 11–5–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2014–N167; FXES11130400000C2–145–FF04E00000]

Endangered and Threatened Wildlife and Plants; Final Recovery Plan for Georgia Pigtoe Mussel, Interrupted Rocksnail, and Rough Hornsnail

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the Fish and Wildlife Service, announce the availability of the final recovery plan for the endangered Georgia pigtoe mussel, interrupted rocksnail, and rough hornsnail. The final recovery plan includes specific recovery objectives and criteria the interrupted rocksnail and rough hornsnail would have to meet in order for us to downlist them to threatened status under the Endangered Species Act of 1973, as amended (Act). Recovery criteria for the Georgia pigtoe will be developed after we complete critical recovery actions and gain a greater understanding of the species.

ADDRESSES: You may obtain a copy of the recovery plan by contacting Jeff Powell at the Alabama Field Office, by U.S. mail at U.S. Fish and Wildlife Service, Alabama Field Office, 1208–B Main Street, Daphne, AL 36526, or by telephone at (251) 441–5858; or by visiting our recovery plan Web site at *http://www.fws.gov/endangered/species/recovery-plans.html.*

FOR FURTHER INFORMATION CONTACT: Jeff Powell (see **ADDRESSES** above).

SUPPLEMENTARY INFORMATION:

Introduction

We listed the Georgia pigtoe mussel (*Pleurobema hanleyianum*), interrupted rocksnail (*Leptoxis foremani*), and rough hornsnail (*Pleurocera foremani*) as endangered species under the Act (16 U.S.C. 1531 *et seq.*) on November 2, 2010 (75 FR 67512). All three species are endemic to the Coosa River drainage of the Mobile River Basin in Alabama and Georgia; the Georgia pigtoe also occurs in a Coosa River tributary in Tennessee. All three species have disappeared from 90 percent or more of their historical ranges, primarily due to impoundment of riverine habitats. A single population of interrupted rocksnail is known to survive in the Oostanaula River, Georgia. There are five localized populations of rough hornsnail, one each in Yellowleaf Creek, Alabama; lower Walnut Creek, Alabama; lower Hatchet and Weogufka Creeks,

Alabama; and the lower Coosa River, Alabama. Surviving populations of Georgia pigtoe occur in the Conasauga River, Georgia, and possibly in the Coosa River (Weiss Bypass), Alabama. Both the rough hornsnail and interrupted rocksnail are State listed as a Priority 1 (P1) species in Alabama, while the Georgia pigtoe is State listed as endangered in Georgia.

Approximately 258 km (160 mi) of stream channels in the Coosa River drainage have been designated as critical habitat for the interrupted rocksnail (101 km (63 mi)), rough hornsnail (27.4 km (17 mi)), and Georgia pigtoe mussel (153 km (95 mi)). Critical habitat is located in Cherokee, Clay, Coosa, Elmore and Shelby Counties, Alabama; Gordon, Floyd, Murray, and Whitfield Counties, Georgia; and Bradley and Polk Counties, Tennessee.

The Georgia pigtoe mussel has a Federal recovery priority number of 5, which indicates that the species faces a high degree of threat but also has a low recovery potential. The interrupted rocksnail and rough hornsnail both have a recovery priority number of 2, which indicates that both species are facing a high degree of threat but have a high recovery potential.

Background

Restoring an endangered or threatened animal or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of our endangered species program. To help guide the recovery effort, we prepare recovery plans for most listed species. Recovery plans describe actions considered necessary for conservation of the species, establish criteria for downlisting or delisting, and estimate time and cost for implementing recovery measures.

The Act requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act requires us to provide public notice and an opportunity for public review and comment during recovery plan development. We will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. We and other Federal agencies will take these comments into account in the course of implementing approved recovery plans.

We made the draft of this recovery plan available for public comment from July 3, 2013, through September 3, 2013 (78 FR 40162). We received no public comments. We considered the information received from peer reviewers in our preparation and approval of this final recovery plan.

Recovery Plan Components

The Service's recovery objectives are to work to reduce threats so that the interrupted rocksnail and rough hornsnail may be downlisted to threatened status, and to prevent further decline of the Georgia pigtoe's Conasauga River population and prevent extinction of the species as a whole. Defining reasonable downlisting or delisting criteria for the Georgia pigtoe is not possible at this time, given the current low number of populations and individuals, lack of information about the species' biology, and magnitude of threats. Therefore, this recovery plan only establishes downlisting criteria for the two snails. Instead of establishing downlisting or delisting criteria at this time for Georgia pigtoe, we are identifying preliminary actions to help us prevent its extinction until we can obtain further information on this species and determine recovery criteria.

Downlisting of the interrupted rocksnail and rough hornsnail will be considered when we:

1. Protect and manage at least three geographically distinct populations for each species (to achieve this criterion, the populations can include the Oostanaula for the interrupted rocksnail and Yellowleaf Creek and Lower Coosa River for the rough hornsnail);

2. Achieve demonstrated and sustainable natural reproduction and recruitment in each population for each species as evident by multiple age classes of individuals, including naturally recruited juveniles, and recruitment rates exceeding mortality rates for a period of 5 years; and

3. Develop and implement habitat and population monitoring programs for each population.

The following actions are identified as necessary to help prevent the extinction of the Georgia pigtoe:

1. Maintain, and where possible conduct efforts to improve, the Conasauga River population;

2. Develop and implement a monitoring plan to evaluate population size in response to management actions;

3. Develop a captive propagation program and establish an ark population (a secure, maintained captive population) to help support the Conasauga River population;

4. Conduct research, such as identification of an appropriate fish host, that is important to gain better understanding of this mussel's life history; and

5. Identify, monitor, and where possible improve potential reintroduction sites in the species' historic range.

Authority

The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533 (f).

Dated: August 20, 2014.

Mike Oetker,

Acting Regional Director, Southeast Region.

[FR Doc. 2014–26362 Filed 11–4–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2014–N230; FXES11130200000F5–156–FF02ENEH00]

Emergency Exemption; Issuance of Emergency Permit To Capture a Suspected Gray Wolf in the Area of the North Rim of the Grand Canyon, Arizona

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance.

SUMMARY: The final rule to list the gray wolf as endangered throughout its range in the United States published in 1978. On October 6, 2014, a suspected gray wolf was seen wandering in the area of the North Rim of the Grand Canyon in Arizona. Deer hunting season is beginning in this area of Arizona, and it is believed that the wolf may be in danger of possible harm and could accidentally be shot either as a result of misunderstanding of status or misidentification. We, the U.S. Fish and Wildlife Service have, under an Endangered Species Act (ESA) permit, authorized qualified researchers to capture, draw blood, and possibly affix a brightly colored GPS radio collar on the suspect wolf and release it back into the general area where it was captured. It is essential for its safety to conduct these actions.

ADDRESSES: Documents and other information concerning the permit are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act. Documents will be available for public inspection, by appointment only, during normal business hours at the U.S. Fish and Wildlife Service, 500 Gold Ave. SW., Room 6034, Albuquerque, NM 87103.

FOR FURTHER INFORMATION CONTACT: Susan Jacobsen, Chief, Division of Classification and Restoration, P.O. Box 1306, Albuquerque, NM 87103; (505) 248–6920.

SUPPLEMENTARY INFORMATION: Several agencies and individuals notified the U.S. Fish and Wildlife Service (Service) that a suspected gray wolf (*Canis lupus*) was wandering in the area of the North Rim of the Grand Canyon in Arizona. Without being able to trap and identify the animal, it is unknown as to whether it is a gray wolf or some type of wolf-dog hybrid. We believe it is in the animal's best interest, with the upcoming deer hunting season opening in this area of Arizona, to capture, affix a brightly colored radio collar (if it is found to be a gray wolf), and draw blood (to identify the species), to help protect the animal from harm. We, the Service, under an Endangered Species Act (16 U.S.C. 1531 *et seq.*) permit, have authorized the following researchers to conduct the above-mentioned activities for gray wolf in the North Rim of the Grand Canyon, Arizona.

Permit TE–676811

Applicant: U.S. Fish and Wildlife Service, Region 2, Regional Director Blanket Permit, Albuquerque, New Mexico.

We approved the applicant's request for an amendment to a current permit for research and recovery purposes to survey for, locate, capture, temporarily hold, draw blood, and radio collar, a gray wolf (*Canis lupus*) within the area of the North Rim of the Grand Canyon, Arizona.

This emergency permit is issued for the sole purpose of protecting the suspected gray wolf in Arizona. Any further authorization for surveys or research of the gray wolf will be processed separately.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: October 30, 2014.

Joy E. Nicholopoulos,

Deputy Regional Director, Southwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2014–26457 Filed 11–5–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTC 00900.L16100000.DP0000 MO#4500073795]

Notice of Public Meeting, Eastern Montana Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Eastern Montana Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Eastern Montana Resource Advisory Council meeting will be held on December 4, 2014 in Billings, Montana. The meeting will start at 8:00 a.m. and adjourn at approximately 4:30 p.m.

ADDRESSES: Billings Hampton Inn, 5110 Southgate Drive, Billings, MT 59101

FOR FURTHER INFORMATION CONTACT: Mark Jacobsen, Public Affairs Specialist, BLM Eastern Montana/Dakotas District, 111 Garryowen Road, Miles City, Montana 59301; (406) 233–2831; *mjacobse@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–677–8339 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 a question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Resource Advisory Council advises the Secretary of the Interior through the BLM on a variety of planning and management issues associated with public land management in Montana. At this meeting, the agenda will include: A welcome to the new RAC members, councilmember and BLM staff introductions, an Eastern Montana/Dakotas District Manager update, Miles City Field Office and Billings Field Office progress briefings, a progress report by the Pumpkin Creek Area RAC subcommittee, individual RAC member reports to BLM managers and other issues that the council may raise during the course of discussion at this meeting. All meetings are open to the public. This RAC meeting will have time allocated for hearing public comments and the public may also present written comments to the council. Depending on the number of persons wishing to comment and the time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations should contact the BLM as provided above.

Authority: 43 CFR 1784.4–2.

Diane M. Friez,

Eastern Montana/Dakotas District Manager.

[FR Doc. 2014–26454 Filed 11–5–14; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L14200000.BJ0000;14X1109AF, MO #4500073723]

Notice of Filing of Plats of Survey; North Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on December 8, 2014.

DATES: Protests of the survey must be filed before December 8, 2014 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Marvin Montoya, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5124 or (406) 896–5007, *Marvin_Montoya@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Chief, Branch of Fluid Minerals, Bureau of Land Management, Montana State Office, Billings, Montana, and was necessary to determine Federal Leasable Mineral Lands.

The lands we surveyed are:

Fifth Principal Meridian, North Dakota

T. 148 N., R. 97 W.

The plat, in 9 sheets:

Representing the dependent resurvey of a portion of the 12th Standard Parallel, through Ranges 96 and 97 West, a portion of the east boundary, a portion of the subdivisional lines, the adjusted original meanders of the former left and right banks of the Little Missouri River, through sections 1, 2, 3, 4, and 12, and the subdivision of section 3, the subdivision of certain sections, and the survey of the meanders of the present left and right banks of the Little Missouri River and informative traverse, through sections 1, 2, 3, 4, and 12, the limits of erosion in sections 1,

2, 3, and 12, the left and right banks and medial line of the abandoned channels of the Little Missouri River in sections 2, 3, and 4, and certain division of accretion and partition lines,

T. 149 N., R. 96 W.

Representing the dependent resurvey of a portion of the subdivisional lines, and the adjusted original meanders of the former left and right banks of the Little Missouri River, through sections 31 and 32, the subdivision of sections 31 and 32, and the survey of Parcels A and B, section 31, the meanders of the present left and right banks of the Little Missouri River and informative traverse, through sections 31 and 32, the limits of erosion in section 31, the left and right banks and medial line of the abandoned channels of the Little Missouri River in section 31, and certain division of accretion and partition lines, and

T. 149 N., R. 97 W.

Representing the dependent resurvey of a portion of the east boundary and the adjusted original meanders of the former left and right banks of the Little Missouri River, through section 36 and the survey of the meanders of the present left and right banks of the Little Missouri River and informative traverse, through section 36, the limits of erosion and the meanders of a 1951 right bank of the Little Missouri River in section 36, the left and right banks and the medial line of the abandoned channels of the Little Missouri River in section 36, and certain partition lines, Township 149 North, Range 97 West, Fifth Principal, Meridian, North Dakota was accepted September 29, 2014.

We will place a copy of the plat, in 9 sheets, and related field notes we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in 9 sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in 9 sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

Joshua F. Alexander,

Chief, Branch of Cadastral Survey, Division of Energy, Minerals and Realty.

[FR Doc. 2014–26409 Filed 11–5–14; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAC08000 XXXL1109RM L19200000.JP0000 LRORBX003800]

Notice of Interim Final Supplementary Rules for Public Lands in El Dorado County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Interim final supplementary rules.

SUMMARY: The California State Director for the Bureau of Land Management (BLM) is establishing interim final supplementary rules and requests public comments. These interim final supplementary rules will become effective immediately upon publication in the **Federal Register**, and will apply to 695 acres of public lands, known as Kanaka Valley, in El Dorado County, California. The BLM has determined that these interim final supplementary rules are necessary to enhance the safety of visitors and local residents and reduce the risk of undue ecological degradation to Kanaka Valley's rare soils and plants and other significant values. These rules are in accordance with the Kanaka Valley Management Plan (2013).

DATES: The interim final supplementary rules are effective immediately and remain in effect until modified or rescinded by the publication of final supplementary rules. The BLM invites comments until January 5, 2015. Comments received, postmarked, or electronically dated after that date will not necessarily be considered in the development of final supplementary rules.

ADDRESSES: Please mail or hand deliver all comments concerning the interim final supplementary rules to the Bureau of Land Management, Attention: Supplementary Rules, BLM Mother Lode Field Office, 5152 Hillsdale Circle, El Dorado Hills, CA 95762.

FOR FURTHER INFORMATION CONTACT: James Barnes, telephone (916) 941–3140; address 5152 Hillsdale Circle, El Dorado Hills, CA 95762; email *jjbarnes@blm.gov* or Web site *http://www.ca.blm.gov/motherlode.*

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

The public is invited to provide comments on these interim final supplementary rules. See **DATES** and **ADDRESSES** for information on submitting comments. Written comments on the interim final supplementary rules should be specific, confined to issues pertinent to the interim final supplementary rules and explain the reason for any recommended change. Comments requesting changes to decisions in the 2013 Kanaka Valley Management Plan and Decision Record would be outside the scope of this rulemaking.

Where possible, comments should reference a specific provision of these interim final supplementary rules. The BLM need not consider or include in the administrative record: (a) comments that the BLM receives after the close of the comment period (see **DATES**), unless they are postmarked or electronically dated before the deadline, or (b) comments delivered to an address other than that listed above (see **ADDRESSES**).

Comments, including names, street addresses, and other contact information of respondents, will be available for public review at the BLM Mother Lode Field Office during regular business hours of 8:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays. Before including your address, telephone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

II. Background

Kanaka Valley is comprised of 695 acres of public lands in El Dorado County, California. The BLM acquired Kanaka Valley through a donation in 2010. In response to the rapidly growing popularity of Kanaka Valley with the recreating public and the need to provide for public safety and protect this area's special environmental values, the BLM developed the 2013 Kanaka Valley Management Plan and Decision Record. This is an area-specific activity-level plan that tiers to the BLM's 2008 Sierra Resource Management Plan. It was needed to help the BLM manage Kanaka Valley's special environmental values and recreational opportunities.

Sections 302 and 310 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1732 and 1740) provide the overall authority for the BLM's management of Kanaka Valley. The BLM is establishing these interim final supplementary rules under the authority of 43 CFR 8365.1–6, which allows BLM State Directors to establish supplementary rules for the protection of persons, property, and public lands and resources.

The supplementary rules outlined in this notice are designed to immediately and effectively reduce risks to public health and safety and the area's environmental resources including, but not limited to, rare gabbro soils and plants. The supplementary rules include provisions to partially open Kanaka Valley to hunting. The seasons of use and methods of take were developed collaboratively by the BLM, adjacent private residents, local stakeholders,

and the California Department of Fish and Wildlife. Given these considerations and the prior analysis of these issues as part of the planning process, the BLM finds good cause under 5 U.S.C. 553(b)(3)(B) that public notice and comment for this rule are ''impractical, unnecessary, or contrary to the public interest,'' and under 5 U.S.C. 553(d) that this rule may properly take effect upon publication. During the planning process that led to the Kanaka Valley Management Plan and Decision Record, the BLM took the following steps to involve the public in making decisions about Kanaka Valley:

- The BLM conducted 16 public meetings from June 2010 to June 2011 to develop the Kanaka Valley Management Plan. The BLM contacted Indian tribes during this time. The BLM also worked closely on hunting- and firearms-related issues with private landowners (many with residences adjacent to Kanaka Valley), hunting groups, and the California Department of Fish and Wildlife during this time.
- The BLM made the draft Kanaka Valley Management Plan and associated Environmental Assessment (EA) available for a 30-day comment period beginning in April 2012. Indian tribes were also afforded a 30-day comment period.
- A public meeting was held to discuss the draft Kanaka Valley Management Plan and associated EA on April 26, 2012, in Cameron Park, CA and on May 5, 2012, at Kanaka Valley.
- The BLM summarized all public comments and addressed them in the Decision Record. All decisions related to these interim final supplementary rules were analyzed in the EA which is available for public viewing at the address specified under **ADDRESSES** and online at: *http://www.ca.blm.gov/motherlode.*

Based on this extensive public participation, the BLM identified the following public safety and resource protection concerns at Kanaka Valley:

- Potential conflicts between firearms use and other recreationists;
- Potential conflicts between firearms use and nearby residents;
- Wildfire risk due to camping and campfires;
- Degradation of natural resources including rare soils and plants; and
- Degradation of cultural resources.

III. Discussion of Interim Final Supplementary Rules

These interim final supplementary rules provide for the protection of persons, property, public lands, and resources, in accordance with the 2013 Kanaka Valley Management Plan and Decision Record.

Rule 1 prohibits the operation of any motorized vehicle outside of county-maintained roads or BLM-designated areas (for example, parking lots) without first obtaining written BLM authorization. Motorized use is allowed by the BLM and its contractors for official administrative purposes. Rule 5 allows riding horses, mountain bikes, and other non-motorized conveyances only on designated trails. Rule 6 allows the recovery of gold or any other mineral resources only by hands and pans. These rules will help prevent resource damage and degradation of the area's rare soils and plants.

Rule 2 prohibits the discharge or use of firearms or other dangerous weapons for the purpose of target shooting. The Kanaka Valley parcel is relatively small (695 acres) and adjoins private lands, many of which are residential properties of less than 20 acres containing occupied dwellings in close proximity to the parcel's boundaries (within 150 yards in at least 10 cases). At most of the 16 public meetings the BLM held from June 2010 to June 2011 while developing the Kanaka Valley Management Plan, members of the public expressed concern about accidental shooting-related injuries and fatalities. Many of those who expressed this concern occupied houses on private lands immediately adjacent to the Kanaka Valley parcel. The issue was also raised multiple times in written public comments to the BLM on the draft Kanaka Valley Management Plan and EA. The BLM's decision to prohibit target shooting at Kanaka Valley had the overwhelming support of members of the public who participated in the Kanaka Valley land-use planning process, including hunting groups.

Rules 3 and 4 prohibit camping and campfires. These rules will reduce the risk of wildfire ignition. There are several occupied dwellings and associated outbuildings on private lands immediately adjacent to the Kanaka Valley parcel. In at least 10 cases these dwellings are within 150 yards of the parcel's boundaries. There is dense grass, brush, and other wildfire-prone vegetation in this area. The issue of wildfire prevention was raised at most of the 16 public meetings the BLM held to develop the Kanaka Valley Management Plan. The issue was also raised in written public comments to the BLM on the draft Kanaka Valley Management Plan and EA. The BLM's decision to establish Rules 3 and 4 prohibiting camping and campfires had overwhelming support of those members of the public who participated in the Kanaka Valley land-use planning process.

Rule 7 allows hunting with the following methods of take:

- Bows and arrows;
- Smoothbore shotguns;
- Muzzleloaders; and
- Air guns of .22 caliber or less that are allowed as a method of take for game species pursuant to California Department of Fish and Wildlife regulations.

Muzzleloaders are allowed only after fire season is declared over by the BLM.

This rule will help prevent accidental shooting-related injuries and fatalities by restricting high-velocity firearms such as rifles. This rule will also help reduce the risk of wildfire ignition. The issue of preventing accidental shooting-related injuries and fatalities was raised by the public at most of the 16 public meetings the BLM held to develop the Kanaka Valley Management Plan. The issue was also raised multiple times in written public comments to the BLM on the draft Kanaka Valley Management Plan and EA. The BLM determined during the Kanaka Valley land-use planning process that the use of high-velocity firearms was unsafe at Kanaka Valley due to the parcel's relatively small size and close proximity to at least 10 occupied dwellings. The BLM's decision to restrict the types of firearms used by hunters at Kanaka Valley had strong support of those members of the public who participated in the Kanaka Valley land-use planning process, including hunting groups.

Rule 8 prohibits hunting for bear, squirrels, rabbits, jackrabbits, waterfowl, furbearers, and non-game species. Rule 9 restricts hunting to deer and turkey during the fall season, deer during the summer archery-only season, and quail and dove during the seasons approved by the California Department of Fish and Wildlife. Rules 8 and 9 were developed collaboratively with adjacent private residents, local stakeholders (including hunting groups), and the California Department of Fish and Wildlife and will help prevent accidental shooting-related injuries and fatalities during periods of high recreational use (i.e., associated with the spring wildflower bloom) at Kanaka Valley, and will help prevent the area's wildlife population from being rapidly depleted. The hunting seasons for Rule 8 species are so unique, lengthy, and overlapping that it would be difficult to effectively manage them, thereby presenting a public safety danger for adjacent residences. The issue of accidental shooting-related injuries and fatalities was raised by the public at

most of the 16 public meetings the BLM held to develop the Kanaka Valley Management Plan. The issue was also raised multiple times in written public comments to the BLM on the draft Kanaka Valley Management Plan and EA. The BLM's decision to restrict hunting of certain game animals at Kanaka Valley was made in consultation with the California Department of Fish and Wildlife and had strong support of those members of the public who participated in the Kanaka Valley land-use planning process, including hunting groups.

Rule 10 allows hunting only in the designated hunting zone, which will be explicitly identified (through maps and signs) by the BLM for hunting. Regulations of the California Department of Fish and Wildlife forbid any person (other than the owner, person in possession of the premises, or a person having the express permission of the owner or person in possession of the premises) to hunt or to discharge while hunting, any firearm or other deadly weapon within 150 yards of an occupied dwelling, residence, or other associated building, barn, or other outbuilding. There are more than 10 occupied dwellings and associated outbuildings within 150 yards of the Kanaka Valley parcel's boundaries. Therefore, Rule 10 implements the 150-yard requirement by establishing a no hunting zone that is clearly delineated by on-the-ground topographic features. The rule is needed to help enforce California state law and regulations and explains a specific instance of how the BLM will apply State laws governing hunting, as required at 43 CFR 8365.1–7.

Rule 11 allows a spring turkey hunt by hunters selected though a lottery process coordinated by the California Department of Fish and Wildlife. Since spring turkey hunting has become very popular in California, a lottery process will help prevent accidental shooting-related injuries and fatalities during a period of high recreational use at Kanaka Valley, and will help prevent the area's turkey population from being rapidly depleted.

IV. Procedural Matters

Executive Order 12866, Regulatory Planning and Review

These interim final supplementary rules are not a significant regulatory action under Executive Order 12866. These interim final supplementary rules will not have an annual effect of $100 million or more on the economy or adversely affect, in a material way, the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities. These interim final supplementary rules will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The interim final supplementary rules do not materially alter the budgetary effects of entitlements, grants, user fees, or loan programs or the right or obligation of their recipients; nor do they raise novel legal or policy issues. They merely impose certain rules on recreational activities on a limited portion of the public lands in California in order to protect human health, safety, and the environment.

Clarity of the Interim Final Supplementary Rules

Executive Order 12866 requires each agency to write regulations that are simple and easy to understand. We invite your comments on how to make these interim final supplementary rules easier to understand, including answers to questions such as the following:

(1) Are the requirements in the interim final supplementary rules clearly stated?

(2) Do the interim final supplementary rules contain technical language or jargon that interferes with their clarity?

(3) Does the format of the interim final supplementary rules (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?

(4) Would the interim final supplementary rules be easier to understand if they were divided into more (but shorter) sections?

(5) Is the description of the interim final supplementary rules in the **SUPPLMENTARY INFORMATION** section of this preamble helpful in understanding the interim final supplementary rules? How could this description be more helpful in making the interim final supplementary rules easier to understand?

Please send any comments you have on the clarity of the interim final supplementary rules to the address specified in the **ADDRESSES** section.

National Environmental Policy Act

These interim final supplementary rules are a component of a larger land-use planning process for Kanaka Valley (i.e., Kanaka Valley Management Plan and Decision Record) that was a Federal action. In developing the Kanaka Valley Management Plan and Decision Record, the BLM prepared the draft Kanaka Valley Management Plan and EA, which includes a complete analysis of each decision corresponding to the interim final supplementary rules. Based on the analysis in this EA, the BLM found that the action, including the interim final supplementary rules, would not have a significant individual or cumulative effect on the quality of the human environment under Section 102(2)(C) of the NEPA (42 U.S.C. 4332(2)(C)). See 40 CFR 1508.4; 43 CFR 46.210. The BLM prepared a Finding of No Significant Impact (FONSI) to document this finding.

The draft management plan, EA, FONSI, and Kanaka Valley Management Plan and Decision Record are on file and available to the public in the BLM administrative record at the address specified under **ADDRESSES**. They are also available to the pubic online at: *http://www.ca.blm.gov/motherlode.*

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act (RFA) of 1980, as amended, 5 U.S.C. 601–612, to ensure that government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. The interim final supplementary rules do not pertain specifically to commercial or governmental entities of any size, but to public recreational use of specific public lands. Therefore, the BLM has determined under the RFA that these interim final supplementary rules would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

These interim final supplementary rules do not constitute a ''major rule'' as defined at 5 U.S.C. 804(2). The interim final supplementary rules generally contain rules of conduct for recreational use of certain public lands. They do not have an effect on business, commercial, or industrial use of the public lands that rises to any of the following thresholds specified in 5 U.S.C. 804(2):

(a) An annual effect on the economy of $100 million or more;

(b) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(c) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

These interim final supplementary rules do not impose an unfunded mandate on State, local or tribal governments in the aggregate, or the private sector, of more than $100 million per year; nor do they have a significant or unique effect on small governments. These interim final supplementary rules do not require anything of State, local, or tribal governments. Therefore, the BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

The interim final supplementary rules are not a government action capable of interfering with constitutionally protected property rights. The interim final supplementary rules do not address property rights in any form and do not cause the impairment of anybody's property rights. Therefore, the Department of the Interior has determined that these interim final supplementary rules would not cause a taking of private property or require further discussion of takings implications under this Executive Order.

Executive Order 13132, Federalism

The interim final supplementary rules will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the BLM has determined that these interim final supplementary rules do not have sufficient Federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

Under Executive Order 12988, the BLM has determined that these interim final supplementary rules will not unduly burden the judicial system and that the requirements of sections 3(a) and 3(b)(2) of the Executive Order are met. The supplementary rules include rules of conduct and prohibited acts, but they are straightforward and not confusing.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

As discussed in the 2013 Kanaka Valley Management Plan and Decision Record, the BLM has been working with both federally recognized tribes and other Native American groups having ancestral and cultural ties to the public lands at Kanaka Valley. The tribes and other Native American groups include Shingle Springs Rancheria, United Auburn Indian Community, Washoe Tribe of California and Nevada, Ione Band of Miwok Indians, Buena Vista Rancheria, Nashville-Eldorado Miwok Tribe, and El Dorado Miwok Tribe.

The tribes and other Native American groups actively participated in the planning process that resulted in the 2013 Kanaka Valley Management Plan and Decision Record. The BLM also provided tribes and Native American groups in the vicinity of Kanaka Valley with copies of the draft Kanaka Valley Management Plan and associated Environmental Assessment. The BLM requested comments, and the tribes and other Native American groups expressed no concerns about the draft management plan or the decisions related to these interim final supplementary rules. For these reasons, the BLM has determined that these interim final supplementary rules do not include policies with tribal implications that have not already been considered in consultation and coordination with Indian tribal governments.

Information Quality Act

In developing these supplementary rules, the BLM did not conduct or use a study, experiment or survey requiring peer review under the Information Quality Act (Section 515 of Pub. L. 106–554). In accordance with the Information Quality Act, the Department of the Interior has issued guidance regarding the quality of information that it relies upon for regulatory decisions. This guidance is available at DOI's Web site at *http://www.doi.gov/ocio/iq.html.*

Executive Order 13211, Effects on the Nation's Energy Supply

These supplementary rules do not comprise a ''significant energy action,'' as defined in Executive Order 13211, since they are not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Paperwork Reduction Act

These interim final supplementary rules do not contain information collection requirements that the Office of Management and Budget must approve under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Author

The principal author of these interim final supplementary rules is James Barnes, Archaeologist, BLM Mother Lode Field Office.

For the reasons stated in the preamble and under the authority for supplementary rules found in 43 CFR 8365.1–6, the BLM California State Director hereby establishes supplementary rules, effective on an interim final basis immediately after the date of publication in the **Federal Register**, for 695 acres of public lands known as Kanaka Valley, managed by the BLM in El Dorado County, California, to read as follows:

Interim Final Supplementary Rules for 695 Acres of Public Lands Within El Dorado County, California

These interim final supplementary rules affect 695 acres of public lands at Kanaka Valley in El Dorado County, California. The legal description of the affected public lands is:

Mount Diablo Meridian

T. 10 N., R. 9 E.,
Sec. 5, unnumbered lot in W½NW¼ and W½SW¼;
Sec. 6, unnumbered lot in E½NE¼, E½SE¼, S½N½ lot 1 in SW¼, and S½NW¼SE¼;
Sec. 7, lot 1 in NW¼, lot 2 in NW¼, and NE¼;
Sec. 8, NW¼NW¼. T. 11 N., R. 9 E.,
Sec. 31, SE¼SE¼SW¼ and SW¼SE¼.

The area described aggregates 695.01 acres, more or less, in El Dorado County, California.

Definitions

Campfire means a controlled fire occurring out of doors, used for cooking, branding, personal warmth, lighting, ceremonial or aesthetic purposes. Campfires include wood fires, charcoal fires, and portable gas stoves using gas, jellied petroleum, or pressurized liquid fuel.

Camping means erecting a tent or a shelter of natural or synthetic material, preparing a sleeping bag or other bedding material, or parking a motor vehicle, motor home, or trailer for the purpose or apparent purpose of overnight occupancy.

Dangerous weapon means any weapon that in the manner of its use, or intended use, is capable of causing death or serious bodily injury.

Designated hunting zone means a zone explicitly identified (through maps and signs) by the BLM for hunting.

Designated trail means a trail developed, maintained, and explicitly identified by the BLM for public non-motorized use. All designated trails will be identified by a combination of maps and signs.

Firearm means any weapon designed to expel a projectile by the action of an explosive.

Hunting means taking or attempting to take wildlife by any means, except by trapping or fishing.

Motorized vehicle means any motorized transportation conveyance designed for use on or off roadways, such as an automobile, motorcycle, or truck.

Target shooting means discharging a firearm or other dangerous weapon for any purpose other than hunting.

Rules

1. You must not operate any motorized vehicle outside of county-maintained roads or BLM-designated areas (i.e., parking lot) without first obtaining written BLM authorization (i.e., right-of-way). BLM employees and BLM contractors are allowed to use motorized vehicles for official administrative purposes without further authorization.
2. You must not discharge or use firearms or other dangerous weapons for the purpose of target shooting.
3. Camping is prohibited.
4. Campfires are prohibited.
5. Riding horses, mountain bikes, and other non-motorized conveyances is allowed only on designated trails.
6. Only hands and pans may be used to recover gold or any other mineral resources.
7. Hunting, as specified in 8 and 9, is allowed only with the following methods of take: Bows and arrows, smoothbore shotguns, muzzleloaders, and air guns of .22 caliber or less that are allowed as a method of take for game species pursuant to California Department of Fish and Wildlife regulations. Muzzleloaders are allowed only after fire season is declared over by the BLM.
8. You must not hunt for bear, squirrels, rabbits, jackrabbits, waterfowl, furbearers, or non-game species.
9. Hunting is restricted to deer and turkey during the fall season, deer during the summer archery-only season, and quail and dove during the seasons approved by the California Department of Fish and Wildlife.
10. Hunting is allowed only in the designated hunting zone.
11. In the spring, turkey may be hunted through a special hunt; participants will be selected through a lottery process coordinated by the California Department of Fish and Wildlife.

Exemptions

The following persons are exempt from these supplementary rules: Any Federal, state, local, and/or military employees acting within the scope of their official duties; members of any organized rescue or fire fighting force performing an official duty; and persons who are expressly authorized or approved by the BLM.

The prohibition of target shooting in Rule 2 has no effect on hunting by licensed hunters in legitimate pursuit of game during the proper season with appropriate firearms, as defined by the California Department of Fish and Wildlife.

Penalties

Any person who violates any of these supplementary rules may be tried before a United States Magistrate and fined no more than $1,000 or imprisoned for no more than 12 months, or both (43 U.S.C. 1733(a); 43 CFR 8360.0–7). Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

James G. Kenna,

State Director.

[FR Doc. 2014–26410 Filed 11–5–14; 8:45 am]

BILLING CODE 4310–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Central Valley Project Improvement Act Water Management Plans

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability.

SUMMARY: The Standard Criteria for Agricultural and Urban Water Management Plans (Criteria) are now available for public comment. To meet the requirements of the Central Valley Project Improvement Act of 1992 and the Reclamation Reform Act of 1982, the Bureau of Reclamation developed and published the Criteria. The Criteria apply to any Water Management Plans submitted to the Bureau of Reclamation as required by applicable Central Valley Project water service contracts, settlement contracts, or any contracts that specifically invokes the Criteria. Note: For the purpose of this announcement, Water Management Plans are considered the same as Water Conservation Plans (Plans).

DATES: All public comments must be received by December 8, 2014.

ADDRESSES: Please mail comments to Ms. Angela Anderson, Bureau of Reclamation, 2800 Cottage Way, MP–410, Sacramento, California 95825; or contact at 916–978–5215, or email at *aanderson@usbr.gov.*

FOR FURTHER INFORMATION CONTACT: To be placed on a mailing list for any subsequent information, please contact Ms. Angela Anderson at the email address or telephone number above.

SUPPLEMENTARY INFORMATION: Section 3405(e) of the Central Valley Project Improvement Act (CVPIA) (Title 34 Pub. L.102–575), requires the Secretary of the Interior to establish and administer an office on Central Valley Project (CVP) water conservation best management practices that shall " . . . develop criteria for evaluating the adequacy of all water conservation plans developed by project contractors, including those plans required by section 210 of the Reclamation Reform Act of 1982." Also, according to Section 3405(e)(1), these criteria must be developed " . . . with the purpose of promoting the highest level of water use efficiency reasonably achievable by project contractors using best available cost-effective technology and best management practices." These criteria state that all parties (Contractors) that contract with the Bureau of Reclamation (Reclamation) for water supplies (municipal and industrial contracts over 2,000 acre-feet and agricultural contracts over 2,000 irrigable acres) must prepare Plans that contain the following information:

1. Description of the District.
2. Inventory of Water Resources.
3. Best Management Practices for Agricultural Contractors.
4. Best Management Practices for Urban Contractors.
5. Plan Implementation.
6. Exemption Process.
7. Five-Year Revisions.

Reclamation will evaluate Plans based on these criteria. The CVPIA requires Reclamation to evaluate and revise, if necessary, the Criteria every 3 years. The Criteria were last updated in 2011 and the proposed 2014 update is currently under review. Public meetings to solicit comments on revisions of the Criteria were held in September 2014. Comments will be incorporated into the finalized document. A copy can be found at the following Web site: *http://www.usbr.gov/mp/watershare/documents/2014_Standard_Criteria.pdf.*

A copy can also be obtained by contacting the person at the address above.

Public Disclosure

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.

Richard J. Woodley,

Regional Resources Manager, Mid-Pacific Region, Bureau of Reclamation.

[FR Doc. 2014–26333 Filed 11–5–14; 8:45 am]

BILLING CODE 4332–90–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX066A000 67F 134S180110; S2D2S SS08011000 SX066A00 33F 13xs501520]

Notice of Proposed Information Collection; Request Comments for 1029–0063

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing that the information collection request for the Abandoned Mine Reclamation Fund—Fee Collection and Coal Production Reporting and the form OSM–1 has been forwarded to the Office of Management and Budget (OMB) for review and comment. The information collection request describes the nature of the information collection and its expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collections but may respond after 30 days. Therefore, public comments should be submitted to OMB by December 8, 2014, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Department of the Interior Desk Officer, by telefax at (202) 395–5806 or via email to *OIRA_Submission@omb.eop.gov.* Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203—SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please refer to OMB Control Number 1029–0063 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review this collection by going to *http://www.reginfo.gov* (Information Collection Review, Currently Under Review, Agency is Department of the Interior, DOI–OSMRE).

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSMRE has submitted a request to OMB to renew its approval for the collection of information found at 30 CFR 870—Abandoned Mine Reclamation Fund—Fee Collection and Coal Production Reporting and the form it implements, the OSM–1, Coal Reclamation Fee Report, and the Amended OSM–1 form. OSMRE is requesting a 3-year term of approval for these information collection activities.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029–0063. Responses are mandatory.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on July 8, 2014 (79 FR 38563). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activities:

Title: 30 CFR 870—Abandoned Mine Reclamation Fund—Fee Collection and Coal Production Reporting.

OMB Control Number: 1029–0063.

Summary: The information is used to maintain a record of coal produced for sale, transfer, or use nationwide each calendar quarter, the method of coal removal and the type of coal, and the basis for coal tonnage reporting in compliance with 30 CFR 870 and section 401 of Public Law 95–87. Individual reclamation fee payment liability is based on this information. Without the collection of information OSMRE could not implement its regulatory responsibilities and collect the fee.

Bureau Form Numbers: OSM–1, Amended OSM–1

Frequency of Collection: Quarterly.

Description of Respondents: Coal mine permittees.

Total Annual Responses: 12,124.

Total Annual Burden Hours: 811.

Non-Hour Burden: $100 for lab analysis fees × 3,260 filings = $326,000.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the addresses listed under **ADDRESSES**. Please refer to the appropriate OMB control number 1029–0063 in your correspondence.

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.

Dated: October 31, 2014.

Harry J. Payne,

Chief, Division of Regulatory Support.

[FR Doc. 2014–26297 Filed 11–5–14; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–14–038]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 12, 2014 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: 1. Agendas for future meetings: none.

2. Minutes.

3. Ratification List.

4. Vote in Inv. Nos. 701–TA–509 and 731–TA–1244 (Final) (1,1,1,2-Tetrafluoroethane (''R–134a'') from China). The Commission is currently scheduled to complete and file its determinations and views of the Commission on November 24, 2014.

5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 3, 2014.

William R. Bishop

Supervisory Hearings and Information Officer.

[FR Doc. 2014–26470 Filed 11–4–14; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[Docket No. ODAG 151]

Notice of Reopening of Comment Period on Federal Advisory Committee Draft Recommendations

AGENCY: Department of Justice.

ACTION: Notice of reopening of comment period.

SUMMARY: This notice announces the reopening of the comment period on the subcommittee draft work products of the National Commission on Forensic Science.

DATES: Electronic comments must be submitted on or before November 21, 2014. The electronic Federal Docket Management System (FDMS) will accept comments until Midnight Eastern Time at the end of that day.

FOR FURTHER INFORMATION CONTACT: Brette Steele, Senior Advisor on Forensic Science and Senior Counsel to the Deputy Attorney General, 950 Pennsylvania Avenue NW., Washington, DC 20530, by email at *Brette.L.Steele@usdoj.gov,* or by phone at (202) 305–0180.

SUPPLEMENTARY INFORMATION: On October 10, 2014, the Department of Justice published in the **Federal Register** a Notice announcing the October 28–29, 2014, Federal Advisory Committee Meeting of the National Commission on Forensic Science (79 FR 61340). That Notice also announced that comments on subcommittee draft work products must be submitted on or before October 27, 2014.

In response to public requests, this Notice extends the deadline for submitting comments on subcommittee draft work products until November 21, 2014.

Posting of Public Comments: Draft work products introduced at the October 28–29, Commission meeting are available at *http://www.regulations.gov.* To ensure proper handling of comments, please reference ''Docket No. ODAG 151'' on all electronic and written correspondence. The Department encourages all comments on subcommittee work products be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *http://www.regulations.gov* will be posted for public review and are part of the official docket record.

In accordance with the Federal Records Act, please note that all comments received are considered part of the public record, and shall be made available for public inspection online at *http://www.regulations.gov.* The comments to be posted may include personally identifiable information (such as your name, address, etc.) and confidential business information voluntarily submitted by the commenter.

You are not required to submit personal identifying information in order to comment on this meeting. Nevertheless, if you want to submit personally identifiable information (such as your name, address, etc.) as part of your comment, but do not want it to be made available for public inspection and posted online, you must include the phrase ''PERSONALLY IDENTIFIABLE INFORMATION'' in the first paragraph of your comment. You must also place all the personally identifiable information you do not want made available for public inspection or posted online in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made available for public inspection and posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made available for public inspection or posted online.

Personally identifiable information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be made available for public inspection and posted on *http://www.regulations.gov.*

Dated: October 31, 2014.

Brette L. Steele,

Senior Advisor on Forensic Science to the Deputy Attorney General.

[FR Doc. 2014–26403 Filed 11–5–14; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2013–0012]

Proposed Modification to the List of Appropriate NRTL Program Test Standards and the Scopes of Recognition of Several NRTLs

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

ACTION: Notice.

SUMMARY: In this notice, OSHA proposes to: (1) Add new test standards to the Nationally Recognized Testing Laboratories (NRTL) Program's list of appropriate test standards; (2) delete or replace several test standards from the NRTL Program's list of appropriate test standards; and (3) update the scopes of recognition of several NRTLs.

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before December 8, 2014. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES:

1. *Electronically:* Tender submissions electronically to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions online for making electronic submissions.

2. *Facsimile:* If submissions, including attachments, are not longer than ten (10) pages, commenters may fax them to the OSHA Docket Office at (202) 693–1648.

3. *Regular or express mail, hand delivery, or messenger (courier) service:* Tender submissions to the OSHA Docket Office, Docket No. OSHA–2013–0012, Technical Data Center, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2350 (TTY number: (877) 889–5627). Note that security procedures may result in significant delays in receiving submissions sent by regular mail. Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by regular or express mail, hand delivery, or messenger (courier) service. The hours of operation for the OSHA Docket Office are 8:15 a.m.–4:45 p.m., e.t.

4. *Instructions:* All submissions must include the Agency name and the OSHA docket number (OSHA–2013–0012). OSHA places comments and other materials, including any personal information, in the public docket

without revision, and these materials may be available online at *http://www.regulations.gov.* Therefore, the Agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

5. *Docket:* To read or download submissions 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 are listed in the *http://www.regulations.gov* index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

6. *Extension of comment period:* Submit requests for an extension of the comment period on or before December 8, 2014 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

1. *Press inquiries:* Contact Mr. 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; email: *Meilinger.francis2@dol.gov.*

2. *General and technical information:* Contact Mr. Kevin Robinson, Acting Director, NRTL Program, Occupational Safety and Health Administration, Room N–3655, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2110; email *robinson.kevin@dol.gov.* OSHA's Web page includes information about the NRTL Program (see *http://www.osha.gov* and select ''N'' in the ''A to Z Index'' located at the top of the Web page).

3. *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 other relevant information, is also available on OSHA's Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRTL Program recognizes organizations that provide product-safety testing and certification services to manufacturers. These organizations perform testing and certification for purposes of the Program, to U.S. consensus-based product-safety test standards. The products covered by the NRTL Program consist of those items for which OSHA safety standards require ''certification'' by an NRTL. The requirements affect electrical products and 38 other types of products. OSHA does not develop or issue these test standards, but generally relies on standards-development organizations (SDOs), which develop and maintain the standards using a method that provides input and consideration of views of industry groups, experts, users, consumers, governmental authorities and others having broad experience in the safety field involved.

A. Addition of New Test Standards to the NRTL List of Appropriate Test Standards

Periodically, OSHA will propose to add new test standards to the NRTL list of appropriate test standards following an evaluation of the test standard document. To qualify as an appropriate test standard, the Agency evaluates the document to (1) verify it represents a product category for which OSHA requires certification by an NRTL, (2) verify the document represents an end product and not a component, and (3) verify the document defines safety test specifications (not installation or operational performance specifications). OSHA becomes aware of new test standards through various avenues. For example, OSHA may become aware of new test standards by: (1) Monitoring notifications issued by certain SDOs; (2) reviewing applications by NRTLs or applicants seeking recognition to include a new test standard in their scopes of recognition; and (3) obtaining notification from manufacturers, manufacturing organizations, government agencies, or other parties that a new test standard may be appropriate to add to its list of appropriate standards. OSHA may determine to include a new test standard in the list, for example, if the test standard is for a particular type of product that another test standard also covers, covers a type of product that no standard previously covered, or is otherwise new to the NRTL Program.

B. SDO Deletion and Replacement of Test Standards

The NRTL Program regulations require that appropriate test standards be current (29 CFR 1910.7(c)). A test standard withdrawn by a standards-development organization is no longer considered an appropriate test standard (Directive, App. C.XIV.B). It is OSHA's policy to remove recognition of withdrawn test standards by issuing a correction notice in the **Federal Register** for all NRTLs recognized for the withdrawn test standards. However, SDOs frequently will designate a replacement standard for standards they withdraw. OSHA will recognize an NRTL for an appropriate replacement test standard if the NRTL has the requisite testing and evaluation capability for the replacement test standard.

One method that NRTLs may use to show such capability involves an analysis to determine whether any testing and evaluation requirements of existing test standards in an NRTL's scope are comparable (i.e., are completely or substantially identical) to the requirements in the replacement test standard. If OSHA's analysis shows the replacement test standard does not require additional or different technical capability than an existing test standard(s), the replacement test standard is comparable to the existing test standard(s), and OSHA can add the replacement test standard to affected NRTLs' scopes of recognition. If OSHA's analysis shows the replacement test standard requires an additional or different technical capability, or the replacement test standard is not comparable to any existing test standards, each affected NRTL that seeks to have OSHA add the replacement test standard to the NRTL's scope of recognition must provide information to OSHA that demonstrates technical capability.

C. Other Reasons for Removal of Test Standards From the NRTL List of Appropriate Test Standards

OSHA may choose to remove a test standard from the NRTL list of appropriate test standards based on an internal review in which NRTL Program staff review the NRTL list of appropriate test standards to determine if the test standards conform to the definition of an appropriate test standard defined in NRTL Program regulations and policy. There are several reasons for removing a test standard based on this review. First, a document that provides the methodology for a single test is a test method rather than an appropriate test

standard (29 CFR 1910.7(c)). As stated above, a test standard must specify the safety requirements for a specific type of product(s). A test method, however, is a ''specified technical procedure for performing a test'' (Directive, App. B). As such, a test method is not an appropriate test standard. While an NRTL may use a test method to determine if certain safety requirements are met, a test method is not itself a safety requirement for a specific product category.

Second, a document that focuses primarily on usage, installation, or maintenance requirements would also not be considered an appropriate test standard (Directive, App. D.IV.B). In some cases, however, a document may also provide safety test specifications in addition to usage, installation, and maintenance requirements. In such cases, the document would be retained as an appropriate test standard based on the safety test specifications.

Finally, a document may not be considered an appropriate test standard if the document covers products for which OSHA does not require testing and certification (Directive, App. D.IV.A). Similarly, a document that covers electrical-product components would not be considered an appropriate test standard. These documents apply to types of components that have limitation(s) or condition(s) on their use, in that they are not appropriate for use as end-use products. These documents also specify that these types of components are for use only as part of an end-use product. NRTLs, however, evaluate such components only in the context of evaluating whether end-use products requiring NRTL approval are safe for use in the workplace. Testing such components alone would not indicate that the end-use products containing the components are safe for use. Accordingly, as a matter of policy, OSHA considers that documents covering such components are not appropriate test standards under the NRTL Program. OSHA notes, however, that it is not proposing to delete from NRTLs' scopes of recognition any test standards covering end-use products that contain such components.[1]

In addition, OSHA notes that, to conform to a test standard covering an end-use product, an NRTL must still determine that the components in the product comply with the components' specific test standards. In making this determination, NRTLs may test the components themselves, or accept the testing of a qualified testing organization that a given component conforms to its particular test standard. OSHA reviews each NRTL's procedures to determine which approach the NRTL will use to address components, and reviews the end-use product testing to verify the NRTL appropriately addresses that product's components.

II. Proposal To Add New Test Standards to the NRTL Program's List of Appropriate Test Standards

In this notice, OSHA proposes to add several new test standards to the NRTL Program's list of appropriate test standards. Table 1 below lists test standards that are new to the NRTL Program. OSHA preliminarily determined that these test standards are appropriate test standards and proposes to include these test standards in the NRTL Program's list of appropriate test standards. OSHA seeks public comment on this preliminary determination.

TABLE 1—TEST STANDARDS OSHA IS PROPOSING TO ADD TO THE NRTL PROGRAM'S LIST OF APPROPRIATE TEST STANDARDS

Test standard	Test standard title
AAMI HA60601–1–11	Medical Electrical Equipment—Part 1–11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare.
AAMI 60601–2–2	Medical electrical equipment—Part 2–2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories.
AAMI 60601–2–4	Medical electrical equipment—Part 2–4: Particular requirements for basic safety and essential performance of cardiac defibrillators.
AAMI 60601–2–16	Medical electrical equipment,—Part 2–16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment.
AAMI 60601–2–19	Medical Electrical Equipment—Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators.
AAMI 60601–2–20	Medical Electrical Equipment—Part 2–20: Particular requirements for the basic safety and essential performance of infant transport incubators.
AAMI 60601–2–21	Medical Electrical Equipment—Part 2–21: Particular requirements for the basic safety and essential performance of infant radiant warmers.
AAMI 60601–2–25	Medical electrical equipment—Part 2–25: Particular requirements for the basic safety and essential performance of electrocardiographs.
AAMI 60601–2–27	Medical electrical equipment—Part 2–27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.
AAMI 60601–2–47	Medical electrical equipment—Part 2–47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
AAMI 60601–2–50	Medical Electrical Equipment—Part 2–50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment.
AAMI 80601–2–30	Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
AAMI 80601–2–58	Medical Electrical Equipment—Part 2–58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery.
ISA 60079–25	Explosive Atmospheres—Part 25: Intrinsically Safe Electrical Systems.
ISA 60079–27	Explosive atmospheres—Part 27: Fieldbus Intrinsically Safe Concept (FISCO) and Fieldbus Non-Incendive Concept (FNICO).

[1] OSHA notes also that some types of devices covered by these documents, such as capacitors and transformers, may be end-use products themselves, and tested under other test standards applicable to such products. For example, the following test standard covers transformers that are end-use products: UL 1562 Standard for Transformers, Distribution, Dry-Type—Over 600 Volts. OSHA is not proposing to delete such test standards from NRTLs' scopes of recognition.

TABLE 1—TEST STANDARDS OSHA IS PROPOSING TO ADD TO THE NRTL PROGRAM'S LIST OF APPROPRIATE TEST STANDARDS—Continued

Test standard	Test standard title
UL 60745–2–23	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–23: Particular Requirements for Die Grinders and Small Rotary Tools.

III. Proposal To Delete or Replace Several Test Standards From the NRTL Program's List of Appropriate Test Standards

In this notice, OSHA proposes to delete several withdrawn and deleted test standards from the NRTL Program's list of appropriate test standards. OSHA also proposes to incorporate into the NRTL Program's list of appropriate test standards replacement test standards for some of the withdrawn and deleted test standards.

Table 2 lists the test standards that OSHA proposes to delete from the NRTL Program's list of appropriate test standards, as well as an abbreviated rationale for OSHA's proposed action. For a full discussion of the rationale, see Sections I.B and I.C of this notice. Table 2 also lists corresponding replacement test standards that OSHA proposes to incorporate into the NRTL Program's list of appropriate test standards (when applicable). OSHA seeks public comment on this preliminary determination.

OSHA notes also that Table 2 lists the subject test standards and the proposed action with regard to each of these test standards without indicating how the proposed action will affect individual NRTLs. Section IV of this notice discusses how the proposed action will affect individual NRTLs.

TABLE 2—LIST OF TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO NRTLS SCOPES OF RECOGNITION

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
FM 3620—Purged and Pressurized Electrical Equipment for Hazardous Locations.	FM 3620 includes references to out- of-date standards.	NFPA 496—Purged and Pressurized Enclosures for Electrical Equipment.
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements is currently listed as an appropriate NRTL standard.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements UL 61010C–1—Process Control Equipment	These three standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements is currently listed as an appropriate NRTL standard.
UL 1004—Electrical Motors	Standard has been withdrawn	UL 1004–1—Rotating Electrical machines—General Requirements is currently listed as an appropriate NRTL standard.
UL 681– Installation and Classification of Burglar and Holdup Alarm System.	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.
UL 827—Central-Station Alarm Services	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.

OSHA seeks comment on whether its proposed deletions and incorporations are appropriate, and whether it omitted any appropriate replacement test standard that is comparable to a withdrawn test standard. If OSHA determines that it omitted any appropriate replacement test standard that is comparable to a withdrawn test standard, it will, in its final determination, incorporate that replacement test standard into the scope of recognition of each affected NRTL.

IV. Proposed Modifications to Affected NRTLs' Scopes of Recognition

In this notice, OSHA proposes to update the scopes of recognition of several NRTLs. The tables in this section (Table 3 thru Table 16) list, for each affected NRTL, the test standard(s) that OSHA proposes to delete from its scope of recognition and, when applicable, the test standard(s) that OSHA proposes to incorporate into its scope of recognition to replace withdrawn (and deleted) test standards. OSHA seeks comment on whether the proposed deletions and incorporations are correct and whether the replacement standard(s) require additional or different technical capability.

TABLE 3—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF CANADIAN STANDARDS ASSOCIATION (CSA)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
FM 3620—Purged and Pressurized Electrical Equipment for Hazardous Locations.	FM 3620 includes references to out-of-date standards.	NFPA 496—Purged and Pressurized Enclosures for Electrical Equipment.

TABLE 3—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF CANADIAN STANDARDS ASSOCIATION (CSA)—Continued

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements. UL 61010C–1—Process Control Equipment	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.
UL 1004—Electrical Motors	Standard has been withdrawn	NRTLs wishing to add UL 1004–1 must submit an application to OSHA.
UL 681—Installation and Classification of Burglar and Holdup Alarm System.	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.
UL 827—Central-Station Alarm Services	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.

TABLE 4—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF CURTIS-STRAUS LLC (CSL)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements.	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.

TABLE 5—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION FM APPROVALS LLC (FM)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
FM 3620—Purged and Pressurized Electrical Equipment for Hazardous Locations.	FM 3620 includes references to out-of-date standards.	NFPA 496—Purged and Pressurized Enclosures for Electrical Equipment.
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements.	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.
UL 827—Central-Station Alarm Services	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.

TABLE 6—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF INTERTEK TESTING SERVICES NA, INC. (ITSNA)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements. UL 61010C–1—Process Control Equipment.	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.

TABLE 6—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF INTERTEK TESTING SERVICES NA, INC. (ITSNA)—Continued

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 1004—Electrical Motors	Standard has been withdrawn	NRTLs wishing to add UL 1004–1 must submit an application to OSHA.
UL 681—Installation and Classification of Burglar and Holdup Alarm System.	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.
UL 827—Central-Station Alarm Services	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.

TABLE 7—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF MET LABORATORIES, INC. (MET)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements. UL 61010C–1—Process Control Equipment.	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.

TABLE 8—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF NEMKO-CCL (CCL)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements.	Standard has been withdrawn and consolidated with others into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.

TABLE 9—TEST STANDARD OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF NSF INTERNATIONAL (NSF)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements.	Standard has been withdrawn and consolidated with others into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.

TABLE 10—TEST STANDARD OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF QPS EVALUATION SERVICES (QPS)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.

TABLE 11—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION SGS NORTH AMERICA, INC. (SGS)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.

TABLE 12—TEST STANDARD OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF SOUTHWEST RESEARCH INSTITUTE (SWRI)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.

TABLE 13—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF TUV RHINELAND OF NORTH AMERICA, INC. (TUV)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements UL 61010C–1—Process Control Equipment	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.
UL 1004—Electrical Motors	Standard has been withdrawn	NRTLs wishing to add UL 1004–1 must submit an application to OSHA.
UL 681– Installation and Classification of Burglar and Holdup Alarm System.	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.
UL 827—Central-Station Alarm Services	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.

TABLE 14—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF TUV SUD AMERICA, INC. (TUVAM)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.
UL 1004—Electrical Motors	Standard has been withdrawn	NRTLs wishing to add UL 1004–1 must submit an application to OSHA.

TABLE 15—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF TUV SUD PRODUCT SERVICES (TUVPSG)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.
UL 1004—Electrical Motors	Standard has been withdrawn	NRTLs wishing to add UL 1004–1 must submit an application to OSHA.

TABLE 16—TEST STANDARDS OSHA PROPOSES TO DELETE FROM OR INCORPORATE INTO THE SCOPE OF RECOGNITION OF UNDERWRITERS LABORATORIES INC. (UL)

Proposed deleted test standard	Reason for proposed deletion	Proposed replacement test standard(s) (if applicable)
UL 60950—Information Technology Equipment	Standard has been withdrawn and directly replaced by a new standard.	UL 60950–1—Information Technology Equipment—Safety—Part 1: General Requirements.
UL 61010A–1—Electrical Equipment for Laboratory Use; Part 1: General Requirements. UL 61010B–1—Electrical Measuring and Test Equipment; Part 1: General Requirements	These standards have been withdrawn and consolidated into a single standard.	UL 61010–1—Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements.
UL 1004—Electrical Motors	Standard has been withdrawn	NRTLs wishing to add UL 1004–1 must submit an application to OSHA.
UL 681—Installation and Classification of Burglar and Holdup Alarm System.	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.
UL 827—Central-Station Alarm Services	Standard is an installation standard and not an end-product standard. It does not meet the requirements of the NRTL Program.	None.

OSHA will incorporate into its informational Web pages the modifications OSHA decides to make to each NRTL's scope of recognition. These Web pages detail the scope of recognition for each NRTL, including the test standards the NRTL may use to test and certify products under OSHA's NRTL Program. OSHA also will add, to its ''Current List of Appropriate Test Standards under the NRTL Program'' Web page, those test standards it adds to the NRTL list of appropriate test standards, and add, to its ''Current List of Removed Test Standards'' Web page, those test standards that OSHA no longer recognizes or permits under the NRTL Program. Access to these Web pages is available at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2)), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on October 31, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2014–26368 Filed 11–5–14; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Computing and Communication Foundations; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Proposal Review Panel for Expeditions in Computing (EIC) Program (#1192) Site Visit.

Date/Time: December 9, 2014, 6:00 p.m.–9:00 p.m.; December 10, 2014, 8:00 a.m.–8:00 p.m.; December 11, 2014, 8:30 a.m.–3:00 p.m.

Place: Yale University, New Haven, Connecticut.

Type of Meeting: Partial closed.

Contact Person For More Information: Ephraim Glinert, National Science Foundation, 4201 Wilson Boulevard, Room 1125, Arlington, VA 22230. Telephone: (703) 292–8950.

Purpose Of Meeting: To assess the progress of the EIC Award: CCF–1139078, Collaborative Research: Socially Assistive Robots'', and to provide advise and recommendations concerning further NSF support for the project.

Agenda: EIC Site Visit.

Tuesday, December 9, 2014

6:00 p.m. to 9:00 p.m.: Closed. Site Team and NSF Staff meets to discuss Site Visit materials, review process and charge.

Wednesday, December 10, 2014

8:00 a.m. to 1:00 p.m.: Open. Presentations by Awardee Institution, faculty staff and students, to the Site Team and NSF Staff; Discussions and question and answer sessions.

1:00 p.m.–8:00 p.m.: Closed. Draft report on education and research activities.

Thursday, December 11, 2014

8:30 a.m.–Noon: Open. Response presentations by Site Team and NSF Staff Awardee Institution; Discussions and question and answer sessions.

Noon to 3:00 p.m.: Closed. Complete written site visit report with preliminary recommendations.

Reason For Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: November 3, 2014.

Suzanne Plimpton,

Acting Committee Management Officer.

[FR Doc. 2014–26364 Filed 11–5–14; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Computing and Communication Foundations; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Proposal Review Panel for Expeditions in Computing (EIC) Program (#1192)—Site Visit.

Date/Time: November 11, 2014, 6:00 p.m.–9:00 p.m.; November 12, 2014, 8:00 a.m.–8:00 p.m.; November 13, 2014. 8:30 a.m.–3:00 p.m.

Place: University of California, Berkeley, Berkeley, CA.

Type of Meeting: Partial closed.

Contact Person For More Information: Christopher Clifton, National Science Foundation, 4201 Wilson Boulevard, Room 1122, Arlington, VA 22230. Telephone: (703) 292–8930.

Purpose of Meeting: To assess the progress of the EIC Award: CCF- 1139158, ''Making Sense at Scale with Algorithms, Machines, and People'', and to provide advice and recommendations concerning further NSF support for the project.

Agenda: EIC Site Visit.

Tuesday, November 11, 2014

6:00 p.m. to 9:00 p.m.: Closed. Site Team and NSF Staff meets to discuss Site Visit materials, review process and charge.

Wednesday, November 12, 2014

8:00 a.m. to 1:00 p.m.: Open. Presentations by Awardee Institution, faculty staff and students to Site Team and NSF Staff; Discussions and question and answer sessions.

1:00 p.m.–8:00 p.m.: Closed. Draft report on education and research activities.

Thursday, November 13, 2014

8:30 a.m.–noon: Open. Response presentations by Site Team and NSF Staff Awardee Institution; Discussions and question and answer sessions.

Noon to 3:00 p.m.: Closed. Complete written site visit report with preliminary recommendations.

Reason For Late Notice: Due to unforeseen scheduling complications and the necessity to proceed with the review of project.

Reason For Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: November 3, 2014.

Suzanne Plimpton,

Acting Committee Management Officer.

[FR Doc. 2014–26363 Filed 11–5–14; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–7005; NRC–2009–0283]

Waste Control Specialists LLC; Order Modifying Exemption

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) in support of the NRC's consideration of the issuance of a new order superseding an order previously issued to Waste Control Specialists LLC (WCS) on October 20, 2009 (2009 Order). The 2009 Order exempted WCS from the NRC's regulations concerning special nuclear material (SNM). The current action is in response to a request by WCS dated July 18, 2014, to temporarily store containers of transuranic waste, originated at the Los Alamos National Laboratory (LANL), in its Federal Facility Waste Disposal Facility (FWF).

DATES: The EA and FONSI are available as of November 6, 2014.

ADDRESSES: Please refer to Docket ID NRC–2009–0283 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2009–0283. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: James Park, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–6935; email: *James.Park@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The WCS operates a facility in Andrews County, Texas, that is licensed to process and store certain types of radioactive material contained in low-level waste (LLW) and mixed waste (MW). The facility also disposes of hazardous and toxic waste. Under an Agreement authorized by the Atomic Energy Act of 1954, as amended (AEA), the NRC can relinquish and a State can assume, regulatory authority over radioactive material specified in an Agreement with the NRC. In 1963, Texas entered into an Agreement and assumed regulatory authority over source material, byproduct material, and SNM under critical mass.

On November 30, 1997, the State of Texas Department of Health (TDH) issued WCS a radioactive materials license (RML) to possess, treat, and store LLW (RML R04971). In 1997, WCS began accepting Resource Conservation and Recovery Act (RCRA) and Toxic Substance Control Act (TSCA) wastes for treatment, storage, and disposal. Later that year, WCS received a license from the TDH for treatment and storage of MW and LLW. The MW and LLW streams may contain quantities of SNM. In 2007, RML R04971 was transferred to the Texas Commission on Environmental Quality (TCEQ). In September 2009, the TCEQ issued RML R04100 to WCS for disposal of LLW.

Section 70.3 of Title 10 of the *Code of Federal Regulations* (10 CFR) requires

persons who own, acquire, deliver, receive, possess, use, or transfer SNM to obtain a license pursuant to the requirements of 10 CFR Part 70. The licensing requirements in 10 CFR Part 70 apply to persons in Agreement States possessing greater than critical mass quantities, as defined in 10 CFR 150.11. However, pursuant to 10 CFR 70.17(a), ''the Commission may grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.''

On September 25, 2000, WCS requested an exemption from the licensing requirements in 10 CFR Part 70 (ADAMS Accession No. ML003759584). On November 21, 2001, the NRC issued an order to WCS (2001 Order) granting an exemption to WCS from certain NRC regulations and permitted WCS, under specified conditions, to possess waste containing SNM in greater quantities than specified in 10 CFR Part 150, at the WCS storage and treatment facility in Andrews County, Texas, without obtaining an NRC license pursuant to 10 CFR Part 70. The 2001 Order was published in the **Federal Register** on November 15, 2001 (66 FR 57489). The conditions specified in the 2001 Order are discussed in the October 2001 EA and November 2001 Safety Evaluation Report (SER) that supported the 2001 Order. The EA and SER are attachments to the November 21, 2001, NRC letter to WCS (ADAMS Accession No. ML030130085).

By letters dated August 6, 2003, and March 14, 2004, WCS requested a modification to the 2001 Order, which would allow it to use additional reagents for chemical stabilization of mixed waste containing SNM. The NRC issued the new order on November 4, 2004 (2004 Order), which superseded the 2001 Order. The 2004 Order was published in the **Federal Register** on November 12, 2004 (69 FR 65468). The new conditions specified in the 2004 Order are discussed in the October 2004 EA and SER that supported the 2004 Order (ADAMS Accession Nos. ML043020614 and ML042250362). The 2004 Order changed the 2001 Order conditions to allow WCS to use such chemical reagents as it deems necessary for treatment and stabilization of mixed waste containing SNM, provided that the SNM mass does not exceed specified concentration limits.

By letter dated December 10, 2007, WCS requested additional modifications to the 2004 Order, which would allow it to discontinue confirmatory sampling of waste streams with certain SNM characteristics and to meet the confirmatory sampling requirements of Condition 7 of the order for sealed sources by using surface smear surveys. The NRC issued the new order to WCS on October 20, 2009 (2009 Order), which superseded the 2004 Order. The 2009 Order was published in the **Federal Register** on October 26, 2009 (74 FR 55071). The new conditions specified in the 2009 Order are discussed in the October 2009 EA and SER that supported the 2009 Order (ADAMS Accession Nos. ML092460509 and ML093070307). The 2009 Order changed the 2004 Order conditions regarding sampling of waste, what is allowed to be in the waste, and the amount of highly water soluble SNM in each waste package.

In July 2013, by Amendment No. 22 of RML R04100, the TCEQ began to merge the license requirements in RML R04971 (for the radioactive waste treatment, storage, and processing facility) with the requirements in RML R04100 (for the LLW land disposal facility). In Amendment No. 22 of RML R04100, the TCEQ license requirements related to the 2009 Order in RML R04971 for the WCS treatment, storage, and processing facility were transferred to RML R04100. Previous orders referred to that location as the treatment, storage, and processing facility. Subsequently, WCS began referring to that location as the ''Treatment, Storage and Disposal Facility.'' The NRC will use the name ''Treatment, Storage, and Disposal Facility'' and the abbreviation TSDF to reference that location in this October 2014 EA and the 2014 Order.

The previous NRC orders (2001, 2004, and 2009) addressed the issue that 10 CFR 70.3 requires persons who own, acquire, deliver, receive, possess, use, or transfer SNM to obtain an NRC license pursuant to the requirements in 10 CFR Part 70. However, 10 CFR 150.10 exempts a person in an Agreement State who possesses SNM in quantities not sufficient to form a critical mass from the NRC's imposed licensing requirements and regulations. The method for calculating the quantity of SNM not sufficient to form a critical mass is set out in 10 CFR 150.11. Therefore, prior to the 2001 Order, WCS was required to comply with NRC regulatory requirements and obtain an NRC specific license to possess SNM in quantities greater than amounts established in 10 CFR 150.11. The 2001 WCS exemption request, to the NRC, proposed to use concentration-based limits rather than mass-based limits at a specific location at the WCS facility. The 2001 Order granted, and the subsequent NRC orders (2004 and 2009) continued, the use of concentration-based limits with conditions at a specific location at the WCS facility. The TCEQ incorporated the concentration-based limits and conditions from each respective order (2001, 2004, and 2009) into the WCS license for the specific location at the WCS facility where the concentration-based limits instead of mass-based limits are applicable.

By letter dated July 18, 2014, WCS requested an exemption from the NRC's regulations to possess SNM in excess of the critical mass limits specified in 10 CFR 150.11 while temporarily storing specific waste at a different location at the WCS facility other than the TSDF (ADAMS Accession No. ML14209A660). The WCS exemption request referenced the WCS June 20, 2014, letter to the NRC that notified the NRC of actions that WCS had taken in response to the on-going U.S. Department of Energy (DOE) investigation of an unplanned radiation release event at the DOE Waste Isolation Pilot Plant (WIPP) facility (*i.e.,* the WIPP incident) (ADAMS Accession No. ML14171A554). The specific waste includes some of the transuranic waste that originated at the DOE Los Alamos National Laboratory (LANL), which are destined to be disposed of at the DOE WIPP facility (i.e., LANL waste). Due to the February 14, 2014, WIPP incident, the DOE suspended operations at the WIPP facility. In April 2014, WCS began receiving some of the LANL waste from DOE, which met the conditions in the 2009 Order. The WCS intended to temporarily store the LANL waste at the TSDF at the WCS facility until WCS ships the waste.

Based on the DOE investigation of the WIPP incident, DOE subsequently informed WCS that some of the LANL waste being temporarily stored at the WCS TSDF could, under certain conditions, react and potentially result in a release of transuranic radionuclides to the environment. On June 12, 2014, WCS responded to DOE's information by starting to voluntarily move the identified LANL waste to the Federal Waste Disposal Facility (FWF) at the WCS facility for temporary storage.

To move the identified LANL waste from the TSDF to the FWF, WCS first loaded the LANL waste containers onto pallets and then using a crane, moved the container-bearing pallets into Modular Concrete Canisters (MCCs). The WCS then filled the void space within each loaded MCC with washed river rock. The WCS moved the loaded MCCs to the FWF and placed the MCCs in a single array. The WCS then poured

a 1-foot, flowable sand layer around and over the MCCs.

The MCCs, washed river rock, and sand layer are intended to reduce the likelihood of an incident similar to the one that happened at the WIPP facility and to provide protection in case such an incident was to occur at the WCS facility. The WCS placed the identified LANL waste for temporary storage in a specific area within the FWF that will be separate from other wastes disposed of at the FWF. That placement will also allow easier accessibility and monitoring of the identified LANL waste temporarily stored at the FWF.

The WCS currently plans for the identified LANL waste at the FWF to be shipped from the FWF. In preparation for that shipment, WCS would need to retrieve the identified LANL waste containers from the MCCs. To gain access to the MCC lids, WCS would remove the sand layer. The WCS would then open each MCC and, using a vacuum truck, remove the washed river rock. The WCS would then use a crane to lift the LANL waste container-bearing pallets from the MCC.

II. Environmental Assessment

Description of the Proposed Action

The proposed action is to decide whether to grant or deny the WCS July 18, 2014, request to modify the conditions of the 2009 Order to reflect the WCS actions already taken in moving the identified LANL waste from temporary storage at the TSDF to temporary storage in the FWF, and, in the future, to prepare the waste for shipment from the FWF.

Need for the Proposed Action

The WCS is making this request so that a new Order to WCS would reflect the actions that WCS has already taken and is expected to take in the future regarding the identified LANL waste at WCS in response to the DOE investigation of the WIPP incident.

The purpose of this EA is to assess the potential environmental impacts of the WCS actions already taken in moving the identified LANL waste from the TSDF to the FWF, temporarily storing the identified LANL waste at the FWF, and preparing for the future shipments of the waste from the FWF. This EA does not approve or deny the requested action. A separate SER has been prepared in support of approval or denial of the requested action.

Environmental Impacts of the Proposed Action

The NRC does not expect that significant changes in radiation hazards to workers occurred from the movement of the identified LANL waste from the TSDF to the FWF or will occur in the future while temporarily storing the identified LANL waste at the FWF or future preparation of the identified LANL waste for shipment from the FWF. To perform those actions, WCS would need to have in place the necessary radiation protection procedures to keep potential radiological doses to workers within regulatory limits. The WCS conducts its radiation protection program with an emphasis on maintaining doses as low as is reasonably achievable.

To address the potential for an incident similar to that which had occurred at the WIPP facility, WCS packed the identified LANL waste-bearing containers into the MCCs, filled the void space with washed river rock, moved the MCCs to the FWF, and is temporarily storing the MCCs in the FWF in a separate placement and arrangement amenable to monitoring in the FWF. All LANL waste while at the WCS facility is covered by both the material control and accounting and security programs for the WCS facility.

If the WCS exemption request is approved by the NRC staff, then the NRC would issue a new order that would supersede the 2009 Order. Conditions 1 through 7 would remain the same as in the 2009 Order, and a new Condition 8 would be created in a new order to address WCS' exemption request. The new Condition 8 would apply to the LANL waste stored in either the TSDF or the FWF. Condition 8 in the 2009 Order would be renumbered as Condition 9 in a new order, and Condition 9 in the 2009 Order would be renumbered as Condition 10 in a new order. A new Condition 11 would be added in a new order to provide the authority for the Director of the Office of Nuclear Material Safety and Safeguards at NRC (or their designee), to, in writing, relax or rescind any of the new order's conditions upon demonstration by the WCS of good cause. The WCS would continue to be permitted to possess SNM at the TSDF that meets the concentration limits and controls. The WCS would continue to be permitted to possess highly water soluble forms of SNM limited to amounts of SNM less than SNM of low strategic significance, as defined in 10 CFR 73.2 at the TSDF.

The State of Texas regulates effluent releases and potential doses to the public under the WCS license. The superseding NRC order would not change the State of Texas' regulation of the WCS facility.

The proposed action would not result in substantive changes to the transportation impacts identified in prior EAs. Movement of the identified LANL waste from the TSDF to the FWF was restricted to the WCS facility and involved the use of on-site cranes. Any increase in the number of trucks entering and leaving the WCS facility in support of the proposed action is expected to have been minimal. The trucks potentially would have supplied the washed river rock and flowable sand layer. That activity took place over a few days to a week, with the consequent impacts (*i.e.,* primarily fugitive dust, exhausts, and traffic load on travelled roads) being temporary in nature. All other environmental impacts would be the same as those evaluated in the EAs that supported the 2001 Order, the 2004 Order, and the 2009 Order.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the WCS' July 18, 2014, request and therefore, to not issue a new order that would supersede the 2009 Order (*i.e.,* the ''no action'' alternative). Under that alternative, WCS would need to remove the identified LANL waste from its temporary storage location at the FWF and return it to the TSDF. The impacts of doing so would be similar to those experienced for the proposed action because the actions to move the identified LANL waste back to the TSDF from the FWF would be the reverse of those taken to move it from the TSDF to the FWF.

Additionally, temporary storage of the identified LANL waste at the TSDF may increase the potential for impacts on the environment at the WCS facility, if an event similar to the WIPP incident were to occur.

Agencies and Persons Consulted

On October 1, 2014, the staff consulted with the TCEQ, providing a copy of the draft EA for review and comment (ADAMS Accession No. ML14280A246). By email dated October 3, 2014, the TCEQ stated they had no substantive comments on the EA, recommending only two minor grammatical changes (ADAMS Accession No. ML14280A246). The NRC staff modified the EA to address the TCEQ comments.

The proposed action does not involve the development or disturbance of additional land. Hence, the NRC has determined that the proposed action will not affect listed endangered or threatened species or their critical habitat. Therefore, no further

consultation is required under Section 7 of the Endangered Species Act. Likewise, the NRC staff has determined that the proposed action does not have the potential to cause effects on historic properties even if they were present. The identified LANL waste is being stored in the FWF, the bottom of which is more than 100 feet below grade, and no ground disturbing activities are associated with the proposed action. Therefore, no consultation is required under Section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC has reviewed WCS's July 18, 2014, request to amend the 2009 Order. The NRC has found that effluent releases and potential radiological doses to the public are not anticipated to change as a result of this action and that occupational exposures are expected to remain within regulatory limits and as low as reasonably achievable. On the basis of the environmental assessment, the NRC concludes that the proposed action did not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Dated at Rockville, Maryland, this 30th day of October 2014.

For the Nuclear Regulatory Commission.

Marissa Bailey,

Director, Division of Fuel Cycle Safety, Safeguards and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2014–26415 Filed 11–5–14; 8:45 am]

BILLING CODE 7590–01–P

PRESIDIO TRUST

Notice of Public Meeting of Presidio Institute Advisory Council

AGENCY: The Presidio Trust.

ACTION: Notice of public meeting of Presidio Institute Advisory Council.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given that a public meeting of the Presidio Institute Advisory Council (Council) will be held from 2:00 p.m. to 4:30 p.m. on Friday, December 12, 2014. The meeting is open to the public, and oral public comment will be received at the meeting. The Council was formed to advise the Executive Director of the Presidio Trust (Trust) on matters pertaining to the rehabilitation and reuse of Fort Winfield Scott as a new national center focused on service and leadership development.

SUPPLEMENTARY INFORMATION: The Trust's Executive Director, in consultation with the Chair of the Board of Directors, has determined that the Council is in the public interest and supports the Trust in performing its duties and responsibilities under the Presidio Trust Act, 16 U.S.C. 460bb appendix.

The Council will advise on the establishment of a new national center (Presidio Institute) focused on service and leadership development, with specific emphasis on: (a) Assessing the role and key opportunities of a national center dedicated to service and leadership at Fort Scott in the Presidio of San Francisco; (b) providing recommendations related to the Presidio Institute's programmatic goals, target audiences, content, implementation and evaluation; (c) providing guidance on a phased development approach that leverages a combination of funding sources including philanthropy; and (d) making recommendations on how to structure the Presidio Institute's business model to best achieve the Presidio Institute's mission and ensure long-term financial self-sufficiency.

Meeting Agenda: This meeting of the Council will feature a business strategy presentation and Council discussion. Staff members will provide updates on Presidio Institute programs. The period from 4:00 p.m. to 4:30 p.m. will be reserved for public comments.

Public Comment: Individuals who would like to offer comments are invited to sign-up at the meeting and speaking times will be assigned on a first-come, first-served basis. Written comments may be submitted on cards that will be provided at the meeting, via mail to Aimee Vincent, Presidio Institute, 1201 Ralston Avenue, San Francisco, CA 94129–0052, or via email to *institute@presidiotrust.gov.* If individuals submitting written comments request that their address or other contact information be withheld from public disclosure, it will be honored to the extent allowable by law. Such requests must be stated prominently at the beginning of the comments. The Trust will make available for public inspection all submissions from organizations or businesses and from persons identifying themselves as representatives or officials of organizations and businesses.

Time: The meeting will be held from 2:00 p.m. to 4:30 p.m. on Friday, December 12, 2014.

Location: The meeting will be held at the Presidio Institute, Building 1202 Ralston Avenue, San Francisco, CA 94129.

FOR FURTHER INFORMATION CONTACT: Additional information is available online at *http://www.presidio.gov/explore/Pages/fort-scott-council.aspx.*

Dated: October 30, 2014.

Karen A. Cook,

General Counsel.

[FR Doc. 2014–26367 Filed 11–5–14; 8:45 am]

BILLING CODE 4310–4R–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

1. Title and purpose of information collection: Application for Benefits Due But Unpaid at Death; OMB 3220–0055.

Under Section 2(g) of the Railroad Unemployment Insurance Act, benefits that accrued but were not paid because of the death of the employee shall be paid to the same individual(s) to whom benefits are payable under Section 6(a)(1) of the Railroad Retirement Act. The provisions relating to the payment of such benefits are prescribed in 20 CFR 325.5 and 20 CFR 335.5.

The RRB provides Form UI–63, Application for Benefits Due But Unpaid at Death, to those applying for the accrued sickness or unemployment benefits unpaid at the death of the employee and for obtaining the information needed to identify the proper payee. One response is requested of each respondent. Completion is required to obtain a benefit. The RRB proposes no changes to Form UI–63.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
UI–63	25	7	3

1.

2. Title and purpose of information collection: Medicare; OMB 3220–0082.

Under Section 7(d) of the Railroad Retirement Act (RRA), the Railroad Retirement Board (RRB) administers the Medicare program for persons covered by the railroad retirement system. The RRB uses Form AA–6, Employee Application for Medicare; Form AA–7, Spouse/Divorced Spouse Application for Medicare; and Form AA–8, Widow/Widower Application for Medicare; to obtain the information needed to determine whether individuals who have not yet filed for benefits under the RRA are qualified for Medicare payments provided under Title XVIII of the Social Security Act.

Further, in order to determine if a qualified railroad retirement beneficiary who is claiming supplementary medical insurance coverage under Medicare is entitled to a Special Enrollment Period (SEP) and/or premium surcharge relief because of coverage under an Employer Group Health Plan (EGHP), the RRB needs to obtain information regarding the claimant's EGHP coverage, if any. The RRB uses Form RL–311–F, Evidence of Coverage Under An Employer Group Health Plan, to obtain the basic information needed to establish EGHP coverage for a qualified railroad retirement beneficiary.

Completion of the forms is required to obtain a benefit. One response is requested of each respondent. The RRB proposes no changes to the forms in the collection.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
AA–6	180	8	24
AA–7	50	8	7
AA–8	10	8	1
RL–311–F	2,000	10	333
Total	2,240		365

3. Request to Non-Railroad Employer for Information About Annuitant's Work and Earnings; OMB 3220–0107.

Under Section 2 of the Railroad Retirement Act (RRA), a railroad employee's retirement annuity or an annuity paid to the spouse of a railroad employee is subject to work deductions in the Tier II component of the annuity and any employee supplemental annuity for any month in which the annuitant works for a Last Pre-Retirement Non-Railroad Employer (LPE). The LPE is defined as the last person, company, or institution, other than a railroad employer, that employed an employee or spouse annuitant. In addition, the employee, spouse, or divorced spouse Tier I annuity benefit is subject to work deductions under Section 2(f)(1) of the RRA for earnings from any non-railroad employer that are over the annual exempt amount. The regulations pertaining to non-payment of annuities by reason of work and LPE are contained in 20 CFR 230.1 and 230.2.

The RRB utilizes Form RL–231–F, Request to Non-Railroad Employer for Information About Annuitant's Work and Earnings, to obtain the information needed to determine if a work deduction should be applied because an annuitant worked in non-railroad employment after the annuity beginning date. One response is requested of each respondent. Completion is voluntary. The RRB proposes no changes to Form RL–231–F.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
RL–231–F	300	30	150

4. Title and purpose of information collection: Gross Earnings Report; OMB 3220–0132.

In order to carry out the financial interchange provisions of section 7(c)(2) of the Railroad Retirement Act (RRA), the RRB obtains annually from railroad employer's the gross earnings for their employees on a one-percent basis, i.e., 1% of each employer's railroad employees. The gross earnings sample is based on the earnings of employees whose social security numbers end with the digits ''30.'' The gross earnings are used to compute payroll taxes under the financial interchange.

The gross earnings information is essential in determining the tax amounts involved in the financial interchange with the Social Security Administration and Centers for Medicare and Medicaid Services. Besides being necessary for current financial interchange calculations, the gross earnings file tabulations are also an integral part of the data needed to estimate future tax income and corresponding financial interchange amounts. These estimates are made for internal use and to satisfy requests from other government agencies and interested groups. In addition, cash flow projections of the social security equivalent benefit account, railroad retirement account and cost estimates made for proposed amendments to laws

administered by the RRB are dependent on input developed from the information collection.

The RRB utilizes Form BA–11 to obtain gross earnings information from railroad employers. Employers have the option of preparing and submitting BA–11 reports online via the RRB's Employer Reporting System or on paper (or in like format) on magnetic tape cartridges, by File Transfer Protocol (FTP), or secure Email. The online BA–11 includes the option to file a ''negative report'' (no employees, or no employees with the digits ''30''). Completion is mandatory. One response is requested of each respondent. The RRB proposes to formally eliminate the paper and magnetic tape cartridge versions of Form BA–11 from the information collection.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
BA–11 File Transfer Protocol	7	300 (5 hours)	35
BA–11 CD–ROM	5	30	2
BA–11 secure E-mail	5	30	2
BA–11 (Internet)—Positive	137	30	68
BA–11 (Internet)—Negative	329	15	82
Total	483		189

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.* Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or emailed to *Charles.Mierzwa@RRB.GOV.* Written comments should be received within 60 days of this notice.

Charles Mierzwa.

Chief of Information Resources Management.

[FR Doc. 2014–26365 Filed 11–5–14; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73489; File No. SR–NYSEARCA–2014–123]

Self-Regulatory Organizations: NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Arca Options Fee Schedule To Modify the Fees Related to the Use of Ports That Provide Connectivity to the Exchange's Trading Systems for Entry of Orders and/or Quotes

October 31, 2014.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 23, 2014, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Options Fee Schedule (''Fee Schedule'') to modify the fees related to the use of ports that provide connectivity to the Exchange's trading systems for entry of orders and/or quotes. The Exchange proposes to implement the fee changes effective November 1, 2014. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to modify the fees related to the use of ports that provide connectivity to the Exchange's trading systems for entry of orders and/or quotes. The Exchange proposes to implement the fee changes on November 1, 2014. The purpose of the proposed fee changes are to ensure a fair and reasonable use of Exchange resources by allowing the Exchange to recoup certain of its connectivity costs (described below), while continuing to offer competitive rates to OTP Holders and OTP Firms (''OTPs'').

The Exchange currently makes available to OTPs order/quote entry ports for connectivity to Exchange trading systems (each a ''Port''). OTPs may be authorized to utilize Port(s) for option activity on NYSE Arca Options and incur monthly Port Fees by the Exchange, as set forth in the table below.

PORT FEES:	
ORDER/QUOTE ENTRY PORT *	Ports 1–5: no charge. Ports 6–100: $200 per port per month. Ports 101 and greater: $100 per port per month.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

	Backup datacenter port: no fee unless utilized during the relevant month, in which case, above fees shall apply.

* For purpose of calculating the number of order/quote entry ports, the Exchange shall aggregate the ports of affiliates.[4]

Thus, while there is no charge to an OTP authorized to utilize five Ports, an OTP will, for example, pay $200 per month for a sixth Port. Once OTPs exceed the first five Ports, the charges may look as follows: An OTP authorized to utilize 50 Ports is charged $9,000 in monthly Port Fees (*i.e.,* 45 × $200); 100 Ports is charged $19,000 in monthly Port Fees (*i.e.,* 95 × $200); or 120 Ports is charged $21,000 in monthly Ports Fees (*i.e.,* 95 × $200 plus 20 × $100). Finally, unutilized Ports that connect to the Exchange via its backup datacenter are considered to have been established for backup purposes and are not charged Port Fees.[5]

At this time, the Exchange is proposing to modify its Port Fees as set forth in the table below, with new charges appearing underlined and deletions appearing in brackets.

PORT FEES:	
ORDER/QUOTE ENTRY PORT*	[Ports 1–5: no charge]. [Ports 6–100: $200 per port per month]. *Ports 1–40: $450 per port per month.* Ports [101]*41* and greater: [$100]*$150* per port per month.
NYSE Arca Market Maker Open Outcry Discount	*Any NYSE Arca Market Maker that executes 50% or more of their market maker volume in open outcry shall receive a discount on their monthly port fees of 60%, not to exceed a maximum dollar discount of $10,000 per month.*

In sum, the Exchange is proposing to no longer offer Ports 1–5 free of charge and will instead charge OTPs $450 per Port, per month for the first 40 Ports that an OTP is authorized to utilize. The Exchange further proposes to charge $150 per Port, per month for any Port in excess of 40 for which an OTP is authorized. Using the example above, an OTP would be charged as follows: An OTP authorized to utilize 50 Ports would be charged $19,500 in monthly Port Fees (*i.e.,* 40 × $450 plus 10 × $150); 100 Ports is charged $27,000 in monthly Port Fees (*i.e.,* 40 × $450 plus 60 × $150); or 120 Ports is charged $30,000 in monthly Ports Fees (*i.e.,* 40 × $450 plus 80 × $150). In addition, the Exchange proposes to offer a discount on monthly Port Fees of 60%, not to exceed $10,000, for any NYSE Arca Market Maker that execute at least 50% of their Market Maker volume in open outcry in any given month.[6]

The Exchange proposes to implement these changes on November 3, 2014[sic]. In this regard, as is the case today, the Exchange notes that billing for Ports would continue to be based on the number of Ports for which an OTP has been authorized for option activity on the third business day prior to the end of the month. Similarly, the Exchange would continue to assess the Port Fees based on the number of Ports authorized—except for Ports that are considered established for backup purposes—such that the level of activity with respect to a particular Port would not affect the assessment of monthly fees. With regard to the discount on monthly Port Fees for Market Maker volume executed in open outcry, the measurement period for billing purposes will be based on the activity in the month prior, such that September Market Maker volumes will be used to decide if the Market Maker qualified for the 60% discount on their October Port Fees.

The Exchange is also proposing a non-substantive, formatting change to the section of the fee schedule that applies to Port Fees. The Exchange is proposing to re-format that section of the Fee Schedule as a table with distinct rows and columns to make the Fee Schedule easier for participants to understand.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[7] in general, and furthers the objectives of Section 6(b)(4) of the Act,[8] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fee changes are reasonable, equitable and not unfairly discriminatory because they are designed to ensure a fair and reasonable use of Exchange resources by allowing the Exchange to recoup for certain of its connectivity costs, while continuing to offer competitive rates to OTPs. The Exchange notes that it has not increased its Port Fees since November 2012,[9] and the proposed increases are intended to adjust the Port Fees to reflect the increased costs that the Exchange bears with respect to maintaining the Ports. Specifically, the Exchange believes that the proposed increase in Port Fees are reasonable because the proposed fees charged for Ports would enable the Exchange to offset, in part, its connectivity costs associated with making such Ports available, including costs based on gateway software and hardware enhancements and resources dedicated to gateway development, quality assurance, and support. In this regard, the Exchange believes that the proposed Port Fees are in line with those charged by other venues, and that in some cases its Port Fees would be less expensive than many of its primary competitors. For example, the Chicago Board Options Exchange (''CBOE'')

[4] An affiliate is a person or firm that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, the firm. *See* Rule 1.1(a).

[5] The Exchange's backup datacenter is currently located in Chicago, Illinois. The Exchange notes that it monitors usage of these particular Ports and, accordingly, if an order/quote is sent to the Exchange via one of these Ports, then the Port is charged the applicable monthly Port Fee.

[6] For example, a Market Maker authorized to utilize 100 Ports is charged $27,000 in monthly Port Fees (*i.e.,* $450 × 40 = $18,000 plus $150 × 60 = $9,000). However, if during that month, the Market Maker executes at least 50% of their volume in open outcry, the Market Maker then becomes eligible for a discount of 60%—or a reduction of $16,200. However, the proposal caps the amount of the available discount to $10,000 per month. Thus, in this example, the Port Fees charged would be $17,000 ($27,000 less the maximum monthly discount of $10,000).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

[9] *See* Securities and Exchange Release No. 34–68230 (November 14, 2012), 77 FR 69670 (November 20, 2012) (SR–NYSEArca–2012–122).

charges $500 per port per month for a Network Access Port.[10] The NASDAQ Options Market (''NOM'') charges $550 per port per month.[11]

The Exchange believes that the proposed fees are reasonable, equitable and not unfairly discriminatory because—just as they do today—OTPs are able to request, and pay for, only those Ports that they require, with no impact to other OTPs.

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to no longer offer the first five ports free of charge as all OTPs are being treated in the same manner. Further, as noted above, the Exchange believes that the proposed fee changes are reasonable, equitable and not unfairly discriminatory because they are designed to ensure a fair and reasonable use of Exchange resources by allowing the Exchange to recoup for certain of its connectivity costs, while continuing to offer competitive rates to OTPs.

The Exchange believes that the proposed monthly per Port fee of $450 for the first 40 Ports is reasonable, equitable and not unfairly discriminatory because it is comparable to the rates of other exchanges.[12] The Exchange also believes that the proposed fees are equitable and not unfairly discriminatory because they would apply to all OTPs that utilize Ports for options activity on the Exchange.

The Exchange also believes that it is reasonable, equitable and not unfairly discriminatory to decrease the monthly per Port rate from $450 to $150 once an OTP has exceeded 40 Ports (*i.e.,* a monthly per Port charge of $150 for Ports 41+). Specifically, reducing the monthly fee to $150 per Port when an OTP needs to utilize more than 40 Ports would enable those firms to maintain those connections to the Exchange, while helping to offset the increased costs of that connection. In addition, the reduced fee is likewise appropriate given that certain market participants, particularly options Market Makers, require more than 40 Ports in order to satisfy their responsibilities and obligations to investors, which stem from the significant number of series that exist for any particular option class[13] and the requirement for NYSE Arca Market Makers to maintain a bid or offer in assigned classes. Furthermore, Market Makers that quote across a significant number, if not all, of the 2,602 classes traded on the Exchange have responsibility for upwards of 650,000 individual option series.[14] Accordingly, the level of activity that is required to satisfy a Market Maker's quoting obligations, which directly relates to the number of Ports required, is such that the Exchange believes it is reasonable, equitable and not unfairly discriminatory to offer a reduced fee to OTPs that utilize more than 40 Ports on the Exchange in a given month.

Further, the Exchange believes that the proposal to offer a 60% discount on Port Fees, not to exceed a maximum discount of $10,000 per month, to those Market Makers that execute at least 50% of their market maker volume in a given month in open outcry is also reasonable, equitable and not unfairly discriminatory. First, the Exchange believes that the trading floor plays an important role in the options market. Specifically, trading floors provide price discovery for large or complex strategies not easily exposed in electronic auctions. In order to encourage robust participation in the Exchange's outcry markets, the Exchange believes that it is reasonable to offer a discount in the manner described for those Market Makers that continue to provide price discovery in open outcry as evidenced by the relative level of their market maker volume executed in open outcry. The Exchange notes that other options exchanges offer similar discounts in the to encourage market makers to maintain a presence in the open outcry market.[15]

As the proposed discount is available to any Market Maker that executes at least 50% of their market maker volume in open outcry, the Exchange believes that the current proposal is not unfairly discriminatory as any market making firm can seek to place individual traders on the trading floor. The Exchange believes the proposal is reasonable and equitable as the price discovery found in the outcry markets benefits all participants. The Exchange notes that the proposed discount would apply for those Market Makers that reach or exceed the volume threshold for open outcry transactions. The Exchange believes that this threshold has been appropriately set to provide an incentive for floor-based market making because this threshold represents a level where the preponderance of volume is in open outcry and therefore not dependent on a Port, but a Port is nonetheless necessary to meet Market Maker quoting obligations. The Exchange notes that Market Makers that do not meet this volume threshold for their options activity in open outcry would continue to be charged at the same rate for Port Fees as all other OTPs.

The Exchange believes that the proposal to re-format the section of the fee schedule describing Port Fees into a table, with distinct rows and columns, is reasonable, equitable and not unfairly discriminatory as the proposed change will reduce confusion and will make the fee schedule more transparent and easier for all participants to understand.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[16] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed fee change is reasonably designed to be fair and equitable, and therefore, will not unduly burden any particular group of market participants trading on the Exchange vis-à-vis another group (*i.e.,* Market Markers versus non-Market Makers). Specifically, the Exchange believes that the reduced fee for OTPs that utilize more than 40 Ports will relieve any undue burden that the proposed fee change might have on Marker Makers. Further, the Exchange believes that the proposed discount to the monthly Port Fee, capped at $10,000 for those Market Maker that executes at least 50% of their market maker volume in open outcry, likewise does not impose any undue burden on competition among and between market participants because as any market making firm can seek to place individual traders on the trading floor. In addition, the Exchange believes that the proposed changes will enhance the competiveness of the Exchange relative

[10] *See* CBOE Fee Schedule *available here, http://www.cboe.com/publish/feeschedule/CBOEFeeSchedule.pdf* (CBOE Command Connectivity Charges, at p 10).

[11] *See* NOM Price List, *available here, http://nasdaq.cchwallstreet.com/NASDAQTools/bookmark.asp?id=nasdaq-rule-options_XVS3&manual=/nasdaq/main/nasdaq-optionsrules* (Section 3, NASDAQ Options Market—Access Services).

[12] *See supra* nn. 10–11.

[13] For example, as of October 9, 2014, there were more than 2350 individual option series overlying Chipotle Mexican Grill, Inc. (NYSE: CMG).

[14] These figures are valid as of October 9, 2014.

[15] *See* the NYSE Amex Options Fee Schedule, *available here, https://www.nyse.com/publicdocs/nyse/markets/amex-options/NYSE_Amex_Options_Fee_Schedule.pdf* (charging lower ATP fees for Floor Market Makers, based on volume transacted in open outcry, to encourage their presence and participation in the outcry markets on the trading floor).

[16] 15 U.S.C. 78f(b)(8).

to other exchanges and, as noted above, the increased fees are comparable to port fees offered by competing option exchanges.[17] The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[18] of the Act and subparagraph (f)(2) of Rule 19b–4[19] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[20] of the Act to determine whether the proposed rule change 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–NYSEARCA–2014–123 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR–NYSEARCA–2014–123. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2014–123 and should be submitted on or before November 28, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–26348 Filed 11–5–14; 8:45 am]

BILLING CODE 8011–01–P

[17] *See supra* nn. 10–11.

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(2).

[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73490; File No. SR–NYSEMKT–2014–92]

Self-Regulatory Organizations: NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Amex Options Fee Schedule To Modify the Fees Related to the Use of Ports That Provide Connectivity to the Exchange's Trading Systems for Entry of Orders and/or Quotes

October 31, 2014.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 23, 2014, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Amex Options Fee Schedule (''Fee Schedule'') to modify the fees related to the use of ports that provide connectivity to the Exchange's trading systems for entry of orders and/or quotes. The Exchange proposes to implement the fee changes effective November 3, 2014. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below,

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to modify the fees related to the use of ports that provide connectivity to the Exchange's trading systems for entry of oreers and/or quotes. The Exchange proposes to implement the fee changes on November 3, 2014. The purpose of the proposed fee changes are to ensure a fair and reasonable use of Exchange resources by allowing the Exchange to recoup certain of its connectivity costs (described below), while continuing to offer competitive rates to ATP Holders.

The Exchange currently makes available to ATP Holders order/quote entry ports for connectivity to Exchange trading systems (each a ''Port''). ATP Holders may be authorized to utilize Port(s) for option activity on NYSE Amex Options and incur monthly Port Fees by the Exchange, as set forth in the table below.

PORT FEES:	
ORDER/QUOTE ENTRY PORT*	Ports 1–5: no charge. Ports 6–100: $200 per port per month. Ports 101 and greater: $100 per port per month. Backup datacenter port: no fee unless utilized during the relevant month, in which case, above fees shall apply.

* For purpose of calculating the number of order/quote entry ports, the Exchange shall aggregate the ports of affiliates.[4]

Thus, while there is no charge to an ATP Holder authorized to utilize five Ports, an ATP Holder will, for example, pay $200 per month for a sixth Port. Once ATP Holders exceed the first five Ports, the charges may look as follows: An ATP Holder authorized to utilize 50 Ports is charged $9,000 in monthly Port Fees (*i.e.,* 45 × $200); 100 Ports is charged $19,000 in monthly Port Fees (*i.e.,* 95 × $200); or 120 Ports is charged $21,000 in monthly Ports Fees (*i.e.,* 95 × $200 plus 20 × $100). Finally, unutilized Ports that connect to the Exchange via its backup datacenter are considered to have been established for backup purposes and are not charged Port Fees.[5]

At this time, the Exchange is proposing to modify its Port Fees as set forth in the table below, with new charges appearing underlined and deletions appearing in brackets.

PORT FEES:	
ORDER/QUOTE ENTRY PORT*	[Ports 1–5: no charge]. [Ports 6–100: $200 per port per month]. *Ports 1–40: $450 per port per month.* Ports [101]*41* and greater: [$100]*$150* per port per month.
NYSE Amex Options Market Maker Open Outcry Discount	*Any NYSE Amex Options Market Maker that executes 50% or more of their market maker volume in open outcry shall receive a discount on their monthly port fees of 60%, not to exceed a maximum dollar discount of $10,000 per month.*

In sum, the Exchange is proposing to no longer offer Ports 1–5 free of charge and will instead charge ATP Holders $450 per Port, per month for the first 40 Ports that an ATP Holder is authorized to utilize. The Exchange further proposes to charge $150 per Port, per month for any Port in excess of 40 for which an ATP Holder is authorized. Using the example above, an ATP Holder would be charged as follows: An ATP Holder authorized to utilize 50 Ports would be charged $19,500 in monthly Port Fees (*i.e.,* 40 × $450 plus 10 × $150); 100 Ports is charged $27,000 in monthly Port Fees (*i.e.,* 40 × $450 plus 60 × $150); or 120 Ports is charged $30,000 in monthly Ports Fees (*i.e.,* 40 × $450 plus 80 × $150). In addition, the Exchange proposes to offer a discount on monthly Port Fees of 60%, not to exceed $10,000, for any NYSE Amex Option Market Maker firms that execute at least 50% of their Market Maker volume in open outcry in any given month.[6]

The Exchange proposes to implement these changes on November 3, 2014. In this regard, as is the case today, the Exchange notes that billing for Ports would continue to be based on the number of Ports for which an ATP Holder has been authorized for option activity on the third business day prior to the end of the month. Similarly, the Exchange would continue to assess the Port Fees based on the number of Ports authorized—except for Ports that are considered established for backup purposes—such that the level of activity with respect to a particular Port would not affect the assessment of monthly fees. With regard to the discount on monthly Port Fees for Market Maker volume executed in open outcry, the measurement period for billing purposes will be based on the activity in the month prior, such that September Market Maker volumes will be used to decide if the Market Maker qualified for the 60% discount on their October Port Fees.

The Exchange is also proposing a non-substantive, formatting change to the section of the fee schedule that applies to Port Fees. The Exchange is proposing to re-format that section of the Fee Schedule as a table with distinct rows and columns to make the Fee Schedule easier for participants to understand.

[4] An affiliate is a person or firm that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, the firm. *See* Rule 900.2NY(1).

[5] The Exchange's backup datacenter is currently located in Chicago, Illinois. The Exchange notes that it monitors usage of these particular Ports and, accordingly, if an order/quote is sent to the Exchange via one of these Ports, then the Port is charged the applicable monthly Port Fee.

[6] For example, a NYSE Amex Market Maker authorized to utilize 100 Ports is charged $27,000 in monthly Port Fees (*i.e.,* $450 × 40 = $18,000 plus $150 × 60 = $9,000). However, if during that month, the NYSE Amex Market Maker executes at least 50% of their volume in open outcry, the NYSE Amex Market Maker then becomes eligible for a discount of 60%—or a reduction of $16,200. However, the proposal caps the amount of the available discount to $10,000 per month. Thus, in this example, the Port Fees charged would be $17,000 ($27,000 less the maximum monthly discount of $10,000).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[7] in general, and furthers the objectives of Section 6(b)(4) of the Act,[8] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fee changes are reasonable, equitable and not unfairly discriminatory because they are designed to ensure a fair and reasonable use of Exchange resources by allowing the Exchange to recoup for certain of its connectivity costs, while continuing to offer competitive rates to ATP Holders. The Exchange notes that it has not increased its Port Fees since November 2012,[9] and the proposed increases are intended to adjust the Port Fees to reflect the increased costs that the Exchange bears with respect to maintaining the Ports. Specifically, the Exchange believes that the proposed increase in Port Fees are reasonable because the proposed fees charged for Ports would enable the Exchange to offset, in part, its connectivity costs associated with making such Ports available, including costs based on gateway software and hardware enhancements and resources dedicated to gateway development, quality assurance, and support. In this regard, the Exchange believes that the proposed Port Fees are in line with those charged by other venues, and that in some cases its Port Fees would be less expensive than many of its primary competitors. For example, the Chicago Board Options Exchange (''CBOE'') charges $500 per port per month for a Network Access Port.[10] The NASDAQ Options Market (''NOM'') charges $550 per port per month.[11]

The Exchange believes that the proposed fees are reasonable, equitable and not unfairly discriminatory because—just as they do today—ATP Holders are able to request, and pay for, only those Ports that they require, with no impact to other ATP Holders.

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to no longer offer the first five ports free of charge as all ATP Holders are being treated in the same manner. Further, as noted above, the Exchange believes that the proposed fee changes are reasonable, equitable and not unfairly discriminatory because they are designed to ensure a fair and reasonable use of Exchange resources by allowing the Exchange to recoup for certain of its connectivity costs, while continuing to offer competitive rates to ATP Holders.

The Exchange believes that the proposed monthly per Port fee of $450 for the first 40 Ports is reasonable, equitable and not unfairly discriminatory because it is comparable to the rates of other exchanges.[12] The Exchange also believes that the proposed fees are equitable and not unfairly discriminatory because they would apply to all ATP Holders that utilize Ports for options activity on the Exchange.

The Exchange also believes that it is reasonable, equitable and not unfairly discriminatory to decrease the monthly per Port rate from $450 to $150 once an ATP Holder has exceeded 40 Ports (*i.e.,* a monthly per Port charge of $150 for Ports 41+). Specifically, reducing the monthly fee to $150 per Port when an ATP Holder needs to utilize more than 40 Ports would enable those firms to maintain those connections to the Exchange, while helping to offset the increased costs of that connection. In addition, the reduced fee is likewise appropriate given that certain market participants, particularly options Market Makers, require more than 40 Ports in order to satisfy their responsibilities and obligations to investors, which stem from the significant number of series that exist for any particular option class[13] and the requirement for NYSE Amex Option Market Makers to maintain a bid or offer in assigned classes. Furthermore, Market Makers that quote across a significant number, if not all, of the 2,482 classes traded on the Exchange have responsibility for upwards of 650,000 individual option series.[14] Accordingly, the level of activity that is required to satisfy a Market Maker's quoting obligations, which directly relates to the number of Ports required, is such that the Exchange believes it is reasonable, equitable and not unfairly discriminatory to offer a reduced fee to ATP Holders that utilize more than 40 Ports on the Exchange in a given month.

Further, the Exchange believes that the proposal to offer a 60% discount on Port Fees, not to exceed a maximum discount of $10,000 per month, to those NYSE Amex Options Market Makers that execute at least 50% of their market maker volume in a given month in open outcry is also reasonable, equitable and not unfairly discriminatory. First, the Exchange believes that the trading floor plays an important role in the options market. Specifically, trading floors provide price discovery for large or complex strategies not easily exposed in electronic auctions. In order to encourage robust participation in the Exchange's outcry markets, the Exchange believes that it is reasonable to offer a discount in the manner described for those NYSE Amex Options Market Makers that continue to provide price discovery in open outcry as evidenced by the relative level of their market maker volume executed in open outcry. The Exchange notes that it has offered similar discounts in the past to encourage NYSE Amex Options Market Makers to maintain a presence in the open outcry market. For example, the Exchange charges a lower ATP fee for Floor Market Makers to encourage their presence and participation in the outcry markets on the trading floor. The qualifying criteria for eligibility for the discounted ATP fees is a function of how much of the Floor Market Maker's volume is transacted in open outcry.[15]

As the proposed discount is available to any NYSE Amex Options Market Maker that executes at least 50% of their market maker volume in open outcry, the Exchange believes that the current proposal is not unfairly discriminatory as any market making firm can seek to place individual traders on the trading floor. The Exchange believes the proposal is reasonable and equitable as the price discovery found in the outcry markets benefits all participants. The Exchange notes that the proposed discount would apply for those Market Makers that reach or exceed the volume threshold for open outcry transactions. The Exchange believes that this threshold has been appropriately set to provide an incentive for floor-based market making because this threshold represents a level where the preponderance of volume is in open

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

[9] *See* Securities and Exchange Release No. 68231 (November 14, 2012), 77 FR 69682 (November 20, 2012) (SR–NYSEMKT–2012–60).

[10] *See* CBOE Fee Schedule *available here, http://www.cboe.com/publish/feeschedule/CBOEFeeSchedule.pdf* (CBOE Command Connectivity Charges, at p 10).

[11] *See* NOM Price List, *available here, http://nasdaq.cchwallstreet.com/NASDAQTools/bookmark.asp?id=nasdaq-rule-options_XVS3&manual=/nasdaq/main/nasdaq-optionsrules/* (Section 3, NASDAQ Options Market—Access Services).

[12] *See supra* nn. 10–11.

[13] For example, as of October 9, 2014, there were more than 2350 individual option series overlying Chipotle Mexican Grill, Inc. (NYSE: CMG).

[14] These figures are valid as of October 9, 2014.

[15] *See* the Fee Schedule, *available here, https://www.nyse.com/publicdocs/nyse/markets/amex-options/NYSE_Amex_Options_Fee_Schedule.pdf.*

outcry and therefore not dependent on a Port, but a Port is nonetheless necessary to meet Market Maker quoting obligations. The Exchange notes that Floor Market Makers that do not meet this volume threshold for their options activity in open outcry would continue to be charged at the same rate for Port Fees as all other ATP Holders.

The Exchange believes that the proposal to re-format the section of the fee schedule describing Port Fees into a table, with distinct rows and columns, is reasonable, equitable and not unfairly discriminatory as the proposed change will reduce confusion and will make the fee schedule more transparent and easier for all participants to understand.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[16] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed fee change is reasonably designed to be fair and equitable, and therefore, will not unduly burden any particular group of market participants trading on the Exchange vis-à-vis another group (*i.e.,* Market Markers versus non-Market Makers). Specifically, the Exchange believes that the reduced fee for ATP Holders that utilize more than 40 Ports will relieve any undue burden that the proposed fee change might have on Marker Makers. Further, the Exchange believes that the proposed discount to the monthly Port Fee, capped at $10,000 for those NYSE Amex Options Market Maker that executes at least 50% of their market maker volume in open outcry, likewise does not impose any undue burden on competition among and between market participants because as any market making firm can seek to place individual traders on the trading floor. In addition, the Exchange believes that the proposed changes will enhance the competiveness of the Exchange relative to other exchanges and, as noted above, the increased fees are comparable to port fees offered by competing option exchanges.[17] The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[18] of the Act and subparagraph (f)(2) of Rule 19b–4[19] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[20] of the Act to determine whether the proposed rule change 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–NYSEMKT–2014–092 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR–NYSEMKT–2014–092. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2014–092 and should be submitted on or before November 28, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–26349 Filed 11–5–14; 8:45 am]

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[16] 15 U.S.C. 78f(b)(8).

[17] *See supra* nn. 10–11.

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(2).

[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73483; File No. SR–OCC–2014–14]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Approving Proposed Rule Change To Better Manage Risks Concentration and Other Risks Associated With Accepting Deposits of Common Stocks for Margin Purposes

October 31, 2014.

On July 15, 2014, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange

Commission (''Commission'') the proposed rule change SR–OCC–2014–14 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder.[2] The proposed rule change was published for comment in the **Federal Register** on August 5, 2014.[3] The Commission did not receive any comments on the proposed rule change. This order approves the proposed rule change.

I. Description

According to OCC, the purpose of this proposed rule change is to permit OCC to better manage concentration risk and wrong-way risk associated with accepting deposits of common stock for margin purposes. In order to manage such risks, OCC proposed to add an Interpretation and Policy to Rule 604, which specifies the forms of margin assets accepted by OCC, that will provide OCC with discretion with respect to giving value to assets deposited by a single clearing member to satisfy its margin requirement(s). In addition, OCC proposed to make clarifying amendments to an existing Interpretation and Policy under Rule 604 that gives OCC discretion to not give value to a particular type of margin collateral across all clearing members.

a. Background

OCC Rule 604 lists the types of assets that clearing members may deposit with OCC to satisfy their margin requirement(s) as well as sets forth eligibility criteria for such assets. According to OCC, common stocks, including Exchange Traded Funds (''ETFs'') and Exchange Traded Notes (''ETNs''), are the most common form of margin assets deposited by clearing members and currently comprise 68% of the $60.6 billion in clearing member margin deposits held by OCC (not including deposits in lieu of margin). According to OCC, since 2009, OCC has used its System for Theoretical Analysis and Numerical Simulations (''STANS''), which is OCC's daily automated Monte Carlo simulation-based margining methodology, to value common stocks deposited by clearing members as margin.[4] The value given to margin deposits depends on factors that include the price volatility and the price correlation relationship of common stock collateral to the balance of the cleared portfolio. The approach used by STANS incentivizes clearing members who chose to meet their margin obligations with deposits of common stocks to choose common stocks that hedge their related open positions.

According to OCC, notwithstanding the value STANS gives to deposits of common stocks, certain factors warrant OCC adjusting the value STANS gives to all clearing member margin deposits of a particular type of margin collateral. Such factors are set forth in Rule 604, Interpretation and Policy .14, and include the number of outstanding shares, number of outstanding shareholders and overall trading volume. OCC is proposing to add a new Interpretation and Policy to Rule 604 (the ''Interpretation'') so that OCC has discretion to not give margin credit to a particular clearing member when such clearing member deposits a concentrated amount of any common stock and when a common stock, deposited as margin, presents ''wrong-way risk'' to OCC. In addition, the Interpretation will provide OCC discretion to grant margin credit to a clearing member when it deposits shares of common stock that serve as a hedge to the clearing member's related open positions and would otherwise be not be given margin credit.[5]

b. Concentrated Deposits of Common Stock

OCC has determined that in the event it is necessary to liquidate a clearing member's positions (including the clearing member's margin collateral), OCC may be exposed to risk arising from a large quantity of a particular common stock deposited as margin by a clearing member. Specifically, depending on the relationship between the average daily trading volume of a particular security and the number of outstanding shares of such security deposited by a clearing member as margin, it is possible that the listed equities markets may not be able to quickly absorb all of the common stock OCC seeks to sell, or OCC may not be able to auction such securities, without an appreciable negative price impact. This occurrence, referred to by OCC as ''concentration risk,'' is greatest when the number of shares being sold is large and the average daily trading volume is low.

OCC's existing authority to not give value to otherwise eligible forms of margin only provides OCC with the discretion to not give value across all clearing member deposits of a particular common stock. However, concentration risk may be a clearing member and account-specific risk. In order to mitigate the concentration risk of a single clearing member, OCC plans to implement automated processes to monitor the composition of a clearing member's margin deposits. Such processes will identify concentration risk at both an account level and across all accounts of a clearing member. OCC proposed to add the Interpretation so that OCC has discretion to limit the margin credit granted to an individual clearing member that maintains a concentrated margin deposit of otherwise eligible common stock.

According to OCC, for the reasons stated above, OCC considers a common stock's average daily trading volume and the number of shares a clearing member deposited as margin to be the two most significant factors when making a decision to limit margin credit due to concentration risk. Accordingly, OCC will not give margin credit to clearing member margin deposits of a particular common stock in respect of a particular account when the deposited amount of such common stock is in excess of two times the average daily trade volume of such common stock over the most recent three month period. OCC's systems will continually assess the composition of clearing member margin deposits for each account maintained by the clearing member, including intra-day collateral substitutions in such accounts, to determine if a clearing member has a margin deposit with a concentrated amount of common stock. With respect to a given account, OCC's systems will automatically set appropriate limits on the amount of a particular common stock for which a clearing member may be given margin credit for any one of its

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 72717 (July 30, 2014), 79 FR 45523 (August 5, 2014) (SR–OCC–2014–14). OCC also filed proposals contained in this proposed rule change as an advance notice under Section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 (''Payment, Clearing and Settlement Supervision Act'') and Rule 19b–4(n)(1) of the Act, which was published for comment in the **Federal Register** on August 15, 2014. 12 U.S.C. 5465(e)(1); 17 CFR 240.19b–4(n)(1). *See* Securities Exchange Act Release No. 72803 (August 11, 2014), 79 FR 48285 (August 15, 2014) (SR–OCC–2014–803). The Commission did not receive any comments on the advance notice.

[4] *See* Securities Exchange Act Release No. 58158 (July 15, 2008), 73 FR 42646 (July 22, 2008) (SR–OCC–2007–20).

[5] According to OCC, consistent with the language contained in existing Interpretation & Policy .14, the Interpretation provides OCC with discretion in determining the amount of margin credit given to deposits of common stock by an individual clearing member as such determination would be based on positions held and common stock deposits made by such clearing member on a given business day. However, as discussed in the following two sections, OCC also has developed certain automated processes as well as additional internal policies that describe how OCC presently intends to exercise such discretion. According to OCC, these additional internal policies are included in OCC's collateral risk management policy, which will not be implemented until approval of this rule change with changes thereto being subject to additional rule filings.

tier accounts. In addition, and with respect to all of a clearing member's accounts, OCC will impose an add-on margin charge if, in aggregate, a clearing member deposits a concentrated amount of a particular common stock as margin across all of its accounts. The add-on margin charge will operate to negate the margin credit given to the concentrated margin deposit, and will be collected, when applicable, as part of OCC's standard morning margin process. OCC will assess the add-on margin charge across all of a clearing member's accounts on a pro-rata basis (based on the amount of the particular common stock in each of a clearing member's accounts).[6]

According to OCC, OCC staff has been monitoring concentrated common stock positions, assessing the impact of the proposed rule change described in this filing and contacting clearing members affected by the proposed rule change. OCC believes that clearing members will be able to comply with the proposed rule change without making significant changes to their day-to-day business operations. In December 2013, an information memo was posted to inform all members of the upcoming change. According to OCC, since January 2014, OCC staff has been in contact with any clearing member that would be affected by the proposed rule change. On a weekly basis, any clearing member that would see a reduction of 10% or more of its collateral value is contacted and provided an explanation of the policy and a list of concentrated positions observed in this analysis. On a monthly basis, all clearing members exhibiting any concentration risk are contacted to provide an explanation of the proposed policy and a list of concentrated positions. In both cases, clearing members are encouraged to proactively reduce concentrated positions to conform to the proposed policy. As of June 2014, twenty-five members would be affected. Implementation of the Interpretation would result in disallowing $1.2 billion in collateral value and result in margin calls for six members totaling $710 million.

Moreover, in July 2014, OCC made an automated report concerning concentrated margin deposits of common stock available to all clearing members.

c. Wrong-Way Risk

OCC also proposed to use the Interpretation to address the risk that the common stock a clearing member has deposited as margin and which is issued by the clearing member itself or an affiliate of the clearing member will lose value in the event the clearing member providing such margin defaults, which is known as ''wrong-way risk.'' According to OCC, wrong-way risk occurs when a clearing member makes a deposit of common stock issued by it or an affiliate and, in the event the clearing member defaults, the clearing member's common stock margin deposit will also be losing value at the same time because there is likely to be a strong correlation between the clearing member's creditworthiness and the value of such common stock. In order to address wrong-way risk, the Interpretation will implement automated systems that will not give margin credit to a clearing member that deposits common stock issued by such clearing member or an affiliate as margin collateral. OCC proposed to define ''affiliate'' broadly in the Interpretation to include any entity with direct or indirect equity ownership of 10% of the clearing member, or any entity for which the clearing member holds 10% of the direct or indirect equity ownership.[7]

OCC has addressed the impact of the change designed to address wrong-way risk. As of June 2014, there were 73 clearing members whose parent or an affiliate has issued securities trading on U.S. exchanges. As of June 2014, there are six clearing members that would be affected by virtue of having made margin deposits of their own or an affiliate's common stock. In total, these shares equaled $132 million and accounted for less than one half of one percent of the total market value of valued securities pledged as margin at OCC. In July 2014, OCC made information available to each clearing member that indicates which of its deposits of common stock would not receive margin credit under the proposed change due to wrong-way risk considerations, as described above.[8]

d. Deposits That Hedge Open Positions

In addition to the above, OCC also proposed to include language in the Interpretation so that it has discretion to give margin credit to common stock deposited as margin that would otherwise not be given margin credit in circumstances when such common stock acts as a hedge (*i.e.,* the member holds an equivalent short position in cleared contracts on the same underlying security). This condition will be checked in both the account and clearing member level. For example, if a clearing member deposits the common stock of an affiliate as margin collateral, which, pursuant to the above, would ordinarily not be given value for the purposes of granting margin credit, OCC may nevertheless give value to such common stock for the purposes of granting margin credit to the extent such common stock acts as a hedge against open positions of the clearing member. In this case, a decline in the value of the margin deposit would be wholly or partially offset by an increase in the value in the open position. Moreover, in such a situation, OCC will systematically limit the margin credit granted to the lesser of a multiple of the daily trading volume or the ''delta equivalent position''[9] for the particular common stock, taking into account the hedging position.[10] OCC believes that this policy will further encourage clearing members to deposit margin collateral that hedges their related open

[6] According to OCC, since a 2-day limit is first checked at each account, it is possible that a clearing member with multiple accounts may have more than 2-days of a given common stock on deposit in aggregate. To control this condition, a final check is done on the aggregate amount of shares held by a clearing member across all of its accounts. For example, if a particular clearing member has three accounts each holding 2-days volume of a specific common stock, the clearing member check would identify that the member was holding six days of volume in aggregate. To mitigate this risk, an add-on charge equal to the market value of four days of volume would be applied to all accounts holding that security on a pro-rata basis.

[7] This standard is based on the provisions of OCC Rule 215(a)(5).

[8] OCC believes that by providing such information clearing members will be better able to adjust their margin deposits at OCC to conform to the proposed rule change if it is approved.

[9] According to OCC, the ''delta equivalent position'' is the equivalent number of underlying shares represented by the aggregation of cleared products on that same underlying instrument. This value is calculated using the ''delta'' of the option or futures contract, which is the ratio between the theoretical change in the price of the options or futures contract to the corresponding change in the price of an underlying asset. Thus, delta measures the sensitivity of an options or futures contract price to changes in the price of the underlying asset. For example, a delta of +0.7 means that for every $1 increase in the price of the underlying stock, the price of a call option will increase by $0.70. Delta for an option or future can be expressed in shares of the underlying asset. For example, a standard put option with a delta of −.45 would have a delta of −45 shares, because the unit of trading is 100 shares.

[10] Assume, for example, an average daily trade volume of 250 shares, a threshold of 2 times the average daily trade volume, and a delta of -300 shares for the options on a particular security in a particular account. A position of 700 shares that did not hedge any short options or futures would receive credit for only 500 shares (*i.e.,* 2 times the average daily trade volume). If the net long position in the account, when combined with the delta of short option and futures position, were only 400, credit would be given for the entire 700 shares since the delta equivalent position is below the 500 share threshold. However, if the option delta were +300, the net long position would be 1000, and credit would only be given for 500 shares because the delta equivalent position would exceed the 500 share threshold.

positions and is in line with the valuation methods within STANS. This policy will also facilitate OCC's management of its and its participants' credit exposure as well as the liquidation of a clearing member's portfolio should the need arise.

e. Other Proposed Changes

OCC also proposed to make certain clarifying changes in order to accommodate the adoption of the Interpretation into its Rules. Primarily, OCC proposed to add language to OCC Rule 604, Interpretation and Policy .14, to clarify that such Interpretation and Policy concerns OCC's authority to not give value to certain margin deposits for all clearing members (whereas the Interpretation applies to particular clearing member(s)). In addition, OCC proposed to remove language from OCC Rule 604, Interpretation and Policy .14, to improve readability as well as to remove ''factors'' concerning number of shares and affiliates since OCC's authority with respect to such factors will be more clearly described in the Interpretation. Finally, OCC proposed to renumber the Interpretations and Policies of Rule 604 in order to accommodate the adoption of the Interpretation.

II. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act [11] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that the 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 Section 17A(b)(3)(F) of the Act,[12] and Rule 17Ad–22(b)(2) of the Act.[13] Section 17A(b)(3)(F) of the Act [14] requires a registered clearing agency to have rules that are designed to, among other things, promote the prompt and accurate clearance and settlement of securities transactions, and 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. OCC's proposed rule change is consistent with this rule because by implementing margin collateral requirements that address concentration risk and wrong-way risk, OCC's proposed rule change is consistent with promoting the prompt and accurate clearance and settlement of securities transactions and assuring the safeguarding of securities and funds which are in OCC's custody or control or for which OCC is responsible. The proposed changes are designed to reduce the risk that clearing member margin assets would be insufficient should OCC need to use such assets to close-out positions of a defaulted clearing member. The changes are also designed to facilitate OCC to timely meet its settlement obligations because the proposed change will diminish the likelihood that a large percentage of the value of a defaulting clearing member's margin assets would not be available to OCC to cover losses in the event of a clearing member default.

OCC's proposed rule change is consistent with Rule17Ad–22(b)(2) of the Act.[15] Rule 17Ad–22(b)(2) of the Act [16] requires a registered clearing agency that performs central counterparty services to, among other things, establish, implement, maintain and enforce written policies and procedures reasonably designed to use margin requirements to limit its credit exposures to participants under normal market conditions. This proposal is consistent with this rule because it is reasonably designed to permit OCC to use margin requirements to limit its credit exposures to clearing members under normal market conditions in two ways. First, it is reasonably designed to limit OCC's credit exposures to clearing members whose collateral portfolios could present concentration risk. Specifically, it addresses concentration risk by particular clearing member and by particular account by giving OCC discretion to disapprove as margin collateral certain securities, based on the number of shares deposited, by particular clearing member and by particular account, while also considering deposits that hedge open positions. It also clarifies that OCC's existing authority to not give value to certain margin deposits applies to all clearing members, as opposed to particular clearing members.[17] Second, it is reasonably designed to limit OCC's credit exposures to clearing members whose collateral portfolios could present wrong-way risk. Specifically, it addresses wrong-way risk presented by clearing members who deposit as margin securities that are issued by the clearing member itself or by an affiliate of the clearing member. It addresses this type of wrong-way risk by giving OCC discretion to disapprove as margin collateral, with respect to a particular clearing member, any security issued by such clearing member or by an affiliate of such clearing member, while also considering deposits that hedge open positions.

Rule 17Ad–22(b)(2) of the Act [18] also requires a registered clearing agency that performs central counterparty services to, among other things, establish, implement, maintain and enforce written policies and procedures reasonably designed to use risk-based models and parameters to set margin requirements. This proposal is consistent with this rule because it permits OCC to use risk-based models and parameters to set margin requirements in a way that takes into account concentration risk and wrong-way risk, as described above.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and, in particular, with the requirements of Section 17A of the Act [19] and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[20] that the proposed rule change (SR–OCC–2014–14) be, and it hereby is, approved, as of the date of this order or the date of a notice by the Commission noticing, pursuant to Section 806(e)(1)(I) of the Payment, Clearing and Settlement Supervision Act,[21] that the Commission does not object to the proposal in OCC's advance notice (SR–OCC–2014–803) and OCC is authorized to implement the proposal, whichever is later.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–26345 Filed 11–5–14; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(2)(C).

[12] 15 U.S.C. 78q–1(b)(3)(F).

[13] 17 CFR 240.17Ad–22(b)(2).

[14] 15 U.S.C. 78q–1(b)(3)(F).

[15] 17 CFR 240.17Ad–22(b)(2).

[16] *Id.*

[17] *See* Rule 604, Interpretation and Policy .15 (providing OCC discretion to disapprove as margin collateral securities that meet certain factors, including trading volume, number of outstanding shareholder, number of outstanding shares, volatility and liquidity).

[18] 17 CFR 240.17Ad–22(b)(2).

[19] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[20] 15 U.S.C. 78s(b)(2).

[21] 12 U.S.C. 5465(e)(1)(I).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73479; File No. SR–CBOE–2014–083]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Delay the Implementation Date of the Requirement To Apply an Indicator to SPX Combo Orders Upon Systematization

October 31, 2014.

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 October 31, 2014, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The 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 delay the implementation date of the requirement to apply an indicator to SPX Combo Orders upon systematization. There is no proposed change to the rule language.

The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of 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

On May 19, 2014, the Exchange submitted a rule change filing (SR–CBOE–2014–046), which became effective on that date, to amend Rule 24.20, ''SPX Combo Orders''. Rule 24.20, as amended, states: ''For an order to be eligible for the trading procedures contained in this Rule, a Trading Permit Holder must apply an indicator to the SPX Combo Order upon systematization as provided in Rule 6.24.'' [3] Pursuant to the rule change filing, the Exchange issued a Regulatory Circular requiring Trading Permit Holders (''TPHs'') to begin applying the combo indicator upon systematization on November 1, 2014.[4] Once the Exchange implements the combo indicator requirement, TPHs will be required to apply the combo indicator upon systematization. Orders that include the combo indicator but do not meet the requirements of an SPX Combo Order (*i.e.,* orders must be at least three legs and include an SPX combination [5]) will be rejected. Additionally, the Public Automatic Routing System (''PAR'') will no longer allow an order to be endorsed as an SPX Combo Order and reported to OPRA as such.[6]

On August 19, 2014, the Exchange submitted a separate rule change filing (SR–CBOE–2014–015) to amend, among other things, Rule 24.20 to include Interpretation and Policy .01.[7] Proposed Interpretation and Policy .01, which has not yet been approved by the Commission, would require that any complex order, including an SPX Combo Order, for twelve (12) legs or less be entered on a single order ticket at time of systemization. In addition, a complex order, including an SPX Combo Order, that contains more than twelve (12) legs may be represented and executed as a single order, and for an SPX Combo Order in accordance with Rule 24.20 if it is split across multiple order tickets and the TPH representing the order identifies for the Exchange the order tickets that are part of the same order (in a manner and form prescribed by the Exchange).

Pursuant to SR–CBOE–2014–046, a third-party vendor updated the Exchange provided Floor Broker Workstation (''FBW) to support the combo indicator. Pursuant to SR–CBOE–2014–015, the Exchange, through a third-party vendor, is in the process of developing an enhanced version of FBW to support the entry of complex orders with up to twelve legs. The third-party vendor has indicated that it will not complete development prior to the current November 1st implementation date established in the combo indicator circular.[8]

The Exchange believes that if the combo indicator requirement is implemented on November 1st, brokers utilizing FBW to execute SPX Combo Orders with more than four legs will be negatively impacted. For example, if a broker wanted to execute an SPX Combo Order with five legs, the current FBW requires the 5-leg order to be split into two orders (*e.g.,* an order with two legs and an order with three legs). Each order would be required to have the combo indicator upon systematization; have at least three legs, and have an SPX combination. Therefore, CBOE would reject the order with two legs.[9] Additionally, a 6-leg SPX Combo Order that was split into separate orders with three legs would also be rejected if one of the 3-leg orders did not have an SPX combination. Therefore, the Exchange is proposing to delay implementation of SR–CBOE–2014–046 in order to allow the third-party vendor more time to complete development of the enhanced version of FBW, which will support the entry of complex orders with up to twelve legs pursuant to SR–CBOE–2014–015.

Although the Exchange believes that users of FBW will be negatively impacted if the 12-leg order ticket is not available prior to the combo indicator requirement, the Exchange intends to implement the combo indicator requirement after this delay, regardless of the third-party vendor's ability to deliver the enhanced version of FBW. If the enhanced version of FBW is not available by the next implementation

[3] Securities Exchange Act Release No. 34–72271 (May 29, 2014), 79 FR 32342 (June 4, 2014) (SR–CBOE–2014–046).

[4] *CBOE Regulatory Circular* RG14–125—Implementation of SPX Combo Order Indicator (August 15, 2014).

[5] SR–CBOE–2014–046 defines an SPX combination as a purchase (sale) of an SPX call and sale (purchase) of an SPX put having the same expiration date and strike price.

[6] Currently, brokers must apply an SPX Combo Order designation for the purposes of price reporting. This is accomplished by endorsing a trade via PAR; however the system changes that allow a combo indicator to be applied upon systematization will remove the capability to endorse an order as an SPX Combo Order on PAR.

[7] Securities Exchange Act Release No. 34–72975 (September 2, 2014), 79 FR 53230 (September 8, 2014) (SR–CBOE–2014–015).

[8] RG14–125, *supra* note 4.

[9] If the broker failed to apply the combo indicator to the 2-leg order upon systematization, the CBOE system would view the order as a non-combo order and would not include a combo identifier for reporting purposes.

date, the Exchange believes it can mitigate the negative impact to FBW users by issuing another Regulatory Circular in advance of the future implementation date that provides FBW users with sufficient time to find and test an alternative system to input SPX Combo Orders with more than four legs.[10] The Exchange believes that requiring the combo indicator on November 1, 2014, as is currently contemplated, does not give FBW users sufficient time to find and test an alternative system. The Exchange will announce the implementation date of the proposed rule change, as well as the Exchange's intent to not delay implementation any further, in a Regulatory Circular to be published no later than 60 days following the effective date of this filing. The implementation date will be no later than 120 days following the effective date of this filing.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that if the combo indicator requirement is implemented on November 1, 2014, brokers utilizing FBW to execute SPX Combo Orders with more than four legs will be negatively impacted. The Exchange believes delaying implementation of the combo indicator requirement will allow the third-party vendor the necessary time to develop an enhanced version of FBW to allow orders to be entered with greater than four legs. Furthermore, the Exchange believes that delaying implementation promotes fair and orderly markets and serves market participants because it will allow trading of SPX Combo Orders to continue uninterrupted. The enhanced version of FBW will also promote fair and orderly markets and serve market participants because it will provide an enhanced audit trail for the Exchange. Finally, if the third-party vendor is unable to develop the enhanced version of FBW prior to the next implementation date for the combo indicator, the Exchange will issue a Regulatory Circular that the Exchange believes will provide FBW users with sufficient time to find and test an alternative system to input SPX Combo Orders with more than four legs.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change or such shorter time as designated by the Commission, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6) thereunder.[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 will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

Under Rule 19b–4(f)(6) of the Act,[16] the proposal does not become operative for 30 days after the date of its filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the five-day pre-filing requirement and the 30-day operative delay period after which a proposed rule change under Rule 19b–4(f)(6) becomes operative. The Exchange states that waiver of the five-day pre-filing requirement and the 30-day operative delay period is appropriate because the implementation date for the combo indicator is currently November 1, 2014. The Exchange also states the proposed rule change does not present any new, unique or substantive issues that make the 30-day operative delay necessary. The Exchange notes that if the combo indicator requirement is implemented on November 1, 2014, brokers utilizing FBW to execute SPX Combo Orders with more than four legs will be negatively impacted. Based on the foregoing, the Commission has determined to waive the five-day pre-filing requirement and the 30-day operative date so that the proposal may take effect upon filing.[17]

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:

[10] The Exchange notes that it will ensure TPHs have access to at least one Exchange provided technology (*e.g.,* PULSe) prior to implementation of SR–CBOE–2014–46 and SR–CBOE–2014–015 that will enable TPHs to enter SPX Combo Orders with up to twelve legs and apply the SPX Combo indicator.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6).

[16] *Id.*

[17] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2014–083 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2014–083. 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–CBOE–2014–083 and should be submitted on or before November 28, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–26342 Filed 11–5–14; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73487; File No. SR–CBOE–2014–067]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Automatic Order Handling Process in No-Bid Series

October 31, 2014.

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 October 22, 2014, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. 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 Exchange rules regarding the automatic order handling process in no-bid series. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of 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 Exchange proposes to amend its rules regarding its automatic order handling process. The proposed rule change seeks to modify subparagraph (vi) to Rule 6.13(b), which sets forth how the CBOE Hybrid System[3] handles market orders to sell in option series for which the national best bid in the series is zero (''no-bid series'').[4] Currently, if the CBOE Hybrid System receives during the trading day or has resting in the electronic book[5] after the opening of trading a market order to sell in a no-bid series, it handles the order as follows:

- If the Exchange best offer in that series is less than or equal to $0.30, then the CBOE Hybrid System will consider, for the remainder of the trading day, the market order as a limit order to sell with a limit price equal to the minimum trading increment applicable to the series and enter the order into the electronic book behind limit orders to sell at the minimum increment that are already resting in the book.
- If the Exchange best offer in that series is greater than $0.30, then the CBOE Hybrid System will route the market order to sell to PAR or, at the order entry firm's discretion, to the order entry firm's booth. If the market order is not eligible to route to PAR, then it will be cancelled.

Based on experience since the implementation of this parameter, the Exchange now proposes to change the parameter from $0.30 to $0.50. The Exchange believes that the automatic handling of market orders to sell in no-bid series if the Exchange best offer is less than or equal to $0.50 would reduce

[3] The CBOE Hybrid System is a trading platform that allows automatic executions to occur electronically and open outcry trades to occur on the floor of the Exchange. To operate in this ''hybrid'' environment, the Exchange has a dynamic order handling system that has the capability to route orders to the trade engine for automatic execution and book entry, to Trading Permit Holder and PAR workstations located in the trading crowds for manual handling, and/or to other order management terminals generally located in booths on the trading floor for manual handling.

[4] The Exchange notes that, for singly listed series, the national best bid is equivalent to the Exchange's best bid and the national best offer is equivalent to the Exchange's best offer.

[5] For example, the Exchange receives a market order to sell prior to the opening of a series and the series opens with a sell market order imbalance pursuant to Rule 6.2B(e)(iii). When the series opens the market order to sell, which was resting in the book prior to the opening of the series, will be routed according to the no-bid procedures in Rule 6.13.

the manual handling of orders and facilitate the CBOE Hybrid System's automatic handling process. Additionally, the $0.50 threshold serves as a protection feature for investors in certain situations, such as when a series is no-bid because the last bid traded just prior to the entry of the market order to sell. The purpose of this threshold is to limit the manual handling of market orders to sell in no-bid series to only those for true zero-bid options, as options in no-bid series with an offer of more than $0.50 are less likely to be worthless.

For example, if the CBOE Hybrid System receives a market order to sell in a no-bid series with a minimum increment of $0.01 and the Exchange best offer is $0.01, the CBOE Hybrid System will consider, for the remainder of the trading day, the order as a limit order with a price of $0.01 and submit it to the electronic book behind other limit orders to sell at the minimum increment that are already resting in the book. At that point, even if the series is no-bid because, for example, the last bid just traded and the limit order trades at $0.01, the next bid entered after the trade would not be higher than $0.01.[6]

However, if the CBOE Hybrid System receives a market order to sell in a no-bid series with a minimum increment of $0.01 and the Exchange best offer is $1.20 (because, for example, the last bid of $1.00 just traded and a new bid has not yet populated the Exchange's quote), the CBOE Hybrid System will instead route the order to PAR (or, at the order entry firm's discretion, to the order entry firm's booth). Manual handling of the order prevents an anomalous execution price, since the next bid entered in that series is likely to be much higher than $0.01.[7] It would be unfair to the entering firm to let its market order trade as a limit order for $0.01 because, for example, the firm submitted the order during the brief time when there were no disseminated bids in a series trading significantly higher than the minimum increment. To combat the potential unfairness outlined above, the order entry firm has the discretion to have the market order to sell routed to a PAR Official,[8] the PAR workstation of a Trading Permit Holder (''TPH User''), or to the order entry firm's booth. A PAR Official that receives such an order will review the terms of the order and handle the order as set forth in Rule 7.12 (e.g., the PAR Official may bring the order to the trading crowd or enter the order into the electronic book at the minimum increment). Currently, TPH Users that receive orders pursuant to the no-bid scenario are systematically blocked from booking the order into the electronic book. The Exchange proposes to allow TPH Users to review the order and handle the order in a similar manner to PAR Officials (e.g., bring the order to the trading crowd or enter the order into the electronic book at the minimum increment). The Exchange notes that PAR Officials and TPH Users must use due diligence to execute orders that they receive at their PAR workstations at the best prices available to them under the Exchange Rules.[9]

The Exchange believes the threshold of $0.50 is reasonable. The Exchange notes that this threshold is equal to or less than the bid-ask differential applicable to all options classes.[10] The Exchange also notes that this threshold is less than the current acceptable price range (''APR'') parameter for series with a bid price of less than $100.00.[11] Pursuant to the price check provision in Rule 6.13(b)(v)[12] the CBOE Hybrid System will not automatically execute a marketable order if the width between the national best bid and national best offer is not within the APR, which the Exchange has currently set at $10.00 for any bid price between $0.00 and $100.00. Instead, the CBOE Hybrid System will route the order to a PAR workstation or the order entry firm's booth, or if the order is not eligible to route to PAR, it will be cancelled.[13] Notwithstanding this provision, proposed Rule 6.13(b)(vi) allows for the potential execution of market orders to sell in no-bid series with offers less than $0.50 as limit orders at the price of a minimum increment. If the threshold in proposed Rule 6.13(b)(vi) were higher, the risk of having a market order trade at a minimum increment in a series that is not truly no-bid would increase.

The proposed rule change will require the Exchange to modify the System in two installments. The first installment will change the $0.30 parameter to $0.50. The second installment will allow market orders to sell in no-bid series that were routed to a PAR workstation of a TPH User to be entered into the electronic book. After the rule change is effective, the Exchange will announce the implementation dates for the two installments in a Regulatory Circular to be published no later than 90 days following the effective date. The implementation date for each installment will be no later than 180 days following the effective date and at least two weeks after the publication of the above Regulatory Circular.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[14] Specifically, the Exchange believes the proposed rule change is consistent with the Section

[6] If the order does not execute during the trading day as a limit order and remains outstanding after the close of trading (i.e., a good-til-cancelled order), the CBOE Hybrid System at that time will no longer consider the order as a limit order and will again handle the order as a market order to sell after the close of trading. The market order will stay on the electronic book until the opening of the next trading day (or until cancelled), at which point it may execute during the open or, if it remains unexecuted after the opening of trading, it will either execute with the best bid at the time or, if the series is still no-bid, again be handled pursuant to proposed Rule 6.13(b)(vi).

[7] Routing the market order to PAR or the order entry firm's booth provides for an alternative means through which the order may be executed before it is simply cancelled.

[8] A ''PAR Official'' is an Exchange employee or independent contractor whom the Exchange may designate as being responsible for (a) operating the PAR workstation in a DPM trading crowd with respect to the classes of options assigned to him/her; (b) when applicable, maintaining the book with respect to the classes of options assigned to him/her; and (c) effecting proper executions of orders placed with him/her. The PAR Official may not be affiliated with any Trading Permit Holder that is approved to act as a Market-Maker. *See* Rule 7.12(a).

[9] *See,* e.g., Rule 7.12(b)(ii) (governing PAR Officials) and Rule 6.73(a). PAR workstations are only available on the trading floor; therefore, the use of a PAR workstation by a TPH User requires the TPH User to comply with Rule 6.73(a).

[10] Bid-Ask differentials are determined by the Exchange on a class-by-class basis. *See* CBOE Rule 8.7(b)(iv) and *Regulatory Circular RG–14–117* (Bid-Ask Differentials). Currently, the opening rotation and open outcry quote widths for a series with a bid of less than $2.00 is $0.50 for all options classes, excluding LEAPS; EEM; NDX; PCLN; RUT; SPX; SPXPM; UltraShorts; UltraLongs; Direxion 3X; and DirexionShares 3X, which all have higher bid-ask differentials. Intraday Electronic Quoting Widths are also higher than $0.50.

[11] The acceptable APR parameter is determined by the Exchange on a class-by-class basis. *See* CBOE Rule 6.13(b)(v) and *CBOE Regulatory Circular RG14–061* (Operational Systems Settings—APR and OEPW).

[12] Rule 6.13(b)(v) also provides that the CBOE Hybrid System will not automatically execute eligible orders that are marketable if the execution would follow an initial partial execution on the Exchange and would be at a subsequent price that is not within an acceptable tick distance from the initial execution. The APR for purposes of Rule 6.13(b)(v) is determined by the Exchange on a class-by-class basis and may not be less than $0.375 between the bid and offer for each option contract for which the bid is less than $2, $0.60 where the bid is at least $2 but does not exceed $5, $0.75 where the bid is more than $5 but does not exceed $10, $1.20 where the bid is more than $10 but does not exceed $20, and $1.50 where the bid is more than $20. An ''acceptable tick distance'' shall be no less than two minimum increments.

[13] *See* CBOE Rule 6.13(b)(v)(B).

[14] 15 U.S.C. 78f(b).

6(b)(5) [15] requirements that the rules of an exchange be 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [16] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the automated handling of market orders to sell in no-bid series if the Exchange best offer is $0.50 or less assists with the maintenance of fair and orderly markets and protects investors and the public interest because it provides for automated handling of these orders, ultimately resulting in more efficient executions of these orders. The Exchange believes that the $0.50 threshold also protects investors and assists with the maintenance of fair and orderly markets by preventing executions of market orders to sell in no-bid series with higher offers at potentially extreme prices in series that are not truly no-bid. The Exchange believes this threshold appropriately reflects the interests of investors, as options in no-bid series with offers higher than $0.50 are less likely to be worthless, and manual handling of these orders will lead to better executions for investors than would occur through automatic handling. The Exchange also believes that the $0.50 threshold promotes fair and orderly markets because market orders to sell in no-bid series with offers of $0.50 or less are likely to be individuals seeking to close out a worthless position for which automatic handling is appropriate.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE 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. More specifically, the Exchange does not believe that the proposed rule changes will impose any burden on intramarket competition because it will be applicable to all TPHs trading on the Exchange trading floor. In addition, the Exchange does not believe the proposed changes will impose any intermarket burden because the Exchange will operate in a similar manner only with a more applicable no-bid series threshold.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [17] and Rule 19b–4(f)(6) [18] thereunder. 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 will institute proceedings to determine whether the proposed rule change 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–CBOE–2014–067 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2014–067. 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–CBOE–2014–067 and should be submitted on or before November 28, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–26346 Filed 11–5–14; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78f(b)(5).

[16] *Id.*

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73482; File No. SR–OCC–2014–803]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of No Objection to Advance Notice Filing to Better Manage Risks Concentration and Other Risks Associated With Accepting Deposits of Common Stocks for Margin Purposes

October 31, 2014.

On July 16, 2014, the Options Clearing Corporation (''OCC'') filed with

the Securities and Exchange Commission (''Commission'') advance notice SR–OCC–2014–803 pursuant to Section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 (''Payment, Clearing and Settlement Supervision Act'') [1] and Rule 19b–4(n)(1) under the Securities Exchange Act of 1934 (''Act'').[2] The advance notice was published for comment in the **Federal Register** on August 15, 2014.[3] On September 8, 2014, pursuant to Section 806(e)(1)(D) of the Payment, Clearing and Settlement Supervision Act, the Commission required OCC to provide additional information concerning this advance notice.[4] The Commission did not receive any comments on the advance notice publication. This publication serves as a notice of no objection to the changes proposed in the advance notice.

I. Description of the Advance Notice

According to OCC, the purpose of this change is to permit OCC to better manage concentration risk and wrong-way risk associated with accepting deposits of common stock for margin purposes. In order to manage such risks, OCC is adding an Interpretation and Policy to Rule 604, which specifies the forms of margin assets accepted by OCC, that will provide OCC with discretion with respect to giving value to assets deposited by a single clearing member to satisfy its margin requirement(s). In addition, OCC is making clarifying amendments to an existing Interpretation and Policy under Rule 604 that gives OCC discretion to not give value to a particular type of margin collateral across all clearing members.

a. Background

OCC Rule 604 lists the types of assets that clearing members may deposit with OCC to satisfy their margin requirement(s) as well as sets forth eligibility criteria for such assets. According to OCC, common stocks, including Exchange Traded Funds (''ETFs'') and Exchange Traded Notes (''ETNs''), are the most common form of margin assets deposited by clearing members and currently comprise 68% of the $60.6 billion in clearing member margin deposits held by OCC (not including deposits in lieu of margin). According to OCC, since 2009, OCC has used its System for Theoretical Analysis and Numerical Simulations (''STANS''), which is OCC's daily automated Monte Carlo simulation-based margining methodology, to value common stocks deposited by clearing members as margin.[5] The value given to margin deposits depends on factors that include the price volatility and the price correlation relationship of common stock collateral to the balance of the cleared portfolio. The approach used by STANS incentivizes clearing members who chose to meet their margin obligations with deposits of common stocks to choose common stocks that hedge their related open positions.

According to OCC, notwithstanding the value STANS gives to deposits of common stocks, certain factors warrant OCC adjusting the value STANS gives to all clearing member margin deposits of a particular type of margin collateral. Such factors are set forth in Rule 604, Interpretation and Policy .14, and include the number of outstanding shares, number of outstanding shareholders and overall trading volume. OCC is proposing to add a new Interpretation and Policy to Rule 604 (the ''Interpretation'') so that OCC has discretion to not give margin credit to a particular clearing member when such clearing member deposits a concentrated amount of any common stock and when a common stock, deposited as margin, presents ''wrong-way risk'' to OCC. In addition, the Interpretation will provide OCC discretion to grant margin credit to a clearing member when it deposits shares of common stock that serve as a hedge to the clearing member's related open positions and would otherwise be not be given margin credit.[6]

b. Concentrated Deposits of Common Stock

OCC has determined that in the event it is necessary to liquidate a clearing member's positions (including the clearing member's margin collateral), OCC may be exposed to risk arising from a large quantity of a particular common stock deposited as margin by a clearing member. Specifically, depending on the relationship between the average daily trading volume of a particular security and the number of outstanding shares of such security deposited by a clearing member as margin, it is possible that the listed equities markets may not be able to quickly absorb all of the common stock OCC seeks to sell, or OCC may not be able to auction such securities, without an appreciable negative price impact. This occurrence, referred to by OCC as ''concentration risk,'' is greatest when the number of shares being sold is large and the average daily trading volume is low.

OCC's existing authority to not give value to otherwise eligible forms of margin only provides OCC with the discretion to not give value across all clearing member deposits of a particular common stock. However, concentration risk may be a clearing member and account-specific risk. In order to mitigate the concentration risk of a single clearing member, OCC plans to implement automated processes to monitor the composition of a clearing member's margin deposits. Such processes will identify concentration risk at both an account level and across all accounts of a clearing member. OCC is adding the Interpretation so that OCC has discretion to limit the margin credit granted to an individual clearing member that maintains a concentrated margin deposit of otherwise eligible common stock.

According to OCC, for reasons stated above, OCC considers a common stock's average daily trading volume and the number of shares a clearing member deposited as margin to be the two most significant factors when making a

[1] 12 U.S.C. 5465(e)(1). The Financial Stability Oversight Council designated OCC a systemically important financial market utility on July 18, 2012. *See* Financial Stability Oversight Council 2012 Annual Report, Appendix A, *http://www.treasury.gov/initiatives/fsoc/Documents/2012%20Annual%20Report.pdf.* Therefore, OCC is required to comply with the Payment, Clearing and Settlement Supervision Act and file advance notices with the Commission. *See* 12 U.S.C. 5465(e).

[2] 17 CFR 240.19b–4(n)(1).

[3] Securities Exchange Act Release No. 72803 (August 11, 2014), 79 FR 48285 (August 15, 2014) (SR–OCC–2014–803). OCC also filed the proposal contained in this advance notice as a proposed rule change under Section 19(b)(1) of the Act and Rule 19b–4 thereunder, which was published for comment in the **Federal Register** on August 5, 2014. 15 U.S.C. 78s(b)(1); 17 CFR 240.19b–4. *See* Securities Exchange Act Release No. 72717 (July 30, 2014), 79 FR 45523 (August 5, 2014) (SR–OCC–2014–14). The Commission did not receive any comments on the proposed rule change.

[4] 12 U.S.C. 5465(e)(1)(D). The Commission received a response with further information for consideration of the advance notice on September 19, 2014, at which time a 60 day review period began pursuant to Sections 806(e)(1)(E) and (G) of the Payment, Clearing and Settlement Supervision Act. *See* 12 U.S.C. 5465(e)(1)(E) and 12 U.S.C. 5465(e)(1)(G).

[5] *See* Securities Exchange Act Release No. 58158 (July 15, 2008), 73 FR 42646 (July 22, 2008) (SR–OCC–2007–20).

[6] According to OCC, consistent with the language contained in existing Interpretation & Policy .14, the Interpretation provides OCC with discretion in determining the amount of margin credit given to deposits of common stock by an individual clearing member as such determination would be based on positions held and common stock deposits made by such clearing member on a given business day. However, as discussed in the following two sections, OCC states that it also has developed certain automated processes as well as additional internal policies that describe how OCC presently intends to exercise such discretion. According to OCC, these additional internal policies are included in OCC's collateral risk management policy, which will not be implemented until approval of this rule change with changes thereto being subject to additional rule filings.

decision to limit margin credit due to concentration risk. Accordingly, OCC will not give margin credit to clearing member margin deposits of a particular common stock in respect of a particular account when the deposited amount of such common stock is in excess of two times the average daily trade volume of such common stock over the most recent three month period. OCC's systems will continually assess the composition of clearing member margin deposits for each account maintained by the clearing member, including intra-day collateral substitutions in such accounts, to determine if a clearing member has a margin deposit with a concentrated amount of common stock. With respect to a given account, OCC's systems will automatically set appropriate limits on the amount of a particular common stock for which a clearing member may be given margin credit for any one of a its tier accounts. In addition, and with respect to all of a clearing member's accounts, OCC will impose an add-on margin charge if, in aggregate, a clearing member deposits a concentrated amount of a particular common stock as margin across all of its accounts. The add-on margin charge will operate to negate the margin credit given to the concentrated margin deposit, and will be collected, when applicable, as part of OCC's standard morning margin process. OCC will assess the add-on margin charge across all of a clearing member's accounts on a pro-rata basis (based on the amount of the particular common stock in each of a clearing member's accounts).[7]

According to OCC, OCC staff has been monitoring concentrated common stock positions, assessing the impact of the proposed change described in this filing and contacting clearing members affected by the proposed change. OCC believes that clearing members will be able to comply with the proposed change without making significant changes to their day-to-day business operations. In December 2013, an information memo was posted to inform all members of the upcoming change. According to OCC, since January 2014, OCC staff has been in contact with any clearing member that would be affected by the proposed change. On a weekly basis, any clearing member that would see a reduction of 10% or more of its collateral value is contacted and provided an explanation of the policy and a list of concentrated positions observed in this analysis. On a monthly basis, all clearing members exhibiting any concentration risk are contacted to provide an explanation of the proposed policy and a list of concentrated positions. In both cases, clearing members are encouraged to proactively reduce concentrated positions to conform to the proposed policy. As of June 2014, twenty-five members would be affected. Implementation of the Interpretation would result in disallowing $1.2 billion in collateral value and result in margin calls for six members totaling $710 million. Moreover, in July 2014, OCC made an automated report concerning concentrated margin deposits of common stock available to all clearing members.

c. Wrong-Way Risk

OCC also will use the Interpretation to address the risk that the common stock a clearing member has deposited as margin and which is issued by the clearing member itself or an affiliate of the clearing member will lose value in the event the clearing member providing such margin defaults, which is known as ''wrong-way risk.'' According to OCC, wrong-way risk occurs when a clearing member makes a deposit of common stock issued by it or an affiliate and, in the event the clearing member defaults, the clearing member's common stock margin deposit will also be losing value at the same time because there is likely to be a strong correlation between the clearing member's creditworthiness and the value of such common stock. In order to address wrong-way risk, the Interpretation will implement automated systems that will not give margin credit to a clearing member that deposits common stock issued by such clearing member or an affiliate as margin collateral. OCC will define ''affiliate'' broadly in the Interpretation to include any entity with direct or indirect equity ownership of 10% of the clearing member, or any entity for which the clearing member holds 10% of the direct or indirect equity ownership.[8]

OCC has addressed the impact of the change designed to address wrong-way risk. As of June 2014, there were 73 clearing members whose parent or an affiliate has issued securities trading on U.S. exchanges. As of June 2014, there are six clearing members that would be affected by virtue of having made margin deposits of their own or an affiliate's common stock. In total, these shares equaled $132 million and accounted for less than one half of one percent of the total market value of valued securities pledged as margin at OCC. In July 2014, OCC made information available to each clearing member that indicates which of its deposits of common stock would not receive margin credit under the proposed change due to wrong-way risk considerations, as described above.[9]

d. Deposits That Hedge Open Positions

In addition to the above, OCC also will include language in the Interpretation so that it has discretion to give margin credit to common stock deposited as margin that would otherwise not be given margin credit in circumstances when such common stock acts as a hedge (*i.e.,* the member holds an equivalent short position in cleared contracts on the same underlying security). This condition will be checked in both the account and clearing member level. For example, if a clearing member deposits the common stock of an affiliate as margin collateral, which, pursuant to the above, would ordinarily not be given value for the purposes of granting margin credit, OCC may nevertheless give value to such common stock for the purposes of granting margin credit to the extent such common stock acts as a hedge against open positions of the clearing member. In this case, a decline in the value of the margin deposit would be wholly or partially offset by an increase in the value in the open position. Moreover, in such a situation, OCC will systematically limit the margin credit granted to the lesser of a multiple of the daily trading volume or the ''delta equivalent position'' [10] for the particular

[7] According to OCC, since a 2-day limit is first checked at each account, it is possible that a clearing member with multiple accounts may have more than 2-days of a given common stock on deposit in aggregate. To control this condition, a final check is done on the aggregate amount of shares held by a clearing member across all of its accounts. For example, if a particular clearing member has three accounts each holding 2-days volume of a specific common stock, the clearing member check would identify that the member was holding six days of volume in aggregate. To mitigate this risk, an add-on charge equal to the market value of four days of volume would be applied to all accounts holding that security on a pro-rata basis.

[8] This standard is based on the provisions of OCC Rule 215(a)(5).

[9] OCC believes that by providing such information clearing members will be better able to adjust their margin deposits at OCC to conform to the proposed change if it is approved.

[10] According to OCC, the ''delta equivalent position'' is the equivalent number of underlying shares represented by the aggregation of cleared products on that same underlying instrument. This value is calculated using the ''delta'' of the option or futures contract, which is the ratio between the theoretical change in the price of the options or futures contract to the corresponding change in the price of an underlying asset. Thus, delta measures the sensitivity of an options or futures contract price to changes in the price of the underlying asset. For example, a delta of +0.7 means that for every $1 increase in the price of the underlying stock, the price of a call option will increase by $0.70. Delta for an option or future can be expressed in shares

common stock, taking into account the hedging position.[11] OCC believes that this policy will further encourage clearing members to deposit margin collateral that hedges their related open positions and is in line with the valuation methods within STANS. This policy will also facilitate OCC's management of its and its participants' credit exposure as well as the liquidation of a clearing member's portfolio should the need arise.

e. Other Proposed Changes

OCC also will make certain clarifying changes in order to accommodate the adoption of the Interpretation into its Rules. Primarily, OCC is adding language to OCC Rule 604, Interpretation and Policy .14, to clarify that such Interpretation and Policy concerns OCC's authority to not give value to certain margin deposits for all clearing members (whereas the Interpretation applies to particular clearing member(s)). In addition, OCC is removing language from OCC Rule 604, Interpretation and Policy .14, to improve readability as well as to remove ''factors'' concerning number of shares and affiliates since OCC's authority with respect to such factors will be more clearly described in the Interpretation. Finally, OCC is renumbering the Interpretations and Policies of Rule 604 in order to accommodate the adoption of the Interpretation.

II. Discussion and Commission Findings

Although the Payment, Clearing and Settlement Supervision Act does not specify a standard of review for an advance notice, the Commission believes its stated purpose is instructive.[12] The stated purpose is to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically-important financial market utilities (''FMU'') and strengthening the liquidity of systemically important FMUs.[13]

Section 805(a)(2) of the Payment, Clearing and Settlement Supervision Act[14] authorizes the Commission to prescribe risk management standards for the payment, clearing, and settlement activities of designated clearing entities and financial institutions engaged in designated activities for which it is the supervisory agency or the appropriate financial regulator. Section 805(b) of the Payment, Clearing and Settlement Supervision Act[15] states that the objectives and principles for the risk management standards prescribed under Section 805(a) shall be to:

- Promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and
- support the stability of the broader financial system.

The Commission has adopted risk management standards under Section 805(a)(2) of the Payment, Clearing and Settlement Supervision Act[16] and the Act (''Clearing Agency Standards'').[17] The Clearing Agency Standards became effective on January 2, 2013 and establish, among other things, minimum requirements regarding how registered clearing agencies must maintain effective risk management procedures and controls.[18] Therefore, it is appropriate for the Commission to review advance notices against these Clearing Agency Standards and the objectives and principles of these risk management standards as described in Section 805(b) of the Payment, Clearing and Settlement Supervision Act.[19]

The proposal in this advance notice is consistent with Clearing Agency Standards, Rule17Ad–22(b)(2) of the Act.[20] Rule 17Ad–22(b)(2) of the Act[21] requires a registered clearing agency that performs central counterparty services to, among other things, establish, implement, maintain and enforce written policies and procedures reasonably designed to use margin requirements to limit its credit exposures to participants under normal market conditions. This proposal is consistent with this rule because it is reasonably designed to permit OCC to use margin requirements to limit its credit exposures to clearing members under normal market conditions in two ways. First, it is reasonably designed to limit OCC's credit exposures to clearing members whose collateral portfolios could present concentration risk. Specifically, it addresses concentration risk by particular clearing member and by particular account by giving OCC discretion to disapprove as margin collateral certain securities, based on the number of shares deposited, by particular clearing member and by particular account, while also considering deposits that hedge open positions. It also clarifies that OCC's existing authority to not give value to certain margin deposits applies to all clearing members, as opposed to particular clearing members.[22] Second, it is reasonably designed to limit OCC's credit exposures to clearing members whose collateral portfolios could present wrong-way risk. Specifically, it addresses wrong-way risk presented by clearing members who deposit as margin securities that are issued by the clearing member itself or by an affiliate of the clearing member. It addresses this type of wrong-way risk by giving OCC discretion to disapprove as margin collateral, with respect to a particular clearing member, any security issued by such clearing member or by an affiliate of such clearing member, while also considering deposits that hedge open positions.

Rule 17Ad–22(b)(2) of the Act[23] also requires a registered clearing agency that performs central counterparty services to, among other things, establish, implement, maintain and enforce written policies and procedures reasonably designed to use risk-based models and parameters to set margin requirements. This proposal is consistent with this rule because it permits OCC to use risk-based models and parameters to set margin requirements in a way that takes into account concentration risk and wrong-way risk, as described above.

The proposal in this advance notice meets the objectives and principles described in Section 805(b) of the Payment, Clearing and Settlement Supervision Act.[24] The changes to

of the underlying asset. For example, a standard put option with a delta of −.45 would have a delta of −45 shares, because the unit of trading is 100 shares.

[11] Assume, for example, an average daily trade volume of 250 shares, a threshold of 2 times the average daily trade volume, and a delta of −300 shares for the options on a particular security in a particular account. A position of 700 shares that did not hedge any short options or futures would receive credit for only 500 shares (*i.e.,* 2 times the average daily trade volume). If the net long position in the account, when combined with the delta of short option and futures position, were only 400, credit would be given for the entire 700 shares since the delta equivalent position is below the 500 share threshold. However, if the option delta were +300, the net long position would be 1000, and credit would only be given for 500 shares because the delta equivalent position would exceed the 500 share threshold.

[12] *See* 12 U.S.C. 5461(b).

[13] *Id.*

[14] 12 U.S.C. 5464(a)(2).

[15] 12 U.S.C. 5464(b).

[16] 12 U.S.C. 5464(a)(2).

[17] *See* Rule 17Ad–22 of the Act. 17 CFR 240.17Ad–22. Securities Exchange Act Release No. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11).

[18] *See* Securities Exchange Act Release No. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11).

[19] 12 U.S.C. 5464(b).

[20] 17 CFR 240.17Ad–22(b)(2).

[21] *Id.*

[22] *See* Rule 604, Interpretation and Policy .15 (providing OCC discretion to disapprove as margin collateral securities that meet certain factors, including trading volume, number of outstanding shareholder, number of outstanding shares, volatility and liquidity).

[23] 17 CFR 240.17Ad–22(b)(2).

[24] 12 U.S.C 5464(b); *See also* 12 U.S.C. 5464(a).

OCC's margin policy, as described above, are designed to reduce the risk that clearing member margin assets would be insufficient should OCC need to use such assets to close-out positions of a defaulted clearing member. The changes are also designed to facilitate OCC to timely meet its settlement obligations because the change will diminish the likelihood that a large percentage of the value of a defaulting clearing member's margin assets would not be available to OCC to cover losses in the event of a clearing member default. Therefore, the proposal (i) promotes robust risk management (including risk management of concentration risk and wrong-way risk), (ii) promotes safety and soundness, (iii) reduces systemic risks (including those caused by concentration risk and wrong-way risk), and (iv) supports the stability of the broader financial system.

III. Conclusion

It is therefore noticed, pursuant to Section 806(e)(1)(I) of the Payment, Clearing and Settlement Supervision Act,[25] that the Commission DOES NOT OBJECT to the proposal in OCC's advance notice (SR–OCC–2014–803) and OCC is AUTHORIZED to implement the proposal as of the date of this notice or the date of an order by the Commission approving a proposed rule change that reflects rule changes that are consistent with the proposal in this advance notice (SR–OCC–2014–14), whichever is later.

By the Commission.

Kevin O'Neill,

Deputy Secretary.

[FR Doc. 2014–26344 Filed 11–5–14; 8:45 am]

BILLING CODE 8011–01–P

[25] 12 U.S.C. 5465(e)(1)(I).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73480; File No. SR–NASDAQ–2014–090]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Granting Approval of Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Relating to the Listing and Trading of Shares of the Validea Market Legends ETF of the ETF Series Solutions ETF Trust

October 31, 2014.

I. Introduction

On September 11, 2014, 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 list and trade the shares (''Shares'') of the Validea Market Legends ETF (''Fund'') under Nasdaq Rule 5735. The proposed rule change was published for comment in the **Federal Register** on September 26, 2014.[3] The Commission received no comments on the proposed rule change. On October 28, 2014, the Exchange filed Amendment No. 1 to the proposed rule change.[4] The Commission is approving the proposed rule change, as modified by Amendment No. l thereto.

II. Description of Proposed Rule Change

The Exchange proposes to list and trade the Shares pursuant to Nasdaq Rule 5735, which governs the listing and trading of Managed Fund Shares on the Exchange. The Shares will be offered by the ETF Series Solutions Trust (''Trust''), which was established as a Delaware business trust on February 9, 2012.[5] The Fund is a series of the Trust. Validea Capital Management, LLC will be the investment adviser (''Adviser'') to the Fund.[6] Quasar Distributors, LLC will be the principal underwriter and distributor of the Fund's Shares. U.S. Bancorp Fund Services, LLC (''USBFS'') will act as the administrator, accounting agent, and transfer agent to the Fund. U.S. Bank National Association will act as the custodian to the Fund.

The Exchange has made the following representations and statements in describing the Fund and its principal investments, other investments, and investment restrictions.[7]

Principal Investments of the Fund

According to the Exchange, the Fund's primary investment objective is to achieve capital appreciation, with a secondary focus on income. The Fund is a non-diversified, actively-managed exchange-traded fund (''ETF'') that will pursue its objectives by investing primarily at least 80% of its assets under normal market conditions,[8] in U.S. exchange-listed equity securities of U.S. companies and foreign equity securities traded on a U.S. exchange as American Depositary Receipts (''ADRs'').[9] The Fund's investment in ADRs may include ADRs representing companies in emerging markets. With respect to its investments in exchange-listed common stocks and ADRs, the Fund will invest in such securities that trade in markets that are members of the Intermarket Surveillance Group (''ISG'').

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 73178 (Sep. 22, 2014), 79 FR 58012 (''Notice'').

[4] In Amendment No. 1, Nasdaq corrected a typographical error, deleting the second use of the word ''not'' in the following statement throughout the filing: ''ADRs not listed on an exchange that is not a member of ISG or a party to a comprehensive surveillance sharing agreement with the Exchange.'' *See infra* note 10 (setting forth the full representation, as amended). Because Amendment No. 1 is a technical amendment that does not raise unique or novel regulatory issues, Amendment No. 1 is not subject to notice and comment.

[5] According to the Exchange, the Trust is registered with the Commission as an investment company under the Investment Company Act of 1940 (''1940 Act'') and has filed a registration statement on Form N–1A (''Registration Statement'') with the Commission. The Exchange states that the Trust has obtained, or will obtain prior to listing Shares of the Fund on the Exchange, an order from the Commission granting certain exemptive relief to the Trust under the 1940 Act. *See* Post-Effective Amendment No. 14 to the Registration Statement on Form N–1A for the Trust, dated July 16, 2014 (File Nos. 333–179562 and 811–22668). *See* Application for an Order (Jun. 16, 2014) (File No. 812–14322).

[6] The Exchange states that the Adviser is not a broker-dealer and is not affiliated with the any broker-dealer. The Exchange represents that in the event (a) the Adviser becomes newly affiliated with a broker-dealer or registers as a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, the Adviser, new adviser, or new sub-adviser, as the case may be, will implement a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition or changes to the portfolio, and the Adviser, new adviser, or new sub-adviser, as the case may be, will be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the portfolio. The Exchange also states that the Adviser does not currently intend to become newly affiliated with any broker-dealer, and the Fund does not currently intend to use a sub-adviser.

[7] The Commission notes that additional information regarding the Trust, the Fund, and the Shares, including investment strategies, risks, creation and redemption procedures, calculation of net asset value (''NAV''), fees, portfolio holdings disclosure policies, distributions, and taxes, among other things, can be found in the Notice and Registration Statement, as applicable. *See supra* notes 3 and 5, respectively.

[8] The term ''under normal market conditions'' as used herein includes, but is not limited to, the absence of adverse market, economic, political or other conditions, including extreme volatility or trading halts in the securities markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or *force majeure* type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance. In periods of extreme market disturbance, the Fund may take temporary defensive positions by overweighting its portfolio in cash/cash-like instruments; however, to the extent possible, the Adviser would continue to seek to achieve the Fund's investment objectives.

[9] ADRs are receipts, typically issued by a bank or trust issuer, which evidence ownership of underlying securities issued by a non-U.S. issuer. For ADRs, the depository is typically a U.S. financial institution and the underlying securities are issued by a non-U.S. issuer. ADRs are not necessarily denominated in the same currency as their underlying securities.

The Fund may invest in the securities of companies of any market capitalization, but the Adviser expects that the Fund will have a bias toward small-cap and mid-cap companies. The Adviser also expects to limit the Fund's investment in any individual economic sector to no more than 40% of the Fund's total assets.

The Exchange notes that the Adviser will select securities using a proprietary quantitative and fundamentals-based system that evaluates investment opportunities based on the published investment strategies of legendary investors whose investment strategies have generally been subject to significant academic or media analysis, such as Warren Buffet, Peter Lynch, and David Dreman. The Adviser's system incorporates 17 stock selection models, each intended to replicate the strategy of a legendary investor. The models incorporate over 300 unique fundamental metrics of companies, including measures relating to profitability, valuation, growth, cash flow, financing, and past performance, among others. The Adviser scores over 6,000 companies based on the metrics of its investor models and expects that the Fund will generally hold approximately 100 securities.

According to the Exchange, the Adviser's system, using historical data, evaluates the long term performance, risks, and correlation of each model, and blends some or all of the models to identify the composite strategy that the Adviser believes is most likely to achieve the Fund's investment objectives while reducing volatility. By utilizing various stock picking methods in the creation of the composite strategy, the Adviser will seek to reduce the volatility of the Fund's returns in different market environments and limit investment style specific risk.

The Exchange notes that the Adviser expects that the Fund will regularly update or ''rebalance'' the securities that it holds, but no more often than once every 28 days and at least 5 times per year. On each such date, securities whose fundamental scores no longer meet the Fund's requirements will be removed and replaced with higher scoring securities. A stock will only be sold in between rebalance dates if the stock has significantly underperformed the overall market since the time the stock was purchased.

Other Investments and Restrictions

While the Fund, under normal circumstances, will invest at least 80% of its assets in U.S. exchange-listed equity securities, the Fund may invest the remaining assets in a variety of other securities in support of its primary investment strategy, including, but not limited to: (a) Equity securities traded over-the-counter; [10] (b) equity securities of other U.S. registered investment companies, including open-end mutual funds, money market mutual funds and exchange-traded funds; and (c) money market instruments.[11]

While the Fund will generally invest in sponsored ADRs that are listed on ISG member exchanges and that the Adviser deems as liquid, in certain limited circumstances, as stated above, the Fund may invest in unlisted or unsponsored ADRs [12] or ADRs that the Adviser deems illiquid at the time of purchase or for which pricing information is not readily available.[13] The issuers of unlisted or unsponsored ADRs are not obligated to disclose material information in the United States. As such, according to the Exchange, there may be less information available regarding such issuers and there may be no correlation between available information and the market value of the ADRs.

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid securities or other illiquid assets (calculated at the time of investment).[14] The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets.

The Fund may not invest more than 25% of the value of its total assets in securities of issuers in any one industry or group of industries. This restriction does not apply to obligations issued or guaranteed by the U.S. government, its agencies or instrumentalities, or securities of other registered investment companies.

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to list and trade the Shares is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[15] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[16] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission notes that the Fund and the Shares must comply with the requirements of Nasdaq Rule 5735 to be listed and traded on the Exchange.

The Commission finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,[17] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. Quotation and last-sale information for the Shares will be available via Nasdaq proprietary quote and trade services and via the Consolidated Tape Association plans for the Shares. In addition, an estimated value, defined in Nasdaq Rule 5735(c)(3) as the ''Intraday Indicative Value,'' [18] will be available on the

[10] The Exchange represents that, while the Fund's investments in equity securities traded over-the-counter include shares of common stock and ADRs, not more than 10% of the net assets of the Fund, in the aggregate, will be invested in: (1) Unlisted or unsponsored ADRs; (2) ADRs not listed on an exchange that is a member of ISG or a party to a comprehensive surveillance sharing agreement with the Exchange; or (3) unlisted common stocks or common stocks not listed on an exchange that is a member of the ISG or a party to a comprehensive surveillance sharing agreement with the Exchange.

[11] The term ''money market instruments,'' as used herein, means: (i) Short-term obligations issued by the U.S. Government; (ii) short term negotiable obligations of commercial banks, fixed time deposits and bankers' acceptances of U.S. and foreign banks and similar institutions; (iii) commercial paper rated at the date of purchase ''Prime-1'' by Moody's Investors Service, Inc. or ''A–1+'' or ''A–1'' by Standard & Poor's, or, if unrated, of comparable quality, as the Adviser of the Fund determines; and (iv) money market mutual funds.

[12] *See supra* note 10 and accompanying text.

[13] *See infra* note 14 and accompanying text.

[14] Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance. *See* Notice, *supra* note 3, 79 FR at 58014.

[15] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[18] According to the Exchange, the Intraday Indicative Value will reflect an estimated intraday value of the Fund's portfolio and will be based

Continued

NASDAQ OMX Information LLC proprietary index data service and will be updated, widely disseminated, and broadly displayed at least every 15 seconds during the Regular Market Session.[19] On each business day, before commencement of trading in Shares in the Regular Market Session [20] on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio, as defined in Nasdaq Rule 5735(c)(2), that will form the basis for the Fund's calculation of NAV at the end of the business day.[21] A basket composition file, which includes the security names, amounts, and share quantities, as applicable, required to be delivered in exchange for the Fund's Shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of Nasdaq via the National Securities Clearing Corporation. The NAV of the Fund's Shares generally will be calculated once daily Monday through Friday as of the close of regular trading on the New York Stock Exchange, generally 4:00 p.m. Eastern time.[22]

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last-sale information for any underlying exchange-traded products will be available via the quote and trade service of their respective primary exchanges. Intra-day, executable price quotations on the securities and other assets held by the Fund will be available from major broker-dealer firms. Intra-day price information on the securities and other assets held by the Fund will also be available through subscription or free services that can be accessed by Authorized Participants and other investors: (a) Pricing information for exchange-traded equity securities; investment company securities; exchange-traded ADRs; or other exchange-traded securities will be publicly available from the Web sites of the exchanges on which they trade,[23] on public financial Web sites, and through subscription services such as Bloomberg and Thompson Reuters; and (b) pricing information regarding over-the-counter equities (including over-the-counter ADRs and certain investment company securities) and money market instruments, will be available through subscription services such as Markit, Bloomberg, and Thompson Reuters. The Fund's Web site, which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund and additional quantitative information.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. Trading in Shares of the Fund will be halted under the conditions specified in Nasdaq Rules 4120 and 4121, including the trading pause provisions under Nasdaq Rules 4120(a)(11) and (12). Trading in the Shares may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable,[24] and trading in the Shares will be subject to Nasdaq Rule 5735(d)(2)(D), which sets forth additional circumstances under which trading in Shares of the Fund may be halted. The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees. Further, the Commission notes that the Reporting Authority, as defined in Nasdaq Rule 5735(c)(4), that provides the Disclosed Portfolio must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the actual components of the portfolio.[25] In addition, the Exchange states that the Adviser is not registered as a broker-dealer and is not affiliated with a broker-dealer and has no present intent or arrangement to become newly affiliated with any broker-dealer. The Fund does not currently intend to use a sub-adviser.[26]

upon the current value for the components of the Disclosed Portfolio. The Exchange states that the Intraday Indicative Value will be based on quotes and closing prices from the securities' local market and may not reflect events that occur subsequent to the local market's close, that premiums and discounts between the Intraday Indicative Value and the market price may occur, and that the Intraday Indicative Value should not be viewed as a ''real time'' update of the NAV per Share of the Fund, which is calculated only once a day.

[19] Currently, the NASDAQ OMX Global Index Data Service (''GIDS'') is the NASDAQ OMX global index data feed service. The Exchange represents that GIDS offers real-time updates, daily summary messages, and access to widely followed indexes and Intraday Indicative Values for ETFs, and that GIDS provides investment professionals with the daily information needed to track or trade NASDAQ OMX indexes, listed ETFs, or third-party partner indexes and ETFs.

[20] *See* Nasdaq Rule 4120(b)(4) (describing the three trading sessions on the Exchange: (1) Pre-Market Session from 4:00 a.m. to 9:30 a.m., Eastern Time; (2) Regular Market Session from 9:30 a.m. to 4:00 p.m. or 4:15 p.m., Eastern Time; and (3) Post-Market Session from 4:00 p.m. or 4:15 p.m. to 8:00 p.m., Eastern Time).

[21] On a daily basis, the Fund will disclose the following information regarding each portfolio holding, as applicable to the type of holding: Ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding); the identity of the security, index, or other asset or instrument underlying the holding, if any; quantity held (as measured by, for example, number of shares); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holding in the Fund's portfolio. The Web site information will be publicly available at no charge.

[22] NAV per Share will be calculated for the Fund by taking the market price of the Fund's total assets, less all liabilities, dividing such amount by the total number of Shares outstanding, and rounding to the nearest cent. The value of the securities, other assets, and liabilities held by the Fund will be determined pursuant to valuation policies and procedures approved by the Trust's Board. Exchange-traded equities, exchange-traded ADRs, and other exchange-traded securities will be valued at the official closing price on their principal exchange or board of trade, or lacking any current reported sale at the time of valuation, at the mean between the most recent bid and asked quotations on its principal exchange or board of trade. Portfolio securities traded on more than one securities exchange will be valued at the last sale price or official closing price, as applicable, on the business day as of which such value is being determined at the close of the exchange representing the principal market for such securities. Equity securities traded over-the-counter and ADRs traded over-the-counter will be valued at the mean between the most recent bid and asked quotations received from pricing services; if the most recent bid and asked quotations are not available, these securities will be valued in accordance with the Fund's fair valuation procedures. Money market instruments with maturities of less than 60 days will be valued at amortized cost; money market instruments with longer maturities will be valued at the mid-point of the bid-ask prices. Investment company shares will be valued at NAV, unless the shares are exchange-traded, in which case they will be valued at the last sale or official closing price on the market on which they primarily trade.

[23] According to the Exchange, quotation and last-sale information for any underlying exchange-traded products will also be available via the quote and trade services of their respective primary exchanges, as well as in accordance with the Unlisted Trading Privileges and the Consolidated Tape Association plans, as applicable.

[24] These reasons may include: (1) The extent to which trading is not occurring in the securities and other financial instruments constituting the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.

[25] *See* Nasdaq Rule 5735(d)(2)(B)(ii).

[26] *See supra* note 6. The Exchange states that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[27] Prior to the commencement of trading, the Exchange states that it will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares.

The Exchange represents that the Shares are deemed to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made the following representations:

(1) The Shares will be subject to Rule 5735, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) The Exchange's surveillance procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund, which include ADRs, exchange-listed investment companies, or other exchange-traded securities with other markets and other entities that are members of ISG, and FINRA may obtain trading information regarding trading in the Shares and such exchange-traded equities held by the Fund from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and such exchange-traded equities held by the Fund from markets and other entities that are members of ISG, or with which the Exchange has in place a comprehensive surveillance sharing agreement. Moreover, FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's Trade Reporting and Compliance Engine.

(4) Not more than 10% of the net assets of the Fund, in the aggregate, will be invested in (a) unlisted or unsponsored ADRs, (b) ADRs not listed on an exchange that is a member of ISG or a party to a comprehensive surveillance sharing agreement with the Exchange, or (c) unlisted common stocks or common stocks not listed on an exchange that is a member of the ISG or a party to a comprehensive surveillance sharing agreement with the Exchange.

(5) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in creation units (and that Shares are not individually redeemable); (b) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (c) the dissemination of information regarding the Intraday Indicative Value through major index service providers such as NASDAQ OMX proprietary index data services or other major market proprietary index services; (d) the risks involved in trading the Shares during the Pre-Market and Post-Market Sessions when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (e) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; (f) trading information; and (g) the dissemination of the Disclosed Portfolio though the Fund's Web site.

(6) For initial and continued listing, the Fund must be in compliance with Rule 10A–3 under the Act.[28]

(7) The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment). The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets.

(8) A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange.

This approval order is based on all of the Exchange's representations, including those set forth above and in the Notice, and the Exchange's description of the Fund.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[29] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[30] that the proposed rule change (SR–NASDAQ–2014–090), as modified by Amendment No. 1 thereto, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–26343 Filed 11–5–14; 8:45 am]

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and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients, as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[27] The Exchange states that FINRA surveils trading on the Exchange pursuant to a regulatory services agreement and that the Exchange is responsible for FINRA's performance under this regulatory services agreement.

[28] *See* 17 CFR 240.10A–3.

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78s(b)(2).

[31] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Commercial Space Transportation Licensing Regulations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our

intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 3, 2014, vol. 79, no. 170, pages 52405–52406. The information will determine if applicant proposals for conducting commercial space launches can be accomplished according to regulations issued by the Office of the Associate Administrator for Commercial Space Transportation.

DATES: Written comments should be submitted by December 8, 2014.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0608.

Title: Commercial Space Transportation Licensing Regulations.

Form Numbers: FAA Form 8800–1.

Type of Review: Renewal of an information collection.

Background: The Commercial Space Launch Act of 1984, 49 U.S.C. App. 2601—2623, as recodified at 49 U.S.C. Subtitle IX, Ch. 701—Commercial Space Launch Activities, 49 U.S.C. 70101–70119 (1994), requires certain data be provided in applying for a license to conduct commercial space launch activities. These data are required to demonstrate to the Federal Aviation Administration (FAA), Associate Administrator for Commercial Space Transportation (AST), that a license applicant's proposed activities meet applicable public safety, national security, and foreign policy interests of the United States.

Respondents: Approximately 4 space launch applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 1544.5 hours.

Estimated Total Annual Burden: 6,178 hours.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on November 3, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110/.

[FR Doc. 2014–26386 Filed 11–5–14; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection(s): Flight Engineers and Flight Navigators

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 3, 2014, vol. 79, no. 170, pages 52404–52405. Information collected is used to determine certification eligibility of Flight Engineers and Flight Navigators.

DATES: Written comments should be submitted by December 8, 2014.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0007.

Title: Flight Engineers and Flight Navigators.

Form Numbers: FAA Form 8400–3.

Type of Review: Renewal of an information collection.

Background: FAA Form 8400–3, Application for an Airman Certificate and/or Rating (for flight engineer and flight navigator) and applications for approval of related training courses are submitted to FAA for evaluation. The information is reviewed to determine applicant eligibility and compliance with prescribed provisions of FAR Part 63, Certification: Flight Crewmembers Other Than Pilots.

Respondents: Approximately 1,004 flight engineers and flight navigators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 15 minutes.

Estimated Total Annual Burden: 498 hours.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on November 3, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–26399 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Malfunction or Defect Report

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval for to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 3, 2014, vol. 79, no. 170, pages 52406–52407. The information collected allows the FAA to evaluate its certification standards, maintenance programs, and regulatory requirements. It is also the basis for issuance of Airworthiness Directives designed to prevent unsafe conditions and accidents.

DATES: Written comments should be submitted by December 8, 2014.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0003

Title: Malfunction or Defect Report

Form Numbers: FAA Form 8010–4

Type of Review: Renewal of an information collection.

Background: Repair stations certificated under Part 145 and air taxi operators certificated under Part 135 mandatorily submit malfunction or defect reports on Federal Aviation Administration (FAA) Form 8010–4. When defects are reported which are likely to exist on other products of the same or similar design, the FAA may disseminate safety information to a particular section of the aviation community. The FAA also may adopt new regulations or issue Airworthiness Directives (AD's) to address a specific problem.

Respondents: Approximately 60,000 operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 9 minutes.

Estimated Total Annual Burden: 9,000 hours.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on November 3, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–26400 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Rotorcraft External Load Operator Certificate Application

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 3, 2009, vol. 79, no. 170, page 52406. Information required from the public by 14 CFR part 133 is used by the FAA to process the operating certificate as a record of aircraft authorized for use, and to monitor Rotorcraft External-Load Operations.

DATES: Written comments should be submitted by December 8, 2014.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0044.

Title: Rotorcraft External Load Operator Certificate Application.

Form Numbers: FAA Form 8710–4.

Type of Review: Renewal of an information collection.

Background: The information required by 14 CFR part 133 is used by the FAA to process the operating certificate as a record of aircraft authorized for use, and to monitor Rotorcraft External-Load Operations. FAA Form 8710–4, Rotorcraft External-Load Operator Certificate Application, provides a record of surveillance activities when completed by an inspector. If the information was not collected, FAA would not be able to meet its regulatory responsibilities under Part 133.

Respondents: Approximately 4,000 applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 2.26 hours.

Estimated Total Annual Burden: 3,268 hours.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submissioncommat;omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on November 3, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–26393 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Reduced Vertical Separation Minimum

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. Aircraft operators seeking operational approval to conduct RVSM operations within the 48 contiguous United States (U.S.), Alaska and a portion of the Gulf of Mexico must submit an application to the Certificate Holding District Office.

DATES: Written comments should be submitted by January 5, 2015.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0679

Title: Reduced Vertical Separation Minimum.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The authority to collect data from aircraft operators seeking operational approval to conduct RVSM operations is contained in Part 91, § 91.180. Aircraft operators seeking operational approval to conduct RVSM operations within the 48 contiguous States of the United States (U.S.), Alaska and that portion of the Gulf of Mexico where the FAA provides air traffic services must submit their application to the Certificate Holding District Office (CHDO).

Respondents: Approximately 370 operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 30 hours.

Estimated Total Annual Burden: 11,100 hours.

ADDRESSES: Send comments to the FAA at the following address: Ms. Kathy DePaepe, Room 126B, Federal Aviation Administration, ASP–110, 6500 S. MacArthur Blvd., Oklahoma City, OK 73169.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on November 3, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–26385 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Aircraft Registration

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval for to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 3, 2014, vol. 79, no. 170, page 52404. The information collected is used by the FAA to register aircraft or hold an aircraft in trust. The information required to register and prove ownership of an aircraft is required by any person wishing to register an aircraft.

DATES: Written comments should be submitted by January 5, 2015.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0042.

Title: Aircraft Registration.

Form Numbers: FAA Forms 8050–1, 8050–2, 8050–4, 8050–98, 8050–117.

Type of Review: Renewal of an information collection.

Background: Public Law 103–272 states that all aircraft must be registered before they may be flown. It sets forth registration eligibility requirements and provides for application for registration as well as suspension and/or revocation of registration. The information collected is used by the FAA to register an aircraft or hold an aircraft in trust. The information requested is required to register and prove ownership.

Respondents: Approximately 146,757 applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 32 minutes.

Estimated Total Annual Burden: 103,982 hours.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on November 3, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–26395 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: General Aviation Awards Program

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 3, 2014, vol. 79, no. 170, page 52405. The collection is used to nominate private citizens for recognition of their significant voluntary contribution to aviation education and flight safety.

DATES: Written comments should be submitted by December 8, 2014.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0574.

Title: General Aviation Awards Program.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The collection is used to nominate private citizens for recognition of their significant voluntary contribution to aviation education and flight safety. The agency/industry committee uses the information collected to select eight regional winners and one national winner from each group. The respondents are private citizens involved in aviation.

Respondents: Approximately 150 applicants.

Frequency: Information is collected annually.

Estimated Average Burden per Response: 1 hour.

Estimated Total Annual Burden: 150 hours.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on November 3, 2014.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2014–26387 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2014–130]

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 November 26, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2000–8093 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: Brenda Robeson, ARM–210, Federal Aviation Administration, Office of Rulemaking, 800 Independence Ave. SW., Washington, DC 20591; email *Brenda.Robeson@faa.gov;* (202) 267–4712.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 3, 2014.

Lirio Liu,

Director, Office of Rulemaking.

Petition For Exemption

Docket No.: FAA–2000–8093.

Petitioner: The Department of the Air Force.

Section of 14 CFR Affected: §§ 91.179(b)(1); 91.177(a)(2) 14 CFR.

Description of Relief Sought:

Due to technological advances in aircraft systems, as well as current and future operational requirements, the Air Force has the need to train aircrew and employ aircraft systems at lower

altitudes and greater distances than granted in the current exemption.

[FR Doc. 2014–26358 Filed 11–5–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

Sunshine Act Meetings; Unified Carrier Registration Plan Board of Directors

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of Unified Carrier Registration Plan Board of Directors Meeting.

TIME AND DATE: The meeting will be held on December 4, 2014, from 12:00 Noon to 3:00 p.m., Eastern Standard Time.

PLACE: This meeting will be open to the public via conference call. Any interested person may call 1–877–422–1931, passcode 2855443940, to listen and participate in this meeting.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Board of Directors (the Board) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement and to that end, may consider matters properly before the Board.

FOR FURTHER INFORMATION CONTACT: Mr. Avelino Gutierrez, Chair, Unified Carrier Registration Board of Directors at (505) 827–4565.

Dated: October 31, 2014.

Larry W. Minor,

Associate Administrator, Office of Policy, Federal Motor Carrier Safety Administration.

[FR Doc. 2014–26519 Filed 11–4–14; 4:15 pm]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Notice To Rescind the Record of Decision (ROD) for the North Metro Corridor Project in the City of Denver, Commerce City, Thornton, Northglenn, and Adams County, Colorado

AGENCY: Federal Transit Administration, DOT.

ACTION: Rescind the Record of Decision.

SUMMARY: The Federal Transit Administration (FTA), in cooperation with the Regional Transportation District (RTD), is issuing this notice to advise the public that the Record of Decision (ROD) for the proposed North Metro Corridor project in Denver, Colorado is being rescinded.

FOR FURTHER INFORMATION CONTACT: Mr. David L. Beckhouse, Team Leader for Planning and Project Development, Federal Transit Administration Region VIII, 12300 West Dakota Avenue, Suite 310, Lakewood, CO 80228, phone 720–963–3306, email *David.Beckhouse@dot.gov.*

SUPPLEMENTARY INFORMATION: The FTA, as the lead federal agency, in cooperation with the Regional Transportation District published a ROD on April 22, 2011 for the North Metro Corridor project, an 18-mile commuter rail and track system to connect Denver Union Station and the State Highway 7/162nd Avenue area in the Denver, Colorado area.

Since that time, RTD notified FTA that federal funds will not be utilized during the final design and construction of the project. Therefore, the FTA has determined that the ROD for the Final Environmental Impact Statement dated January 3, 2011 will be rescinded since there will be no federal action, and the requirements of the National Environmental Policy Act pursuant to 42 U.S.C. 4321, et se. and 23 Code of Federal Regulations 771 no longer apply.

Comments and questions concerning the proposed action should be directed to FTA at the address provided above.

Dated: October 31, 2014.

Linda M. Gehrke,

Regional Administrator, Federal Transit Administration, Region VIII.

[FR Doc. 2014–26370 Filed 11–5–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

United States Mint

Pricing for the American $1 Coin and Currency Set

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is announcing a price of $13.95 for the American $1 Coin and Currency Set.

FOR FURTHER INFORMATION CONTACT: Marc Landry, Acting Associate Director for Sales and Marketing; United States Mint; 801 9th Street NW., Washington, DC 20220; or call 202–354–7500.

Authority: 31 U.S.C. 5111, 5112 & 9701.

Dated: November 3, 2014.

Beverly Ortega Babers,

Chief Administrative Officer, United States Mint.

[FR Doc. 2014–26372 Filed 11–5–14; 8:45 am]

BILLING CODE 4810–37–P

FEDERAL REGISTER

Vol. 79 Thursday,

No. 215 November 6, 2014

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, et al.

Medicare and Medicaid Programs; CY 2015 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 484, 488, 498

[CMS–1611–F]

RIN 0938–AS14

Medicare and Medicaid Programs; CY 2015 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates Home Health Prospective Payment System (HH PPS) rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor under the Medicare prospective payment system for home health agencies (HHAs), effective for episodes ending on or after January 1, 2015. As required by the Affordable Care Act, this rule implements the second year of the four-year phase-in of the rebasing adjustments to the HH PPS payment rates. This rule provides information on our efforts to monitor the potential impacts of the rebasing adjustments and the Affordable Care Act mandated face-to-face encounter requirement. This rule also implements: Changes to simplify the face-to-face encounter regulatory requirements; changes to the HH PPS case-mix weights; changes to the home health quality reporting program requirements; changes to simplify the therapy reassessment timeframes; a revision to the Speech-Language Pathology (SLP) personnel qualifications; minor technical regulations text changes; and limitations on the reviewability of the civil monetary penalty provisions. Finally, this rule also discusses Medicare coverage of insulin injections under the HH PPS, the delay in the implementation of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM), and a HH value-based purchasing (HH VBP) model.

DATES: *Effective Date:* These regulations are effective on January 1, 2015.

FOR FURTHER INFORMATION CONTACT:

Hillary Loeffler, (410) 786–0456, for general information about the HH PPS.

Joan Proctor, (410) 786–0949, for information about the HH PPS Grouper, ICD–9–CM coding, and ICD–10–CM Conversion.

Kristine Leddy, (410) 786–8953, for information about rebasing and the HH PPS case-mix weights.

Hudson Osgood, (410) 786–7897, for information about the HH market basket.

Alan Levitt, MD, (410) 786–6892, for information about the HH quality reporting program.

Lori Teichman, (410) 786–6684, for information about HHCAHPS.

Peggye Wilkerson, (410) 786–4857, for information about survey and enforcement requirements for HHAs.

Robert Flemming, (410) 786–4830, for information about the HH VBP model.

Danielle Shearer, (410) 786–6617, for information about SLP personnel qualifications.

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Acronyms

In addition, because of the many terms to which we refer by abbreviation in this final rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ACH LOS Acute Care Hospital Length of Stay
ADL Activities of Daily Living
APU Annual Payment Update
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113
CAD Coronary Artery Disease
CAH Critical Access Hospital
CBSA Core-Based Statistical Area
CASPER Certification and Survey Provider Enhanced Reports
CHF Congestive Heart Failure
CMI Case-Mix Index
CMN Certificate of Medical Necessity
CMP Civil Money Penalty
CMS Centers for Medicare & Medicaid Services
CoPs Conditions of Participation
COPD Chronic Obstructive Pulmonary Disease
CPI Center for Program Integrity
CVD Cardiovascular Disease
CY Calendar Year

DM Diabetes Mellitus
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DIF DME Information Form
DRA Deficit Reduction Act of 2005, Pub. L. 109–171, enacted February 8, 2006
FDL Fixed Dollar Loss
FI Fiscal Intermediaries
FR Federal Register
FY Fiscal Year
HAVEN Home Assessment Validation and Entry System
HCC Hierarchical Condition Categories
HCPCS Healthcare Common Procedure Coding System
HCIS Health Care Information System
HH Home Health
HHA Home Health Agency
HHCAHPS Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey
HH PPS Home Health Prospective Payment System
HHRG Home Health Resource Group
HIPPS Health Insurance Prospective Payment System
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
IH Inpatient Hospitalization
IRF Inpatient Rehabilitation Facility
IT Information Technology
LTCH Long-Term Care Hospital
LUPA Low-Utilization Payment Adjustment
MEPS Medical Expenditures Panel Survey
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, enacted December 8, 2003
MSA Metropolitan Statistical Area
MSS Medical Social Services
NQF National Quality Forum
NRS Non-Routine Supplies
OASIS Outcome and Assessment Information Set
OBRA Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–2–3, enacted December 22, 1987
OCESAA Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. 105–277, enacted October 21, 1998
OES Occupational Employment Statistics
OIG Office of Inspector General
OT Occupational Therapy
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health IT
MFP Multifactor productivity
PAMA Protecting Access to Medicare Act of 2014
PAC–PRD Post-Acute Care Payment Reform Demonstration
PEP Partial Episode Payment Adjustment
PT Physical Therapy
QAO Quality Assessments Only
QAP Quality Assurance Plan
PRRB Provider Reimbursement Review Board
RAP Request for Anticipated Payment
RF Renal Failure
RFA Regulatory Flexibility Act, Pub. L. 96—354
RHHIs Regional Home Health Intermediaries
RIA Regulatory Impact Analysis
SAF Standard Analytic File
SLP Speech-Language Pathology
SN Skilled Nursing
SNF Skilled Nursing Facility
SOC Start of Care
UMRA Unfunded Mandates Reform Act of 1995.

I. Executive Summary

A. Purpose

This rule updates the payment rates for HHAs for calendar year (CY) 2015, as required under section 1895(b) of the Social Security Act (the Act). This will reflect the second year of the four-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit rates, and the NRS conversion factor finalized in the CY 2014 HH PPS final rule (78 FR 72256), required under section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively referred to as the ''Affordable Care Act''). Updates to payment rates under the HH PPS will also include a change in the home health wage index to incorporate the new Office of Management and Budget (OMB) core-based statistical area (CBSA) definitions and updates to the payment rates by the home health payment update percentage reflective of the productivity adjustment mandated by 3401(e) of the Affordable Care Act.

This final rule also discusses: Our efforts to monitor the potential impacts of the Affordable Care Act mandated rebasing adjustments and the face-to-face encounter requirement (sections 3131(a) and 6407, respectively, of the Affordable Care Act); coverage of insulin injections under the HH PPS; and the delay in the implementation of the International Classification of Diseases, 10th Edition, Clinical Modification (ICD–10–CM) as a result of recent Congressional action (section 212 of the Protecting Access to Medicare Act, Public Law 113–93 (''PAMA'')). This final rule also: Simplifies the regulations at § 424.22(a)(1)(v) that govern the face-to-face encounter requirement mandated by section 6407 of the Affordable Care Act; recalibrates the HH PPS case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act; makes changes to the home health quality reporting program requirements under section 1895(b)(3)(B)(v)(II) of the Act; simplifies the therapy reassessment timeframes specified in regulation at § 409.44(c)(2)(C) and (D); revises the personnel qualifications for Speech-Language Pathology (SLP) at § 484.4; and makes minor technical changes to the regulations text at § 424.22(b)(1) and § 484.250(a)(1). This final rule will also place limitations on the reviewability of CMS's decision to impose a civil monetary penalty for noncompliance with Federal participation requirements. Finally, this rule discusses comments received on the HH Value-Based Purchasing (VBP) model.

B. Summary of the Major Provisions

As required by section 3131(a) of the Affordable Care Act and finalized in the CY 2014 HH final rule, ''Medicare and Medicaid Programs; Home Health Prospective Payment System Rate Update for CY 2014, Home Health Quality Reporting Requirements, and Cost Allocation of Home Health Survey Expenses'' (78 FR 77256, December 2, 2013), we are implementing the second year of the four-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor in section III.D.4. The rebasing adjustments for CY 2015 will reduce the national, standardized 60-day episode payment amount by $80.95, increase the national per-visit payment amounts by 3.5 percent of the national per-visit payment amounts in CY 2010 with the increases ranging from $1.79 for home health aide services to $6.34 for medical social services as described in section II.C, and reduce the NRS conversion factor by 2.82 percent.

This final rule also discusses our efforts to monitor the potential impacts of the rebasing adjustments and the Affordable Care Act mandated face-to-face encounter requirement in sections III.A. Section III B implements changes to the face-to-face encounter narrative requirement by eliminating the narrative as part of the certification of eligibility and by outlining procedures for obtaining documentation from the certifying physician and/or the acute/post-acute care facility that: (1) Establish that the patient was eligible for the home health benefit; and (2) demonstrate that the face-to-face encounter was related to the primary reason the patient requires home health services, occurred within the required timeframe, and was performed either by the certifying physician, an acute/post-acute care physician that cared for the patient in that setting, or allowed non-physician practitioner (NPP). In addition, associated physician claims for certification/re-certification of eligibility (patient not present) will not

be eligible to be paid when a patient does not meet home health eligibility criteria. We will also clarify that the face-to-face encounter requirement is applicable for all episodes initiated with the completion of a Start-of-Care OASIS assessment, which we consider certifications, not re-certifications. In section III.C of the final rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget neutral manner. In section III.D.1 of this final rule, we are updating the payment rates under the HH PPS by the home health payment update percentage of 2.1 percent (using the 2010-based Home Health Agency (HHA) market basket update of 2.6 percent, minus 0.5 percentage point for productivity as required by section 1895(b)(3)(B)(vi)(I) of the Act. In section III.D.3 of this final rule, we are updating the home health wage index using a 50/50 blend of the existing core-based statistical area (CBSA) designations and the new CBSA designations set out in a February 28, 2013, Office of Management and Budget (OMB) bulletin.

This final rule also implements changes to the home health quality reporting program in section III.D.2, including the establishment of a minimum threshold for submission of OASIS assessments for purposes of quality reporting compliance, the establishment of a policy for the adoption of changes to measures that occur in-between rulemaking cycles as a result of the NQF process, and submission dates for the HHCAHPS Survey moving forward through CY 2017. In section III.E of this final rule, we discuss our rationale for maintaining the existing fixed-dollar loss (FDL) and loss-sharing ratios used in calculating high-cost outlier payments under the HH PPS. In section III.F, we discuss our recent analysis of home health claims identified with skilled nursing visits that appear to have been for the sole purpose of insulin injection assistance, without any secondary diagnoses indicating that the patient was physically or mentally unable to self-inject. We discuss, in section III.G of this final rule, the delay in the implementation of ICD–10–CM as a result of section 212 of PAMA. In section III.H of this final rule, we discuss our finalizing of a change in the therapy reassessment regulations by requiring that therapy reassessments are to occur at least every 30 calendar days. In section III.I of this final rule, we discuss a HH VBP model. In section III.J we discuss our revision to the personnel qualifications for SLP. In section III.K we discuss minor technical regulations text changes. In section III.L we discuss our revision to the civil monetary provisions, which place limitations on the reviewability of the civil monetary penalty imposed on a HHA for noncompliance with federal participation requirements.

C. Summary of Costs and Transfers

TABLE 1—SUMMARY OF COSTS AND TRANSFERS

Provision Description	Costs	Transfers
CY 2015 HH PPS Payment Rate Update.	A net reduction in burden of $21.55 million associated with certifying patient eligibility for home health services & certification form revisions.	The overall economic impact of this final rule is an estimated $60 million in decreased payments to HHAs.

II. Background

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare HH services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered HH services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Social Security Act (the Act), entitled ''Prospective Payment For Home Health Services.'' Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare.

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels, respectively. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected for the year. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) for Fiscal Year 1999, (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement

Act (BBRA) of 1999, (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for HH services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of HH services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If a HHA does not submit quality data, the HH market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS; section 3131(c) of the Affordable Care Act amended section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. The amended section 421(a) of the MMA now requires, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016, that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act.

B. System for Payment of Home Health Services

Generally, Medicare makes payment under the HH PPS on the basis of a national standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national standardized 60-day episode rate includes the six HH disciplines (skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is no longer part of the national standardized 60-day episode rate and is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor (See section II.D.4.e). Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode.

For episodes with four or fewer visits, Medicare pays national per-visit rates based on the discipline(s) providing the services. An episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low-utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

C. Updates to the HH PPS

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the HH PPS for CY 2008. The CY 2008 HH PPS final rule included an analysis performed on CY 2005 HH claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. Case-mix represents the variations in conditions of the patient population served by the HHAs. Subsequently, a more detailed analysis was performed on the 2005 case-mix data to evaluate if any portion of the 12.78 percent increase was associated with a change in the actual clinical condition of HH patients. We examined data on demographics, family severity, and non-HH Part A Medicare expenditures to predict the average case-mix weight for 2005. We identified 8.03 percent of the total case-mix change as real, and therefore, decreased the 12.78 percent of total case-mix change by 8.03 percent to get a final nominal case-mix increase measure of 11.75 percent (0.1278 * (1—0.0803) = 0.1175).

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

In the CY 2012 HH PPS final rule (76 FR 68526), we updated the 60-day national episode rates and the national per-visit rates. In addition, as discussed in the CY 2012 HH PPS final rule (76 FR 68528), our analysis indicated that there was a 22.59 percent increase in overall case-mix from 2000 to 2009 and that only 15.76 percent of that overall observed case-mix percentage increase was due to real case-mix change. As a result of our analysis, we identified a 19.03 percent nominal increase in case-mix. At that time, to fully account for the 19.03 percent nominal case-mix growth identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013.

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented a 1.32 percent reduction to the payment rates for CY 2013 to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from 2000 to 2010 (0.2390 * (1—0.1597) = 0.2008). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change will be 2.18 percent. Although we considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, we finalized the 1.32 percent payment reduction to the national, standardized 60-day episode rates in the CY 2012 HH PPS final rule (76 FR 68532).

Section 3131(a) of the Affordable Care Act requires that, beginning in CY 2014, CMS apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, CMS must phase in any adjustment over a four-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. The statute specifies that the maximum rebasing adjustment is to be no more than 3.5 percent per year of the CY 2010 rates. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of $80.95 per year, increases to the national per-visit payment rates per year as reflected in Table 2, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper.

TABLE 2—MAXIMUM ADJUSTMENTS TO THE NATIONAL PER-VISIT PAYMENT RATES (NOT TO EXCEED 3.5 PERCENT OF THE AMOUNT(S) IN CY 2010)

	2010 National per-visit payment rates	Maximum adjustments per year (CY 2014 through CY 2017)
Skilled Nursing	$113.01	$3.96
Home Health Aide	51.18	1.79
Physical Therapy	123.57	4.32
Occupational Therapy	124.40	4.35
Speech-Language Pathology	134.27	4.70
Medical Social Services	181.16	6.34

III. Provisions of the Proposed Rule and Responses to Comments

We received approximately 337 timely responses from the public, many of which contained multiple comments on the CY 2015 HH PPS proposed rule (79 FR 38366). Many of the comments were identical, but submitted by multiple commenters. We received comments from various trade associations, HHAs, individual registered nurses, physicians, clinicians, therapists, therapy assistants, health care industry organizations, and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments received, and our responses.

A. Monitoring for Potential Impacts—Affordable Care Act Rebasing Adjustments and the Face-to-Face Encounter Requirement

1. Affordable Care Act Rebasing Adjustments

As we stated in the CY 2015 HH PPS proposed rule (79 FR 38370), we do not have a sufficient amount of CY 2014 home health claims data to analyze as part of our effort in monitoring the potential impacts of the rebasing adjustments finalized in the CY 2014 HH PPS final rule (78 FR 72293). However, we analyzed 2012 home health agency cost report data to determine whether the average cost per episode was higher using 2012 cost report data compared to the 2011 cost report data used in calculating the rebasing adjustments. Specifically, we re-estimated the cost of a 60-day episode using 2012 cost report and 2012 claims data, rather than using 2011 cost report and 2012 claims data. To determine the 2012 average cost per visit per discipline, we applied the same trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) and weighted the costs per visit from the 2012 cost reports by size, facility type, and urban/rural location so the costs per visit were nationally representative. The 2012 average number of visits was taken from 2012 claims data. We estimate the cost of a 60-day episode to be $2,413.82 using 2012 cost report data (Table 3).

TABLE 3—AVERAGE COSTS PER VISIT AND AVERAGE NUMBER OF VISITS FOR A 60-DAY EPISODE

Discipline	2012 Average costs per visit	2012 Average number of visits	2012 60-day episode costs
Skilled Nursing	$130.49	9.55	$ 1,246.18
Home Health Aide	61.62	2.60	160.21
Physical Therapy	160.03	4.80	768.14
Occupational Therapy	157.78	1.09	171.98
Speech-Language Pathology	172.08	0.22	37.86
Medical Social Services	210.36	0.14	29.45
Total			2,413.82

Source: FY 2012 Medicare cost report data and 2012 Medicare claims data from the standard analytic file (as of June 2013) for episodes ending on or before December 31, 2012 for which we could link an OASIS assessment.

Using the current claims data for CY 2013 (as of June 30, 2014), we re-examined the 2012 visit distribution and re-calculated the 2013 estimated cost per episode using the updated 2013 visit profile. We estimate the 2013 60-day episode cost to be $2,485.24 (Table 4).

TABLE 4—2013 ESTIMATED COST PER EPISODE

Discipline	2012 Average costs per visit	2013 Average number of visits	2013 HH Market basket	2013 Estimated cost per episode
Skilled Nursing	$130.49	9.28	1.023	$1,238.80
Home Health Aide	61.62	2.41	1.023	151.92
Physical Therapy	160.03	5.03	1.023	823.46
Occupational Therapy	157.78	1.22	1.023	196.92
Speech-Language Pathology	172.08	0.25	1.023	44.01
Medical Social Services	210.36	0.14	1.023	30.13
Total				2,485.24

Source: FY 2012 Medicare cost report data and 2013 Medicare claims data from the standard analytic file (as of June 30, 2014) for episodes (excluding low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes) ending on or before December 31, 2013 for which we could link an OASIS assessment.

In the CY 2014 HH PPS final rule (78 FR 72277), using 2011 cost report data, we estimated the 2012 60-day episode cost to be about $2,507.83 ($2,453.71 * 0.9981 * 1.024) and the 2013 60-day episode cost to be $2,565.51 ($2,453.71 * 0.9981 * 1.024 * 1.023). Using 2012 cost report data, the 2012 and 2013 estimated cost per episode ($2,413.82 and $2,485.24, respectively) are lower than the episode costs we estimated using 2011 cost report data for the CY 2014 HH PPS final rule.[1]

In the CY 2014 HH PPS final rule, we stated that our analysis of 2011 cost report data and 2012 claims data indicated a need for a −3.45 percent rebasing adjustment to the national, standardized 60-day episode payment rate each year for four years. However, as specified by statute, the rebasing adjustment is limited to 3.5 percent of the CY 2010 national, standardized 60-day episode payment rate of $2,312.94 (74 FR 58106), or $80.95. We stated that given that a −3.45 percent adjustment for CY 2014 through CY 2017 will result in larger dollar amount reductions than the maximum dollar amount allowed under section 3131(a) of the Affordable Care Act of $80.95, we are limited to implementing a reduction of $80.95 (approximately 2.8 percent for CY 2014) to the national, standardized 60-day episode payment amount each year for CY 2014 through CY 2017. Our latest analysis of 2012 cost report and 2013 claims data suggests that an even larger reduction (−4.21 percent) than the reduction described in the CY 2014 final rule (−3.45 percent) will be needed in order to align payments to costs. We stated in the CY 2015 HH PPS proposed rule that we would continue to monitor potential impacts of rebasing as more data become available (79 FR 38371).

Although we finalized the rebasing adjustments in the CY 2014 HH PPS final rule and did not propose any changes to those adjustments, we received a number of comments on the rebasing and on our analysis of 2012 cost report data in the CY 2015 HH PPS proposed rule. Those comments and our responses are summarized below.

Comment: Commenters urged CMS to postpone or stop the implementation of the rebasing reductions. Commenters expressed concerns with the rebasing methodology, impact analysis, and process outlined in the CY 2014 HH PPS proposed and final rules and stated that a more comprehensive study is needed to evaluate the rebasing reductions. Some commenters also stated that the findings on the study on access to care mandated by section 3131(d) of the Affordable Care Act were not fully considered prior to the implementation or rebasing and urged CMS to take into account these findings and reconsider the rebasing adjustments.

Response: We thank the commenters for their comments. We did not propose changes to the rebasing adjustments for CY 2014 through CY 2017 finalized in the CY 2014 HH PPS final rule. The comments received regarding the rebasing adjustments were nearly identical to the comments submitted during the comment period for the CY 2014 HH PPS proposed rule. Therefore, we encourage commenters to review our responses to the comments we received on the rebasing adjustments in the CY 2014 HH PPS final rule (78 FR 72282–72294).

Comment: Several commenters were concerned with the impact of the rebasing adjustments and urged CMS to monitor the impact of the reductions and provided suggestions for the impact and monitoring analyses.

Response: As we noted in the CY 2015 HH PPS proposed rule, sufficient claims data for CY 2014 is not available for analysis. We plan to provide an update on our monitoring efforts once sufficient CY 2014 claims data become available. In their public comments on the CY 2015 HH PPS proposed rule, MedPAC stated that given the 12 percent or higher margins for for-profit and non-profit agencies in 2012, they do not expect the reductions to materially affect the operations of most agencies and recommended to Congress that rebasing be implemented in a shorter period, that the annual payment update be eliminated, and that such changes to statute would help bring payments closer to costs than the current approach to rebasing. MedPAC is required to conduct a study and submit a report on the impact of the rebasing adjustments on access to care, quality outcomes, the number of home health agencies, and rural agencies, urban agencies, for-profit agencies and non-profit agencies to be submitted no later than January 1, 2015.

Comment: A commenter stated that CMS did not indicate in the CY 2015 HH PPS proposed rule how many 2012 cost reports were audited and how many were trimmed out (excluded) from the analysis. The commenter requested that CMS include this information in the final rule for the sake of transparency.

Response: None of the 2012 cost reports were audited. Of the 10,485 cost reports in the sample, which contained 10,310 unique provider numbers, 6,135 cost reports were used in the results presented in the CY 2015 HH PPS proposed rule (79 FR 38370–38371). We used same trimming and weighting methodology described in the CY 2014 HH PPS proposed rule (78 FR 40284–40286).

Comment: Commenters expressed concern with the reduction to the NRS conversion factor. The commenter was concerned that reductions to payments for NRS may impact patients with wounds and requested that CMS re-

[1] The 2012 estimated cost per episode cited is based on FY 2012 cost report data and CY 2012 claims data (as of June 30, 2013) and the 2013 estimated cost per episode is based on FY 2012 cost report data and CY 2013 claims data (as of June 30, 2014).

evaluate the utilization of and charges associated with surgical dressings compared to other supplies in the NRS group and suggested CMS consider a separate conversion factor for surgical dressings. Another commenter stated that it is difficult to determine whether actual hospital-based HHA NRS costs had been included into the total cost of services measured. The commenter stated that there is a flaw in the hospital-based cost report where the NRS cost data does not flow to the total cost. The commenter recommended that CMS review the hospital based cost reports for this problem and fix the NRS adjustment equitably if that flaw exists.

Response: We researched whether hospital-based HHA costs for NRS were included in our rebasing calculations in the CY 2014 HH PPS proposed and final rules. We noted in the CY 2014 HH PPS final rule that NRS costs for hospital-based HHAs are to be reported on CMS form 2552–10, worksheet H, line 12 (78 FR 72291). This data flows to worksheet H3, part 1, line 15. However, line 15, columns 6 through 11 are shaded out and not currently populated. We are in the process of ''un-shading'' those columns for future data collection. Of the over 11,000 HHAs included in the Regulatory Impact Analysis in section V., less than 10 percent are facility-based HHAs. We believe that using NRS cost data solely from freestanding HHAs, given the unavailability of the hospital-based HHA NRS cost data for FY 2011, is appropriate. We examined cost report data for both freestanding and hospital-based HHAs (using instances where the hospital-based HHA submitted cost report data using the older version of the Medicare hospital cost report (CMS form 2552–96) that allows columns 6 through 11 on line 15 on worksheet H6 part 1to be populated). We found that the average NRS cost per visit varies substantially from year-to-year, with the five-year average NRS cost per visit at $2.27.

Once the hospital-based cost report data becomes available, we will analyze those costs and take them into consideration as we work to address any findings from the home health study required by section 3131(d) of the Affordable Care Act, monitor the potential impact of the rebasing adjustments and other recent payment changes, and develop payment options to ensure ongoing access to care for vulnerable populations. The work may include potential revisions to the NRS and case-mix weights methodology to better reflect costs of treating Medicare beneficiaries.

Comment: Commenters urged CMS to use the authority granted under section 1871 of the Social Security Act to modify the rebasing adjustments finalized in the CY 2014 HH PPS final rule. The commenter stated that CMS has authority to modify final regulations if CMS finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. Commenters urged CMS to modify payment rates in order to secure seniors' access to home health care, ensure high quality of care, and preserve jobs. Another commenter stated that section 1895 of the Social Security Act allows CMS to implement a less aggressive approach to rebasing.

Response: Section 1871(b)(2)(C) of the Act cross-references section 553(b)(3)(B) of the Administrative Procedure Act. Both the Social Security Act and the Administrative Procedure Act permit us to waive the requirements of notice and a period for comment if, among other things, the Secretary determines that notice and comment are impracticable, unnecessary, or contrary to the public interest. Normally, we only waive notice and comment when we believe there are unusual circumstances that would warrant expedited implementation of a rule, or when the rule changes are technical and/or involve no exercise of discretion on the part of the Secretary. In the context of this notice-and-comment rulemaking, it appears that the commenter is requesting that we adjust our rebasing rates without having previously announced our intention to do so. We do not believe that circumstances have changed in a way that would require an immediate change to our rebasing rate; and even if circumstances changed, we do not believe that changing the rate without a period for notice and comment would be in the public interest. We also note that calculation of the rates pursuant to the rebasing provision at section 1895(b)(3)(A)(iii) of the Act took place after a period of notice and comment in the CY 2014 HH PPS rule (see 78 FR 72278 through 72281). Section 1895 of the Act states that we must phase in any adjustment over a four-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. We do not have the authority to implement rebasing in another manner. Therefore, we will move forward with the rebasing reductions finalized in the CY 2014 HH PPS final rule.

2. Affordable Care Act Face-to-Face Encounter Requirement

Effective January 1, 2011, section 6407 the Affordable Care Act requires that, as a condition for payment, prior to certifying a patient's eligibility for the Medicare home health benefit, the physician must document that the physician himself or herself, or an allowed non-physician practitioner (NPP), as described below, had a face-to-face encounter with the patient. The regulations at § 424.22(a)(1)(v) currently require that that the face-to-face encounter be related to the primary reason the patient requires home health services and occur no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care. In addition, as part of the certification of eligibility, the certifying physician must document the date of the encounter and include an explanation (narrative) of why the clinical findings of such encounter support that the patient is homebound, as defined in subsections 1814(a) and 1835(a) of the Act, and in need of either intermittent skilled nursing services or therapy services, as defined in § 409.42(c). The face-to-face encounter requirement was enacted, in part, to discourage physicians certifying patient eligibility for the Medicare home health benefit from relying solely on information provided by the HHAs when making eligibility determinations and other decisions about patient care.

In the CY 2011 HH PPS final rule, in which we implemented the face-to-face encounter provision of the Affordable Care Act, some commenters expressed concern that this requirement would diminish access to home health services (75 FR 70427). We examined home health claims data from before implementation of the face-to-face encounter requirement (CY 2010), the year of implementation (CY 2011), and the years following implementation (CY 2012 and CY 2013), to determine whether there were indications of access issues as a result of this requirement. Nationally, utilization (as measured by the number of episodes) held relatively constant over the first year of implementation (comparing CY 2010 and CY 2011) (see Table 5 below). Between CY 2010 and CY 2013, there was a 1.8 percent decrease in number of episodes, however, there was a 1.5 percent increase in the number of home health users (beneficiaries with at least one home health episode). Also, the number of HHAs providing at least one home health episode increased steadily from CY 2010 through CY 2013 with an

aggregate increase of 8.9 percent (see Table 5 below).

Home health users as a percentage of Part A and/or Part B fee-for-service (FFS) beneficiaries decreased slightly from 9.3 percent in CY 2010 to 9.0 percent in CY 2013. The number of episodes per Part A and/or Part B FFS beneficiaries decreased slightly between CY 2010 and CY 2013, with 0.19 (or 19 episodes per 100 Medicare Part A and/or Part B FFS beneficiaries) in CY 2010 and 0.17 (or 17 episodes per 100 Medicare Part A and/or Part B FFS beneficiaries) in CY 2013. We note these observed decreases between CY 2010 to CY 2013, for the most part, are likely the result of an increase in FFS enrollment between CY 2010 and CY 2013 of 4.6 percent. Newly eligible Medicare beneficiaries are typically not of the age where home health services are needed and therefore, without any changes in utilization, we will expect home health users and the number of episodes per Part A and/or B FFS beneficiaries to decrease with an increase in the number of newly enrolled FFS beneficiaries.

TABLE 5—HOME HEALTH STATISTICS, CY 2010 THROUGH CY 2013

	2010	2011	2012	2013
Number of episodes	6,833,669	6,821,459	6,727,875	6,708,923
Beneficiaries receiving at least 1 episode (Home Health Users)	3,431,696	3,449,231	3,446,122	3,484,579
Part A and/or B FFS beneficiaries	36,818,078	37,686,526	38,224,640	38,505,609
Episodes per Part A and/or B FFS beneficiaries	0.19	0.18	0.18	0.17
Home health users as a percentage of Part A and/or B FFS beneficiaries	9.3%	9.2%	9.0%	9.0%
HHAs providing at least 1 episode	10,916	11,446	11,746	11,889

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on May 14, 2014 and August 19, 2014. Medicare enrollment information obtained from the CCW Master Beneficiary Summary File. Beneficiaries are the total number of beneficiaries in a given year with at least 1 month of Part A and/or Part B Fee-for-Service coverage without having any months of Medicare Advantage coverage.

Note(s): These results include all episode types (Normal, PEP, Outlier, LUPA) and also include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim—first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

Although home health utilization at the national level decreased slightly from CY 2010 and CY 2013, the decrease in utilization did not occur in all states. For example, California, New Jersey and Virginia experienced an increase in the number of episodes from CY 2010 to CY 2013. Also, the number of episodes per Part A and/or Part B FFS beneficiaries for these states increased or remained roughly the same between CY 2010 through CY 2013 (see Table 6).

TABLE 6—HOME HEALTH STATISTICS FOR SELECT STATES WITH INCREASING NUMBERS OF HOME HEALTH EPISODES BETWEEN CY 2010 AND CY 2011

	Year	AL	CA	MA	NJ	VA
Number of Episodes	2010	149,242	428,491	183,271	142,328	142,660
	2011	151,131	451,749	186,849	143,127	149,154
	2012	151,812	477,732	183,625	142,129	154,677
	2013	148,972	508,838	186,871	143,674	160,105
Beneficiaries Receiving at Least 1 Episode (Home Health Users)	2010	68,949	259,013	103,954	95,804	83,933
	2011	70,539	270,259	107,520	97,190	86,796
	2012	71,186	281,023	106,910	96,534	89,879
	2013	71,703	294,150	110,573	97,385	94,393
Part A and/or Part B FFS Beneficiaries	2010	689,302	3,199,845	890,472	1,205,049	1,014,248
	2011	717,413	3,294,574	934,312	1,228,239	1,055,516
	2012	732,952	3,397,936	959,015	1,232,950	1,086,474
	2013	739,868	3,444,078	976,814	1,245,275	1,119,886
Episodes per Part A and/or Part B FFS beneficiaries	2010	0.22	0.13	0.21	0.12	0.14
	2011	0.21	0.14	0.20	0.12	0.14
	2012	0.21	0.14	0.19	0.12	0.14
	2013	0.20	0.15	0.19	0.12	0.14
Home Health Users as a Percentage of Part A and/or B FFS beneficiaries	2010	10.00%	8.09%	11.67%	7.95%	8.28%
	2011	9.83%	8.20%	11.51%	7.91%	8.22%
	2012	9.71%	8.27%	11.15%	7.83%	8.27%
	2013	9.69%	8.54%	11.32%	7.82%	8.43%
Providers Providing at Least 1 Episode	2010	148	925	138	49	196
	2011	150	1,013	150	48	209
	2012	148	1,073	160	47	219
	2013	150	1,157	165	46	224

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on May 14, 2014 and August 19, 2014. Medicare enrollment information obtained from the CCW Master Beneficiary Summary File. Beneficiaries are the total number of beneficiaries in a given year with at least 1 month of Part A and/or Part B Fee-for-Service coverage without having any months of Medicare Advantage coverage.

Note(s): These results include all episode types (Normal, PEP, Outlier, LUPA) and also include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim—first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

The states with the highest utilization of Medicare home health (as measured by the number of episodes per Part A and/or Part B FFS beneficiaries) are Texas, Florida, Oklahoma, Mississippi, and Louisiana (Table 7 and Figure 1 below). In aggregate, for CY 2010 through CY 2013 the number of episodes for these states decreased by 8.0 percent; however, even with this decrease from CY 2010 through CY 2013, the five states listed in Table 7 continue to be among the states with the highest utilization of Medicare home health nationally (see Figure 1). If we were to exclude the five states listed in Table 7 from the national figures in Table 5, home health users (beneficiaries with at least one home health episode) as a percentage of Part A and/or Part B fee-for-service (FFS) beneficiaries would decrease from to 9.0 percent to 8.1 percent for CY 2013 and the number of episodes per Part A and/or Part B FFS beneficiaries would decrease from 0.17 (or 17 episodes per 100 Medicare Part A and/or Part B FFS beneficiaries) to 0.14 (or 14 episodes per 100 Medicare Part A and/or Part B FFS beneficiaries) for CY 2013.

Texas, accounting for roughly 17 percent of HHA episodes in 2010, experienced a 12 percent decrease in the number of episodes and a 9 percent decrease in the number of home health users between CY 2010 and CY 2013 (see Table 7 below). We also note that Texas is one of the states that has areas with suspect billing practices. A temporary moratoria on enrollment of new HHAs, effective July 30, 2013, were put in place for Miami, FL and Chicago, IL. In January of 2014, CMS announced new temporary moratoria on enrollment of new HHAs in four additional areas —Fort Lauderdale, FL; Detroit, MI; Dallas, TX; and Houston, TX. If we were to exclude Texas from the national average (see Table 5 above), there would be a 0.13 percent increase in number of episodes between CY 2010 and CY 2013 rather than a 1.8 percent decrease as observed at the national level. The number of home health users would increase 2.8 percent compared to the national average with an increase of 1.5 percent.

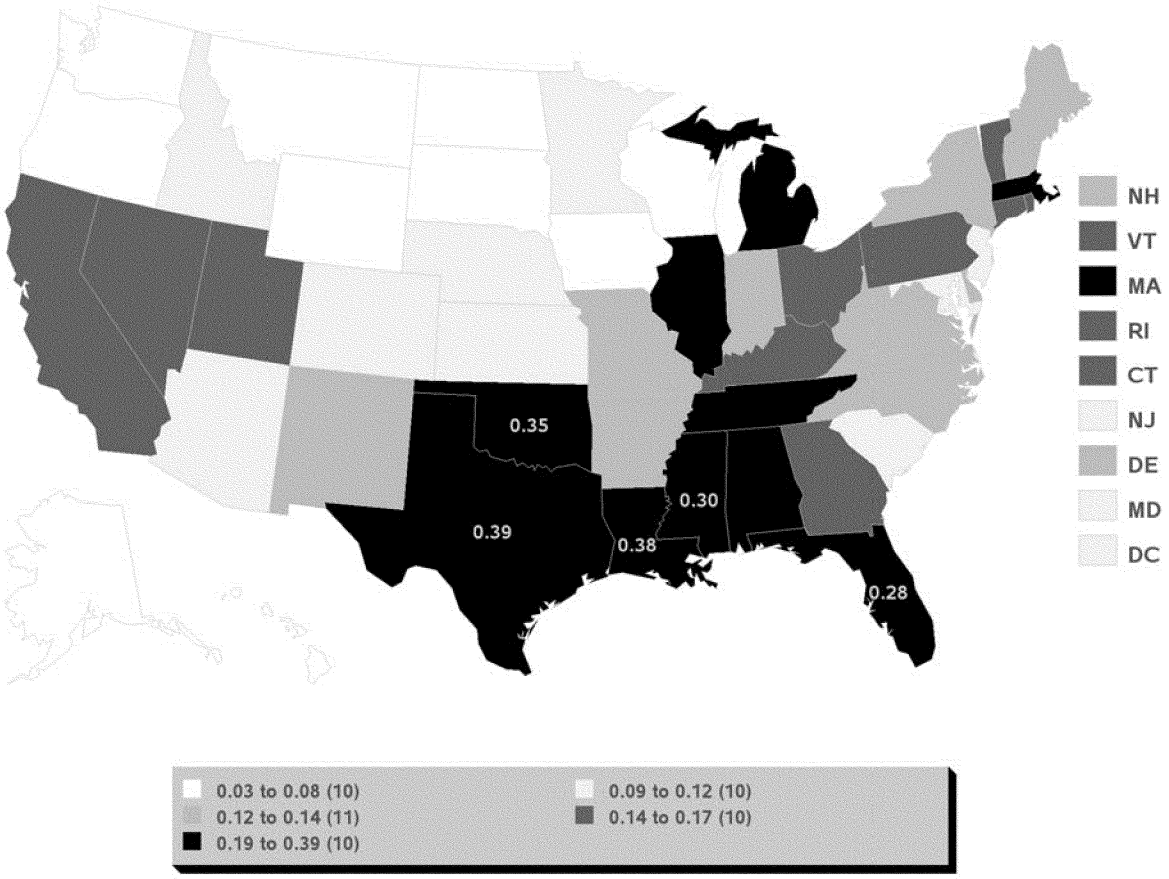
TABLE 7—HOME HEALTH STATISTICS FOR THE STATES WITH THE HIGHEST NUMBER OF HOME HEALTH EPISODES PER PART A AND/OR PART B FFS BENEFICIARIES, CY 2010 THROUGH CY 2013

	Year	TX	FL	OK	MS	LA
Number of Episodes	2010	1,127,852	689,183	208,555	153,169	256,014
	2011	1,107,605	701,426	203,112	153,983	249,479
	2012	1,054,244	691,255	196,887	148,516	230,115
	2013	995,555	689,269	196,713	143,428	215,590
Beneficiaries Receiving at Least 1 Episode (Home Health Users)	2010	366,844	355,181	68,440	55,132	77,976
	2011	363,474	355,900	67,218	55,818	77,677
	2012	350,803	354,838	65,948	55,438	74,755
	2013	333,396	357,099	66,502	55,453	73,888
Part A and/or Part B FFS Beneficiaries	2010	2,500,237	2,422,141	533,792	465,129	544,555
	2011	2,597,406	2,454,124	549,687	476,497	561,531
	2012	2,604,458	2,451,790	558,500	480,218	568,483
	2013	2,535,611	2,454,216	568,815	483,439	574,654
Episodes per Part A and/or Part B FFS beneficiaries	2010	0.45	0.28	0.39	0.33	0.47
	2011	0.43	0.29	0.37	0.32	0.44
	2012	0.40	0.28	0.35	0.31	0.40
	2013	0.39	0.28	0.35	0.30	0.38
Home Health Users as a Percentage of Part A and/or Part B FFS Beneficiaries	2010	14.67%	14.66%	12.82%	11.85%	14.32%
	2011	13.99%	14.50%	12.23%	11.71%	13.83%
	2012	13.47%	14.47%	11.81%	11.54%	13.15%
	2013	13.15%	14.55%	11.69%	11.47%	12.86%
Providers Providing at Least 1 Episode	2010	2,352	1,348	240	53	213
	2011	2,472	1,426	252	51	216
	2012	2,549	1,430	254	48	213
	2013	2,600	1,357	262	48	210

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on May 14, 2014 and August 19, 2014. Medicare enrollment information obtained from the CCW Master Beneficiary Summary File. Beneficiaries are the total number of beneficiaries in a given year with at least 1 month of Part A and/or Part B Fee-for-Service coverage without having any months of Medicare Advantage coverage.

Note(s): These results include all episode types (Normal, PEP, Outlier, LUPA) and also include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim—first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

Figure 1: Home Health Episodes per Part A and/or Part B FFS Beneficiaries - CY 2013



For CY 2011, in addition to the implementation of the Affordable Care Act face-to-face encounter requirement, HHAs were also subject to new therapy reassessment requirements, payments were reduced to account for increases in nominal case-mix, and the Affordable Care Act mandated that the HH PPS payment rates be reduced by 5 percent to pay up to, but no more than 2.5 percent of total HH PPS payments as outlier payments. The estimated net impact to HHAs for CY 2011 was a decrease in total HH PPS payments of 4.78 percent. Therefore, any changes in utilization between CY 2010 and CY 2011 cannot be solely attributable to the implementation of the face-to-face encounter requirement. For CY 2012 we recalibrated the case-mix weights, including the removal of two hypertension codes from scoring points in the HH PPS Grouper and lowering the case-mix weights for high therapy cases estimated net impact to HHAs, and reduced HH PPS rates in CY 2012 by 3.79 percent to account for additional growth in aggregate case-mix that was unrelated to changes in patients' health status. The estimated net impact to HHAs for CY 2012 was a decrease in total HH PPS payments of 2.31 percent. Again, any changes in utilization between CY 2011 and CY 2012 cannot be solely attributable to the implementation of the face-to-face encounter requirement. Given that a decrease in the number of episodes from CY 2010 to CY 2013 occurred in states that have the highest home health utilization (number of episodes per Part A and/or Part B FFS beneficiaries) and not all states experienced declines in episode volume during that time period, we believe that the implementation of the face-to-face encounter requirement could be considered a contributing factor. We will continue to monitor for potential impacts due to the implementation of the face-to-face encounter requirements and other policy changes in the future. Independent effects of any one policy may be difficult to discern in years where multiple policy changes occur in any given year.

B. Changes to the Face-to-Face Encounter Requirements

1. Background on Statutory and Regulatory Requirements

As a condition for payment, section 6407 of the Affordable Care Act requires that, prior to certifying a patient's eligibility for the Medicare home health benefit, the physician must document that the physician himself or herself or an allowed non-physician practitioner (NPP) had a face-to-face encounter with the patient. Specifically, sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as amended by the Affordable Care Act, state that, in addition to the certifying physician, a nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, working in collaboration with the physician in accordance with state law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act) as authorized by state law, or a physician assistant (as defined in section 1861(aa)(5) of the Act) under the supervision of the

physician may perform the face-to-face encounter.

The goal of the Affordable Care Act provision is to achieve greater physician accountability in certifying a patient's eligibility and in establishing a patient's plan of care. We believe this goal is better achieved if the face-to-face encounter occurs close to the start of home health care, increasing the likelihood that the clinical conditions exhibited by the patient during the encounter are related to the primary reason the patient needs home health care. The certifying physician is responsible for determining whether the patient meets the eligibility criteria (that is, homebound status and need for skilled services) and for understanding the current clinical needs of the patient such that the physician can establish an effective plan of care. As such, CMS regulations at § 424.22(a)(1)(v) require that the face-to-face encounter be related to the primary reason the patient requires home health services and occur no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care. In addition, current regulations require that, as part of the certification of eligibility, the certifying physician must document the date of the encounter and include an explanation (narrative) of why the clinical findings of such encounter support that the patient is homebound, as defined in sections 1835(a) and 1814(a) of the Act, and in need of either intermittent skilled nursing services, physical therapy, or speech-language pathology services, as defined in § 409.42(c).

The ''Requirements for Home Health Services'' describes certifying a patient's eligibility for the Medicare home health benefit, and as stated in the ''Content of the Certification'' under § 424.22 (a)(1), a physician must certify that:

- The individual needs or needed intermittent skilled nursing care, physical therapy, and/or speech-language pathology services as defined in § 409.42(c).
- Home health services are or were required because the individual was confined to the home (as defined in sections 1835(a) and 1814(a) of the Act), except when receiving outpatient services.
- A plan for furnishing the services has been established and is or will be periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine (a doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under state law).[2]
- Home health services will be or were furnished while the individual is or was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.
- A face-to-face patient encounter occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was related to the primary reason the patient requires home health services. This also includes documenting the date of the encounter and including an explanation of why the clinical findings of such encounter support that the patient is homebound (as defined in sections 1835(a) and 1814(a) of the Act) and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(c). The documentation must be clearly titled and dated and the documentation must be signed by the certifying physician.

CMS regulations at § 424.22(a)(1)(i) also require that, for instances where the physician orders skilled nursing visits for management and evaluation of the patient's care plan,[3] the physician must include a brief narrative that describes the clinical justification of this need and the narrative must be located immediately before the physician's signature. If the narrative exists as an addendum to the certification form, in addition to the physician's signature on the certification form, the physician must sign immediately after the narrative in the addendum.

When there is a continuous need for home health care after an initial 60-day episode of care, a physician is also required to recertify the patient's eligibility for the home health benefit. In accordance with § 424.22(b), a recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed and dated by the physician who reviews the plan of care. In recertifying the patient's eligibility for the home health benefit, the recertification must indicate the continuing need for skilled services and estimate how much longer the skilled services will be required. The need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care, physical therapy, or speech–language pathology services. Again, for instances where the physician ordering skilled nursing visits for management and evaluation of the patient's care plan, the physician must include a brief narrative that describes the clinical justification of this need and the narrative must be located immediately before the physician's signature. If the narrative exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately after the narrative in the addendum.

In the CY 2012 HH PPS final rule (76 FR 68597), we stated that, in addition to the certifying physician and allowed NPPs (as defined by the Act and discussed above), the physician who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health care, and who had privileges in such facility, could also perform the face-to-face encounter. In the CY 2013 HH PPS final rule (77 FR 67068) we revised our regulations so that an allowed NPP, collaborating with or under the supervision of the physician who cared for the patient in the acute/post-acute care facility, could communicate the clinical findings that supported the patient's needs for skilled care and homebound status to the acute/post-acute care physician. In turn, the acute/post-acute care physician would communicate the clinical findings that supported the patient's needs for skilled care and homebound status from the encounter performed by the NPP to the certifying physician to document. Policy always permitted such NPPs in the acute/post-acute care setting from which the patient is directly admitted to home health care to perform the face-to-face encounter and communicate directly with the certifying physician the clinical findings from the encounter and how such findings support that the patient was homebound and needed skilled services (77 FR 67106).

[2] The physician cannot have a financial relationship as defined in § 411.354 of the chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

[3] Skilled nursing visits for management and evaluation of the patient's care plan are reasonable and necessary where underlying conditions or complications require that only a registered nurse can ensure that essential *unskilled* care is achieving its purpose. For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition (reference § 409.33 and section 40.1.2.2 in Chapter 7 of the Medicare Benefits Policy Manual (Pub. 100–02)).

2. Changes to the Face-to-Face Encounter Narrative Requirement and Non-Coverage of Associated Physician Certification/Re-Certification Claims

Each year, the CMS' Office of Financial Management (OFM), under the Comprehensive Error Rate Testing (CERT) program, calculates the Medicare Fee-for-Service (FFS) improper payment rate. For the FY 2013 report period (reflecting claims processed between July 2011 and June 2012), the national Medicare FFS improper payment rate was calculated to be 10.1 percent.[4] For that same report period, the improper payment rate for home health services was 17.3 percent, representing a projected improper payment amount of approximately $3 billion.[5] The improper payments identified by the CERT program represent instances in which a health care provider fails to comply with the Medicare coverage and billing requirements and are not necessarily a result of fraudulent activity.[6]

The majority of home health improper payments were due to ''insufficient documentation'' errors. ''Insufficient documentation'' errors occur when the medical documentation submitted is inadequate to support payment for the services billed or when a specific documentation element that is required (as described above) is missing. Most ''insufficient documentation'' errors for home health occurred when the narrative portion of the face-to-face encounter documentation did not sufficiently describe how the clinical findings from the encounter supported the beneficiary's homebound status and need for skilled services, as required by § 424.22(a)(1)(v).

The home health industry continues to voice concerns regarding the implementation of the Affordable Care Act face-to-face encounter documentation requirement. The home health industry cites challenges that HHAs face in meeting the face-to-face encounter documentation requirements regarding the required narrative, including a perceived lack of established standards for compliance that can be adequately understood and applied by the physicians and HHAs. In addition, the home health industry conveys frustration with having to rely on the physician to satisfy the face-to-face encounter documentation requirements without incentives to encourage physician compliance. Correspondence received to date has expressed concern over the ''extensive and redundant'' narrative required by regulation for face-to-face encounter documentation purposes when detailed evidence to support the physician certification of homebound status and medical necessity is available in clinical records. In addition, correspondence stated that the narrative requirement was not explicit in the Affordable Care Act provision requiring a face-to-face encounter as part of the certification of eligibility and that a narrative requirement goes beyond Congressional intent.

While we do not agree that the narrative requirement goes beyond Congressional intent, we agree that there should be sufficient evidence in the patient's medical record to demonstrate that the patient meets the Medicare home health eligibility criteria. Therefore, in an effort to simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with certification requirements, we proposed that:

(1) The narrative requirement in regulation at § 424.22(a)(1)(v) would be eliminated. The certifying physician would still be required to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner as defined in § 424.22(a)(1)(v)(A), and to document the date of the encounter as part of the certification of eligibility.

For instances where the physician is ordering skilled nursing visits for management and evaluation of the patient's care plan, the physician would still be required to include a brief narrative that describes the clinical justification of this need as part of the certification/re-certification of eligibility as outlined in § 424.22(a)(1)(i) and § 424.22(b)(2). This requirement was implemented in the CY 2010 HH PPS final rule (74 FR 58111) and is not changing. We note that this requirement predates the Affordable Care Act, and is a long-established policy of CMS.

(2) In determining whether the patient is or was eligible to receive services under the Medicare home health benefit at the start of care, we proposed to review only the medical record for the patient from the certifying physician or the acute/post-acute care facility (if the patient in that setting was directly admitted to home health) used to support the physician's certification of patient eligibility, as described in paragraphs (a)(1) and (b) of the section. If the patient's medical record, used by the physician in certifying eligibility, was not sufficient to demonstrate that the patient was eligible to receive services under the Medicare home health benefit, payment would not be rendered for home health services provided.

(3) Physician claims for certification/recertification of eligibility for home health services (G0180 and G0179, respectively) would not be covered if the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit. However, rather than specify this in our regulations, this proposal would be implemented through future sub-regulatory guidance. We believed that these proposals were responsive to home health industry concerns regarding the face-to-face encounter requirements articulated above. We invited comment on these proposals and the associated change in the regulations text at § 424.22 the CY 2015 HH PPS proposed rule (79 FR 38376).

The following is a summary of the comments we received regarding (1) the proposed elimination of the face-to-face encounter narrative requirement as part of the certification of eligibility; and (2) the proposal to review only the medical record for the patient from the certifying physician or the acute/post-acute care facility (if the patient in that setting was directly admitted to home health), used to support the physician's certification of patient eligibility, in determining whether the patient is or was eligible to receive services under the Medicare home health benefit at the start of care.

Comment: A few commenters urged CMS to remove the face-to-face requirement entirely. Commenters went on to note that since the intent of the face-to-face encounter is to combat fraud, CMS should be able to determine which HHAs are providing care by fraudulent means and should investigate those HHAs.

[4] U.S. Department of Health and Human Services, ''*FY 2013 Agency Financial Report*'', accessed on April, 23, 2014 at: *http://www.hhs.gov/afr/2013-hhs-agency-financial-report.pdf*.

[5] U.S. Department of Health and Human Services, ''*The Supplementary Appendices for the Medicare Fee-for-Service 2013 Improper Payment Rate Report*'', accessed on April, 23, 2014 at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/November2013ReportPeriodAppendixFinal12-13-2013_508Compliance_Approved12-27-13.pdf*.

[6] The CERT improper payment rate is not a ''fraud rate,'' but is a measurement of payments made that did not meet Medicare requirements. The CERT program cannot label a claim fraudulent.

Response: As we note above, as a condition for payment, section 6407 of the Affordable Care Act requires that, prior to certifying a patient's eligibility for the Medicare home health benefit, the physician must document that the physician himself or herself or an allowed NPP had a face-to-face encounter with the patient. As such, we do not have the legal authority to eliminate the face-to-face encounter requirement. We also note above that the goal of this provision was to achieve greater physician accountability in certifying a patient's eligibility, increasing communication between the physician and home health agency to improve patient care, and in establishing a patient's plan of care. CMS's Center for Program Integrity (CPI) is currently engaged in a variety of activities aimed at reducing fraud and abuse. Such activities include provider/contractor audits, policy reviews, and the identification and monitoring of program vulnerabilities. CPI is actively collaborating with the U.S. Department of Justice, the Department of Health & Human Services' Office of Inspector General, state law enforcement agencies, other federal entities, and other CMS component(s) for the purposes of detecting, deterring, monitoring and combating fraud and abuse, as well as taking action against those that commit or participate in fraudulent or other unlawful activities.

Comment: Several commenters stated that CMS overstepped its statutory authority by requiring the face-to-face encounter narrative as part of the certification of patient eligibility for the home health benefit.

Response: We disagree with the commenters. We believe that our policy is consistent with the text, structure, and purpose of the statute. As a condition for payment, section 6407 of the Affordable Care Act requires that, prior to certifying a patient's eligibility for the Medicare home health benefit, the physician must ''document'' that the physician himself or herself or an allowed NPP had a face-to-face encounter with the patient. The statutory text does not specify what the statutory term ''document'' means and we believe it is reasonable to interpret the requirement to ''document'' the face-to-face encounter as requiring the certifying physician to explain why the Medicare beneficiary is homebound and in need of skilled home health services. This interpretation is supported by the structure and purpose of the statute. Medicare payment for home health services is intended for individuals who are confined to the home and need skilled home health services. The face-to-face requirement and the documentation requirement help ensure that individuals do not receive home health services unnecessarily and that Medicare makes payment appropriately (that is, when the patient is homebound and needs skilled home health services). Nothing in the text of the statute indicates that the current required explanation is outside the scope of the Secretary's legal authority. In addition, this is similar to the long-standing Medicare policy for skilled nursing visits for management and evaluation of the patient's care plan (where underlying conditions or complications require that only a registered nurse can ensure that essential unskilled care is achieving its purpose), which was previously accepted by the home health community.

Comment: Nearly all commenters were supportive of the proposal to eliminate the face-to-face encounter narrative as part of the certification of eligibility and urged CMS to finalize the proposal. Commenters cited challenges in getting certifying physicians, whom the HHA has no control over, to document the narrative sufficiently. Other commenters noted that policies surrounding the narrative requirement contained confusing nuances and reviews of narrative sufficiency were too subjective. Some commenters noted instances where medical necessity and patient eligibility for the Medicare home health benefit were clearly demonstrated in the medical record; however, the entire claim was denied because the certifying physician's narrative was deemed insufficient.

In contrast, in its comments, MedPAC stated that the narrative should continue to be a requirement as part of the certification of eligibility for Medicare home health services. MedPAC stated that eliminating the narrative increases the risk of unnecessary or unauthorized home health care services. MedPAC suggested that CMS keep the current narrative requirement in effect for at least another year while it considers other potential improvements. Another commenter also disagreed with the proposed elimination of the face-to-face encounter narrative as part of the certification of eligibility stating that the elimination of the narrative may increase confusion about the Medicare home health eligibility requirements.

Response: We thank the vast majority of the commenters for their support of this proposal. As explained in the proposed rule, we proposed to eliminate the narrative requirement in an effort to simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with certification requirements. We believe that the current narrative requirement can be useful for HHAs and medical review auditors, and is a permissible interpretation of section 6407 of the Affordable Care Act. However, as the proposed rule reflects, we acknowledge the concerns expressed by stakeholders regarding application of the narrative requirement. Balancing the considerations raised by stakeholders and commenters in light of our experience, we are finalizing our proposal to eliminate the narrative requirement. We will continue to evaluate whether further policy changes are warranted in the future.

Comment: A few commenters asked that CMS affirm that a narrative for instances where the physician is ordering skilled nursing for management and evaluation of the patient's care plan (that is, instances where the patient's underlying conditions or complications require that only a registered nurse can ensure that essential unskilled care is achieving its purpose) should be a rare occurrence and asked how physicians and HHAs should identify cases that would require a narrative. Some commenters requested that CMS affirm in the final rule that while CMS proposed to eliminate the face-to-face encounter narrative, a narrative will still be required for instances where the physician is ordering skilled nursing visits for the management and evaluation of the patient's care plan. Several commenters recommended that CMS eliminate all narrative requirements for home health for consistency and to promote a better understanding of the certification/re-certification requirements by physicians.

Response: Instances where a physician is ordering skilled nursing for the management and evaluation of the patient's care plan (when the patient's underlying conditions and/or complications require a registered nurse to ensure that non-skilled care is achieving its purpose), should be rare and therefore a narrative that explains the need for such services as part of the certification/re-certification of patient eligibility for the Medicare home health benefit should also be rare. Analysis of CY 2012 home health claims data showed that only 1.5 percent of all home health visits were for management & evaluation of the patient's care plan (see Table 8 below).

TABLE 8—PERCENTAGE OF HOME HEALTH VISITS BY HCPCS CODE, CY 2012

Type of visit	Percent of total
G0154—Direct skilled services provided by a RN/LPN	67.6
G0162—Skilled services by a RN for management and evaluation of the plan of care (the patient's underlying conditions or complications requires an RN to ensure that essential non-skilled care achieves its purpose)	1.5
G0163—Skilled services of a RN/LPN for the observation and assessment of the patient's condition (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment)	10.5
G0164—Skilled services of a RN/LPN, in the training and/or education of a patient or family member	20.4

Source: CY 2012 Medicare claims data for episodes ending on or before December 31, 2012 (as of June 30, 2013) for which we had a linked OASIS assessment.

Note(s): RN = Registered Nurse, LPN = Licensed Practical Nurse.

We note that section 40.1.2.2 in Chapter 7 of the Medicare Benefits Policy Manual provides information on how to identify whether the patient is receiving skilled nursing services for management and evaluation of the patient's care plan. Skilled nursing services in such instances can be ''reasonable and necessary where underlying conditions or complications require that only a registered nurse can ensure that essential unskilled care is achieving its purpose. For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition.'' [7] Section 40.1.2.2 also provides several examples in which skilled nursing services for management and evaluation of the patient's care plan could be considered reasonable and necessary.

As indicated above in Table 8, instances where the physician is ordering skilled nursing visits for management and evaluation of the patient's care plan should be infrequent. Because the purpose of these visits require a skilled nurse to ensure that unskilled care is achieving its purpose, we believe that it is still appropriate for the physician to include a brief narrative that describes the clinical justification of this need as part of the certification/re-certification of eligibility as outlined in § 424.22(a)(1)(i) and § 424.22(b)(2).

Comment: Several commenters stated that CMS should halt current medical review activities with regard to the face-to-face encounter narrative and reopen any past denials that were made based on an insufficient face-to-face encounter narrative by making the implementation of the elimination of the face-to-face encounter narrative retroactive.

Response: The changes finalized in CY 2015 HH PPS final rule will become effective for episodes that begin on or after January 1, 2015. Although we are eliminating the narrative requirement prospectively, the narrative requirement continues to apply to services furnished during episodes that begin before January 1, 2015.

Comment: One commenter stated that for claims currently undergoing retrospective review, CMS should find HHAs ''without fault'' under 42 U.S.C. 1395gg and section 1870 of the Act in receiving payments where the physician has provided the narrative, although perhaps not sufficient, in addition to meeting all other certification requirements. In finding the HHAs ''without fault'' CMS would simply be acknowledging that the nature of the earlier face-to-face guidance could lead to a provider acting in good faith in submitting a claim that might not meet the documentation standards. One commenter stated that CMS should issue clarifying guidance, to be applied to claims currently being reviewed, that explains what constitutes a compliant or sufficient narrative.

Response: Providers are required to submit documentation adequate to justify payment under Medicare. Where we deny a claim due to insufficient documentation of the face-to-face encounter, we are also inherently determining that the provider is not without fault because the provider has not met its burden to submit documentation adequate to justify payment. The Medicare Financial Management Manual addresses the ''without fault'' clause of section 1395gg of the Act and states that a provider is not without fault if it fails to provide the documentation necessary to determine that the billed-for services are covered.[8] We believe that we have provided sufficient education and guidance to providers on the requirements for sufficiently documenting the face-to-face encounter as part of the certification of eligibility.

CMS has issued several educational articles and a set of Q&As to help aide physicians and HHAs in complying with the face-to-face encounter narrative requirement. The most recent article issued—MLN Matters® SE1405: Documentation Requirements for Home Health Prospective Payment System (HH PPS) Face-to-Face Encounter—explains what constitutes a sufficient face-to-face encounter narrative and includes several examples. Other articles and a set of Q&As on the face-to-face encounter requirement and physician certification of eligibility can be found on the Home Health Agency (HHA) center Web page at: *http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html* under ''spotlights''.

Comment: Several commenters stated that CMS should educate its contractors to ensure that there are consistent and standardized audit practices. Other commenters stated that if CMS reviews the certifying physician's and/or facility's medical record for the patient, CMS should adequately prepare physicians to implement this new policy by educating physicians on the requirements for home health eligibility, how to sufficiently document patient eligibility, and the Medicare definition of confined to the home.

Response: We use several methods to ensure consistency in medical reviews, including contractor oversight and the use of inter-rater reliability to ensure that all reviewers are interpreting the policy the same. We offer a range of educational resources through online manuals and Web site postings for HHAs and physicians who order these services. When appropriate, we also provide direct guidance and education to Medicare providers and suppliers. We encourage HHAs to work with their designated MAC to address any issues that arise in the claims payment process. We agree with commenters who suggested that we educate physicians regarding any policy changes finalized in this final rule and provide general education to physicians on certifying beneficiaries for Medicare home health services. We will do so via,

[7] Medicare Benefit Policy Manual, (CMS Pub. 100–02), Ch. 7, sec. 40.1.2.2. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.*

[8] Medicare Financial Management Manual, (CMS Pub. 100–06), Ch. 3, sec. 90.1(E). Available at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/fin106c03.pdf*

for example, open door forums, email listserv announcements, and MedLearn articles.

Comment: A few commenters stated that the certifying physician would not have, nor should be required to have, sufficient documentation within his/her medical record for the patient to support his/her certification that the patient is eligible for the Medicare home health benefit. Several commenters stated that HHAs should not be liable for documentation errors made by physicians, whom they have little direct control over and some commenters stated that it is neither reasonable for the HHA to obtain all the documentation needed from the certifying physician and/or the acute/post-acute care facility that may have been used to certify patient eligibility and/or lead to the referral for home care. A few commenters stated that CMS' proposals to base reimbursement of one provider on documentation maintained by another, separate provider is unprecedented. Several commenters stated that if CMS begins reviewing the certifying physician's records for the patient, physician's will cease to refer patients to home health out of fear of patient record audits and frustration with administrative burden.

Response: In accordance with the statutory language at sections 1814(a)(2) and 1835(a)(2) of the Act, physicians are required to have, and thus be able to provide, material that appropriately supports their certification and recertification of Medicare home health beneficiaries, as provided by regulations. When we proposed to require a face-to-face encounter narrative, comments, which were summarized and addressed in the CY 2011 HH PPS final rule (75 FR 70431), communicated to CMS that ''the HHA has no control over the quality of the physician's documentation and no method to enforce proper physician documentation''. We stated in our response that:

> ''it is important to reiterate that to be eligible for Medicare's [home health] benefit, the patient must be under the care of a physician, and it is ultimately the responsibility of the HHA that this criterion is met. We have always held the HHA responsible for ensuring that there is a physician-signed plan of care, physician-signed orders, and a physician-signed certification. Therefore, we will also hold the agencies responsible for the certifying physician's encounter documentation. By statute, this documentation is a requirement for payment just as a physician-signed certification of eligibility is a requirement for payment'' (75 FR 70430).

We also stated in the CY 2011 HH PPS final rule that: ''we would expect that a physician who performs a medically necessary physician service, which also satisfies the face-to-face encounter requirement, would maintain medical record documentation concerning the encounter, and the clinical findings associated with that encounter would be consistent with the physician's certification documentation'' (75 FR 70431). While we stated that the HHA was ''held harmless'' if the certification of eligibility, including the face-to-face encounter narrative, was sufficient, we noted that the certifying physician was still expected to fulfill his or her responsibility for ensuring appropriate medical record documentation associated with the certification and/or encounter and any associated Medicare billing (75 FR 70431). Since we proposed to eliminate the face-to-face encounter narrative, with respect to which commenters were overwhelmingly supportive, the only other source that would substantiate the certification of eligibility is the certifying physician's and/or the acute/post-acute care facility's medical record for the patient.

We do not agree that requiring documentation from the certifying physician's and/or acute/post-acute care facility's medical record for the patient to substantiate the certification of eligibility is unprecedented. For any Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) item to be covered by Medicare:

> ''the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). . . . However, neither a physician's order nor a certificate of medical necessity (CMN) nor a DME information form (DIF) nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier prepared statement or physician attestation (if applicable).'' [9]

The analysis in section III.A in this final rule shows that since the implementation of the face-to-face encounter requirement there has been little change in home health utilization. As such, we would not expect the elimination of the narrative and the review of documentation from the certifying physician's and/or post-acute/acute care facility's medical record for the patient to have a substantial impact on utilization for those beneficiaries who are truly eligible to receive services under the Medicare home health benefit. We will continue to monitor for potential impacts due to the face-to-face encounter requirements and other policy changes in the future.

Comment: Commenters were generally opposed to using only the certifying physician's and/or acute/post-acute care facility's medical record for the patient to determine initial patient eligibility for the home health benefit. Commenters generally went on to state that all medical necessity and eligibility determinations should be based on whether the full patient record, regardless of who holds it, establishes that the patient is homebound and in need of skilled care. Other commenters suggested that CMS adopt a policy that allows the certifying physician documentation that supports the certification of eligibility for home health services to be maintained in the medical record of the HHA or allow information from the HHA to be incorporated into the certifying physician's medical record for the patient. One commenter noted that when MAC and RAC reviews are conducted, it can be years after the service was actually provided and it could be difficult to obtain information from the facility/certifying physician years later as the medical record for the patient may have been moved off-site for storage.

Response: In accordance with the statutory language at sections 1814(a)(2) and 1835(a)(2) of the Act, a physician is required to certify and re-certify the patient's eligibility for the home health benefit. This is also a condition for Medicare payment per the regulations at § 424.22. Without a valid certification/re-certification of eligibility, there can be no payment made to the HHA. Section 1833(e) of the Act further states that: ''No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.'' Similarly, section 1815(a) of the Act states that: ''. . . no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period

[9] Medicare Program Integrity Manual (CMS Pub. 100–08) Ch.5, sec. 5.7. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c05.pdf.*

with respect to which the amounts are being paid or any prior period.'' Since the certification/re-certification of eligibility is a requirement for payment and a physician, independent from the HHA as outlined in § 424.22(d), must complete the certification/re-certification of eligibility, only the certifying physician's and/or the acute/post-acute care facility's medical record for the patient that was used as the basis for the certification of eligibility can demonstrate whether the certification/re-certification of eligibility is valid.

We agree with the suggestions made by the commenters that the certifying physician and/or acute/post-acute care facility should provide the documentation that substantiates the patient's eligibility to the HHA upon request. The HHA must provide the documentation from the certifying physician and/or acute/post-acute care facility that substantiates the patient's eligibility for the Medicare home health benefit to CMS and/or its contractors upon request. We also agree with commenters that it would be permissible for the HHA to communicate with and provide information to the certifying physician about the patient's homebound status and need for skilled care and for the certifying physician to incorporate this information into his or her medical record for the patient. However, the certifying physician must review and sign off on anything incorporated into his or her medical record for the patient that is used to support his/her certification/re-certification of patient eligibility for the home health benefit. In addition, any information from the HHA (including the comprehensive assessment) that is incorporated into the certifying physician's and/or the acute/post-acute care facility's medical record for the patient (if the patient was directly admitted to home health) and used to support the certification of patient eligibility for the home health benefit, must corroborate the certifying physician's and/or the acute/post-acute care facility's own documentation/medical record entries, including the diagnoses and the patient's condition reported on the comprehensive assessment.

Comment: Commenters questioned how the process of reviewing the certifying physician and/or acute/post-acute care facility medical record for the patient would be operationalized. Specifically, commenters asked if medical review auditors would contact the certifying physician and/or acute/post-acute care facility directly to obtain records for review and if HHAs would be penalized if certifying physician and/or acute/post-acute care facility patient records are not readily available for review. Some commenters questioned whether medical record reviews would happen upon request, such as a MAC or RAC additional documentation request, or if the HHA would be responsible for obtaining the supporting documentation from the certifying physician and/or acute/post-acute care facility and, if so, whether the documentation should be obtained upon referral. A few commenters stated that if HHAs are responsible for securing supporting documentation, it could lead to delays in accepting patients, which in turn could lead to issues in complying with other regulations, such as the timeframe required for completing the initial assessment.

Response: After reviewing all of the public comments received, we believe that the best process is for the certifying physician and/or the acute/post-acute care facility (if the patient in that setting was directly admitted to home health) to provide the documentation used as the basis for the certification of home health eligibility, upon request, to the home health agency, review entities, and/or CMS. The HHA will obtain the documentation from the certifying physician and/or acute/post-acute care facility that substantiates the certification of patient eligibility for its own medical record for the patient and must be able to provide it to CMS and its review entities upon request. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided. Obtaining documentation from the certifying physician and/or acute/post-acute care facility should not lead to delays in accepting patients. We require certifications to be obtained at the time the plan of care is established or as soon thereafter as possible.[10] This allows flexibility for HHAs to develop the plan of care in consultation with the physician, if needed.

The plan of care requirements in the Medicare Conditions of Participation (CoPs) at § 484.18(a) states that the plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

The Medicare CoPs, at § 484.55(a), require the completion of an initial assessment within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date. The initial assessment visit must be done to determine the immediate care and support needs of the patient and to determine eligibility for the Medicare home health benefit, including homebound status. The Medicare CoPs, at § 484.55(b), require a comprehensive assessment to be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care, and for eligibility for the Medicare home health benefit to be determined, including homebound status. We would expect that the findings from initial assessment and/or comprehensive assessment of the patient would be communicated to the certifying physician. The certifying physician can incorporate this information into his/her medical record for the patient and use it to develop the plan of care and to support his/her certification of patient eligibility. The certifying physician must review and sign off on anything incorporated it into his or her medical record for the patient that is used to substantiate the certification/re-certification of patient eligibility for the home health benefit.

Also, per the regulations at § 424.22(a)(1)(v), the face-to-face encounter itself, can occur up to 30 days after the start of care. As such, there may be instances where the certification of patient eligibility and associated supporting documentation may not be available until after the patient has been accepted by the HHA and services have commenced. As noted above, the certification must be obtained at the time the plan of care is established or as soon thereafter as possible. Therefore, it is not acceptable for HHAs to wait until the end of the 60-day episode of care to obtain a completed certification of

[10] Medicare General Information, Entitlement, and Eligibility Manual (CMS Pub. 100–01) Ch. 4, sec. 30.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c04.pdf.*

patient eligibility and supporting documentation from the certifying physician and/or the acute/post-acute care facility (if the patient was directly admitted to home health).

Comment: Commenters stated that most of the issues with the face-to-face encounter narrative stemmed from a misunderstanding by providers and physicians on what is considered a sufficient narrative. Therefore, if the certifying physician's and/or acute/post-acute care facility's medical record for the patient is reviewed to determine initial patient eligibility for the home health benefit, then CMS should define what it would consider sufficient documentation to substantiate the certification of eligibility. Some commenters stated that it is impossible for the HHA to ensure that the documentation in the certifying physician and/or acute/post-acute care facility medical record for the patient is sufficiently detailed to support the certification of patient eligibility. A few commenters stated that some physicians are reluctant or resistant to providing additional documentation or changing previous practices in order to comply with new requirements.

Response: HHAs should obtain as much documentation from the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) as they deem necessary to assure themselves that the Medicare home health patient eligibility criteria have been met. As previously noted, we have issued several educational articles and a set of Q&As to help aide physicians and HHAs in complying with the face-to-face encounter narrative requirement and similarly could be used as a guide on what would be considered adequate documentation in the certifying physician's and/or acute/post-acute care facility's medical record for the patient to substantiate eligibility for the Medicare home health benefit. The most recent article issued—*MLN Matters® SE1405: Documentation Requirements for Home Health Prospective Payment System (HH PPS) Face-to-Face Encounter*—explains what constitutes a sufficient face-to-face encounter narrative and includes several examples. Other articles, including SE1405, and a set of Q&As on the face-to-face encounter requirement and physician certification of eligibility can be found on the Home Health Agency (HHA) center Web page at: *http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html* under ''spotlights''.

The Medicare Financial Management Manual requires providers to provide the documentation necessary to determine that the billed-for services are covered.[11] Home health services cannot be covered without a valid patient certification/re-certification of eligibility, in accordance with our regulations at § 424.22. The certifying physician and/or the acute/post-acute care facility medical record for the patient must contain information that justifies the referral for Medicare home health services, including the need for the skilled services initially ordered and the patient's homebound status. This information can be found most often in clinical and progress notes and discharge summaries. In addition, the certifying physician's and/or acute/post-acute care facility's medical record for the patient must contain the actual clinical note for the face-to-face encounter visit that demonstrates that the visit occurred within the required timeframe, was related to the primary reason the patient requires home health services, and was performed by either: (1) The certifying physician; (2) a physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health; or (3) an allowed NPP as set out in § 424.22(a)(1)(v)(A).

It is permissible for the HHA to communicate with and provide information to the certifying physician about the patient's homebound status and need for skilled care and for the certifying physician to incorporate this information into his or her medical record for the patient. The certifying physician must review and sign off on anything incorporated it into his or her medical record for the patient that is used to support his/her certification/re-certification of patient eligibility for the home health benefit. In addition, any information from the HHA (including the comprehensive assessment) that is incorporated into the certifying physician's and/or the acute/post-acute care facility's medical record for the patient (if the patient was directly admitted to home health) and used to support the certification of patient eligibility for the home health benefit, must corroborate the certifying physician's and/or the acute/post-acute care facility's own documentation/medical record entries, including the diagnoses and the patient's condition reported on the comprehensive assessment. With respect to DMEPOS, it has been our longstanding policy that records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that a DMEPOS item is reasonable and necessary. We believe the same safeguards are necessary for home health patient eligibility determinations and consistent with the statutory intent in sections 1814(a), 1835(a) and 1877 of the Act, which require a physician, who does not have financial relationship with the HHA, to certify the patient's eligibility for home health services.

We want to remind certifying physicians and acute/post-acute care facilities of their responsibility to provide the medical record documentation that supports the certification of patient eligibility for the Medicare home health benefit. Certifying physicians who show patterns of non-compliance with this requirement, including those physicians whose records are inadequate or incomplete for this purpose, may be subject to increased reviews, such as through provider-specific probe reviews.

Comment: A few commenters questioned whether a certification statement will still be required, if the certification statement can be added to the plan of care, and what exactly constitutes a sufficient certification of eligibility. One commenter recommended that CMS consider a signed and dated order for home health services for an eligible patient by an eligible practitioner as satisfying the certification requirements.

Response: As a reminder, the statute at sections 1814(a)(2)(C) and 1835(a)(2)(A) outlines the certification and re-certification requirements for Medicare home health services. These requirements are also reflected in regulations at § 424.22(a) and (b). A physician will still be required to certify patient eligibility for the Medicare home health benefit. Specifically for a certification of eligibility to be sufficient, a physician must certify that:

- The individual needs or needed intermittent skilled nursing care, physical therapy, and/or speech-language pathology services as defined in § 409.42(c).
- Home health services are or were required because the individual was confined to the home (as defined in sections 1835(a) and 1814(a) of the Act), except when receiving outpatient services.
- A plan for furnishing the services has been established and is or will be

[11] Medicare Financial Management Manual, (CMS Pub. 100–06), Ch. 3, sec. 90.1(E). Available at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/fin106c03.pdf*

periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine (a doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under state law).[12]

- Home health services will be or were furnished while the individual is or was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.
- A face-to-face patient encounter occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care, was related to the primary reason the patient requires home health services, and was performed by the certifying physician, a physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health, or an allowed NPP defined in § 424.22(a)(1)(v). The certifying physician must also document the date of the encounter as part of the certification.

For instances where the physician orders skilled nursing visits for management and evaluation of the patient's care plan,[13] the certifying physician must include a brief narrative that describes the clinical justification of this need and the narrative must be located immediately before the physician's signature. If the narrative exists as an addendum to the certification form, in addition to the physician's signature on the certification form, the physician must sign immediately after the narrative in the addendum.

When there is a continuous need for home health care after an initial 60-day episode of care, a physician is also required to recertify the patient's eligibility for the home health benefit. In accordance with § 424.22(b), a recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed and dated by the physician who reviews the plan of care. In recertifying the patient's eligibility for the home health benefit, the recertification must indicate the continuing need for skilled services and estimate how much longer the skilled services will be required. The need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care, physical therapy, or speech–language pathology services. Again, for instances where the physician ordering skilled nursing visits for management and evaluation of the patient's care plan, the physician must include a brief narrative that describes the clinical justification of this need and the narrative must be located immediately before the physician's signature. If the narrative exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately after the narrative in the addendum.

Comment: One commenter strongly believed that allowing a face-to-face encounter to occur up to 90 days prior to the start of home health care was not appropriate, stating that if a physician saw the patient 90 days ago and did not order home health care at that time, then it is unclear why is home health being ordered at a later date. Several commenters recommended that CMS eliminate the face-to-face encounter requirement altogether for instances where the patient was admitted directly from an acute/post-acute care facility since the patient would have seen a physician.

Response: We did not propose to alter the timeframes during which a face-to-face encounter can occur nor did we propose to eliminate the face-to-face requirement for instances where the patient was admitted directly from an acute/post-acute care facility. We refer the commenters to the CY 2011 HH PPS final rule (75 FR 70428–70429), where we outlined our rationale on why the face-to-face encounter timeframe of up to 90 days prior and no more than 30 days after the start of home health care was finalized. We believe that sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act do not provide the Secretary with the authority to eliminate the face-to-face encounter requirement altogether for instances where the patient was admitted directly from an acute/post-acute care facility. However, since we are finalizing the elimination of the face-to-face narrative requirement as part of the certification of eligibility for home health services, and, as commenters' noted, an encounter with a physician would have certainly occurred when a patient is admitted directly from an acute/post-acute care facility, documenting the date of the face-to-face encounter should not be burdensome. Although a home health patient would have seen a physician if they were admitted directly from an acute/post-acute care facility, the certification of eligibility still requires that the encounter be related to the primary reason for home health care. Therefore, we believe that documentation of a face-to-face encounter as part of the certification of eligibility should still be required for patients admitted into home health care directly from an acute/post-acute care facility.

Comment: Several commenters, including MedPAC, asked that CMS develop a standardized form for use in certifying patient eligibility for the home health benefit and/or making referrals to home health. MedPAC noted that CMS concurred with three recommendations in a recent audit by the Office of Inspector General (OIG), including the consideration of a standardized form for the face-to-face encounter narrative to simplify compliance. Other commenters asked that CMS consider requiring the use of CMS–485 form again.

Response: We do not believe that a standard certification/recertification of eligibility form is necessary given the elimination of the face-to-face narrative. The regulations at 42 CFR 424.22 clearly articulate what elements need to be contained in a certification/re-certification form created by an HHA. We are pursuing development of an electronic clinical template that would allow electronic health records vendors, in all 50 states, to assist physicians in thoroughly documenting patient eligibility for the Medicare home health benefit. In order to facilitate adoption of suggested clinical elements by the provider community, we are currently collaborating with the Office of the National Coordinator for Health IT (ONC) and the electronic Determination of Coverage (eDoC) workgroup in developing the interoperability standards necessary for an electronic clinical template. We do not believe that we should require the use of the old CMS–485 form. The CMS–485 form was discontinued over a decade ago to provide HHAs with more plan of care flexibility. We encourage HHAs and physicians to work together in developing formats for the home health plan of care that best meets their needs.

[12] The physician cannot have a financial relationship as defined in § 411.354 of the chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation.

[13] Skilled nursing visits for management and evaluation of the patient's care plan are reasonable and necessary where underlying conditions or complications require that only a registered nurse can ensure that essential unskilled care is achieving its purpose. For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition (reference § 409.33 and section 40.1.2.2 in Chapter 7 of the Medicare Benefits Policy Manual (Pub. 100–02)).

Comment: We received several comments advocating for us to allow other types of clinicians to certify eligibility and order home health services, such as physician assistants, nurse practitioners, and advanced-practice registered nurses.

Response: These comments are outside the scope of this rule. We remind the commenters that the statute (sections 1814(a) and 1835(b) of the Act) require a physician to certify patient eligibility for the Medicare home health benefit. We do not have the authority to allow for someone other than a Doctor of Medicine, Osteopathy or Podiatry to certify patient eligibility for the Medicare home health benefit. A change to the statute would require an act of the Congress.

Comment: Some commenters recommended statutory changes.

Response: We remind commenters that only the Congress (not CMS) has the authority to make statutory changes.

Final Decision: We are finalizing our proposal to eliminate the face-to-face encounter narrative as part of the certification of patient eligibility for the Medicare home health benefit, effective for episodes beginning on or after January 1, 2015. The certifying physician will still be required to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner as defined in § 424.22(a)(1)(v)(A), and to document the date of the encounter as part of the certification of eligibility. For instances where the physician is ordering skilled nursing visits for management and evaluation of the patient's care plan, the physician will still be required to include a brief narrative that describes the clinical justification of this need as part of the certification/re-certification of eligibility as outlined in § 424.22(a)(1)(i) and § 424.22(b)(2).

In determining whether the patient is or was eligible to receive services under the Medicare home health benefit at the start of care, we will require documentation in the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) to be used as the basis for certification of home health eligibility. We will require the documentation to be provided upon request to the home health agency, review entities, and/or CMS. Criteria for patient eligibility are described at § 424.22(a)(1) and § 424.22(b). HHAs should obtain as much documentation from the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) as they deem necessary to assure themselves that the Medicare home health patient eligibility criteria have been met and must be able to provide it to CMS and its review entities upon request. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided.

Again, we want to remind certifying physicians and acute/post-acute care facilities of their responsibility to provide the medical record documentation that supports the certification of patient eligibility for the Medicare home health benefit. Certifying physicians who show patterns of non-compliance with this requirement, including those physicians whose records are inadequate or incomplete for this purpose, may be subject to increased reviews, such as through provider-specific probe reviews.

The following is a summary of the comments we received regarding the proposal to non-cover physician claims for certification/re-certification of patient eligibility for Medicare home health services when the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit.

Comments: A few commenters appreciated the proposal to non-cover physician claims for certification/re-certification of patient eligibility for Medicare-covered home health services when the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit. Commenters who supported this proposal thanked CMS for linking physician billing to HHA billing as a first step in encouraging more physician accountability.

Response: We thank the commenters for their support. We agree that this is an important first step in reminding physicians that coordination and collaboration between the physician and the HHA is essential in providing quality patient care. Coordination and collaboration should include sharing pertinent patient information with one another, especially with regard to the patient's skilled needs and homebound status. Both entities—the physician who is ultimately responsible for the patient while he/she is receiving home health services and the HHA providing such services—should be held accountable and compensated for their services when appropriate.

Comment: Most commenters generally disagreed with the proposal to non-cover physician claims for certification/re-certification of patient eligibility for Medicare home health services when the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit. One commenter questioned how CMS will identify ''Part B claims for certification/re-certification'' and stated that the face-to-face encounter visit could occur during one of several Evaluation & Management (E&M) visits. Several commenters stated that while they support encouraging physicians to engage in the planning and oversight of home health services, they are concerned that some physicians, with limited understanding of the regulations, may be reluctant to refer to home health because of concerns about denials of reimbursement. Other commenters stated that physician claims for certification/recertification should not be denied because physicians are ''in good faith'' certifying the patient's eligibility for the home health benefit and billing for certification/recertification also includes activities performed to ensure the initial implementation of the plan of care. A few commenters suggested that, at a minimum, finalizing this proposal should be delayed until it can be proposed as part of the annual changes to the physician fee schedule.

Response: Physician certification or re-certification claims are Part B physician claims paid for under the Physician Fee Schedule. These claims are claims billed using HCPCS code G0180 (certification) or G0179 (re-certification). These claims are not Evaluation and Management claims and are billed when the patient is not present. The descriptions of these two codes indicate that they are used to bill for certification or re-certification of patient eligibility ''*for Medicare-covered* home health services under a home health plan of care (patient not present), including contacts with home health

agency and review of reports of patient status required by physicians to affirm the initial implementation of the plan of care that meets patient's needs, per certification period.'' As underlined above, we note that these codes are for physician certification or re-certification for Medicare-covered home health services. If there are no Medicare-covered home health services, these codes should not be billed or paid. As such, if the HHA claim is denied, the corresponding physician claim should not be covered because there is no longer a corresponding claim for Medicare-covered home health services. Physicians still have the option of billing Part B for E&M visits provided, transition care management, and other services as long as they follow the required billing instructions. We believe that including this proposal in the CY 2015 HH PPS proposal rule is sufficient and there is no need to re-propose this policy in next year's Physician Fee Schedule proposed rule. We received over 300 comments on the CY 2015 HH PPS proposed rule, many of which were from physician associations, such as the American College of Physicians, American Academy of Home Care Medicine, American Medical Association, and the Society of Hospital Medicine, among others.

Comment: Commenters stated that non-coverage of physician claims for certification/re-certification when the HHA claim itself was non-covered would most likely not result in a change in physician practices/behaviors due to the small payment amounts for such claims. HHAs will still encounter issues with obtaining the necessary certification/re-recertification and supporting documentation form the certifying physician.

Response: While the non-coverage of physician claims for certification/re-certification of patient eligibility for Medicare-covered home health services following the denial of a HHA claim may not serve as a sufficient incentive for encouraging certifying physicians to work collaboratively with HHAs and to provide the necessary documentation to substantiate the certification of eligibility, certifying physicians who show patterns of non-compliance with providing sufficient documentation, including those physicians whose records are inadequate or incomplete for this purpose, may be subject to increased reviews, such as through provider-specific probe reviews. Claims subject to increased review may include services unrelated to the home health claim being reviewed or the beneficiary who was referred for home health services.

Final Decision: We are finalizing this proposal as proposed. Physician claims for certification/recertification of eligibility for home health services (G0180 and G0179, respectively) will not be covered if the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit. This proposal will be implemented through future sub-regulatory guidance.

3. Proposed Clarification on When Documentation of a Face-to-Face Encounter Is Required

In the CY 2011 HH PPS final rule (75 FR 70372), in response to a commenter who asked whether the face-to-face encounter is required only for the first episode, we stated that the Congress enacted the face-to-face encounter requirement to apply to the physician's certification, not recertifications. In sub-regulatory guidance (face-to-face encounter Q&As on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Home-Health-Questions-Answers.pdf*), response to Q&A #11 states that the face-to-face encounter requirement applies to ''initial episodes'' (the first in a series of episodes separated by no more than a 60-day gap). The distinction between what is considered a certification (versus a recertification) and what is considered an initial episode is important in determining whether the face-to-face encounter requirement is applicable.

Recent inquiries question whether the face-to-face encounter requirement applies to situations where the beneficiary was discharged from home health with goals met/no expectation of return to home health care and readmitted to home health less than 60 days later. In this situation, the second episode will be considered a certification, not a recertification, because the HHA will be required to complete a new Start of Care (SOC) OASIS to initiate care. However, for payment purposes, the second episode is considered a subsequent episode, because there was no gap of 60 days or more between the first and second episodes of care. Therefore, in order to determine when documentation of a patient's face-to-face encounter is required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, we proposed to clarify that the face-to-face encounter requirement is applicable for certifications (not recertifications), rather than initial episodes. A certification (versus recertification) is considered to be any time that a new SOC OASIS is completed to initiate care. Because we proposed to clarify that a certification is considered to be any time that a new SOC OASIS is completed to initiate care, we will also revise Q&A #11 on the CMS Web site (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Home-Health-Questions-Answers.pdf*) to reflect this proposed clarification. If a patient was transferred to the hospital and remained in the hospital after day 61 (or after the first day of the next certification period), once the patient returns home, a new SOC OASIS must be completed. Therefore, this new episode will not be considered continuous and a face-to-face encounter needs to be documented as part of the certification of patient eligibility.[14]

Comment: One commenter stated that they were confused by the proposal and were seeking clarification as to whether CMS was proposing to require documentation of a face-to-face encounter for all certification episodes, initial and re-certifications.

Response: We are not requiring documentation of a face-to-face encounter for all certification periods. Documentation of a face-to-face encounter is only required for certifications and not re-certifications. As previously noted, a certification (versus recertification) is considered to be any time that a new SOC OASIS is completed to initiate care. A recertification is any second or later episode of continuous home health care (where a recertification/follow-up OASIS is completed).[15]

Comment: A few commenters were supportive of the proposed clarification on when documentation of a face-to-face encounter is required. One commenter stated that their agency has been obtaining these since the inception of the face-to-face requirement and that the

[14] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/downloads/OASISConsiderationsforPPS.pdf*

[15] We note that for instances where the patient was hospitalized and then returns to home health during the last 5 days of an episode of care, the requirement to complete a resumption of care OASIS could overlap with the time period requiring completion of a recertification/follow-up OASIS. In these instances, only the resumption of care OASIS is necessary and the subsequent episode of care would still be considered ''continuous'' and thus require a re-certification of patient eligibility. If the patient receives a re-certification assessment during days 56–60, is hospitalized, and returns home *on* day 61 following, if the HHRG remains the same then the second episode of care would be considered continuous and thus be considered a re-certification. However, if the HHRG is different, this would result in a new Start of Care (SOC) OASIS and thus be considered a new certification.

proposed clarification would not present a change. The commenter goes on to state that the proposed clarification helps to ensure that the patient continues to have real oversight from the community physician that is overseeing the patient's care.

Response: We thank the commenters for their support of the proposed clarification. We have heard, anecdotally, from several HHAs that they are already in compliance with this proposed clarification and, as such, this clarification will pose no additional burden for those HHAs. We agree that equating a certification with any time a SOC OASIS is completed to initiate care will further encourage physician accountability in certifying a patient's eligibility for the Medicare home health benefit and in establishing and overseeing the patient's plan of care.

Comment: Several other commenters focused their comments solely on instances where a patient was discharged and then readmitted during the same 60-day episode of care. Commenters stated that CMS should not finalize its proposal as these episodes are currently subject to partial episode payment (PEP) adjustments and that the PEP adjustment is an appropriate safeguard to prevent inappropriate utilization. A few commenters asked CMS to clarify whether instances where the patient is returning to home health post-discharge with care initiated with a new SOC OASIS, but during (what would have been) the same 60-day episode of care, would require documentation of a new physician face-to-face encounter. A few commenters expressed concerns with the current PEP policy and stated that some HHAs are not discharging patients that have finished their course of treatment so that those episodes will not become PEPs if the patient is discharged and returns to home care within (what would have been) the 60-day episode of care.

Response: A Partial Episode Payment (PEP) is applied to home health episodes that either end in discharge and are then followed by readmission to the same home health agency (HHA) within (what would have been) the original 60-day episode, or result in a transfer to a HHA that is different than the HHA that provided the initial home health episode. The purpose of this clarification is to ensure that HHAs understand when they must document that a face-to-face encounter occurred. For instances where a patient was discharged and then readmitted during (what would have been) the same 60-day episode of care, the second episode would be considered a certification as it would be initiated with a SOC OASIS and would require documentation of a face-to-face encounter. Depending on when the face-to-face encounter occurred, the face-to-face encounter from the PEP episode could be used for the new certification as long as it was performed within the required timeframe and is still related to the primary reason the patient requires home health services. The average number of days between a PEP episode and a subsequent episode of care was 17.5 days, with the 25th percentile at 5 days and the 75th percentile at 24 days in CY 2012 and approximately 60 percent of the time there was a hospitalization between a PEP episode and the subsequent episode of care. For those instances where the patient was hospitalized between the PEP episode and the subsequent episode of care, the patient would have seen a physician, so documenting the face-to-face encounter as part of the certification of eligibility for the subsequent episode of care should be easily accomplished.

PEP episodes are paid a rate which is proportional to the days of service provided during the episode. In CY 2012 only 2.2 percent of episodes were PEP episodes. Table 9 below compares the number of days in between the last visit and the ''through'' date on the claim for PEPs and Non-PEP episodes. The distribution below for non-PEP episodes does not indicate that there is a wide-spread issue with HHAs refusing to discharge patients that have otherwise met all goals long before the end of the 60-day episode in hopes of avoiding PEPs. However, we will continue to monitor PEP episodes and will consider whether a refinement to the PEP policy is necessary in the future.

TABLE 9—DISTRIBUTION OF DAYS BETWEEN THE LAST EPISODE VISIT AND EPISODE THROUGH DATE FOR NON-PEP EPISODES (N = 3,796,143) AND PEP EPISODES (8,105) AT LEAST 55 DAYS IN LENGTH, CY 2012

Distribution point	*Non-PEP episodes*	*PEP Episodes*
10th Percentile ..	1.0	1.0
25th Percentile ..	1.0	1.0
50th Percentile (Median)	2.0	1.0
Mean Average ..	4.7	6.9
75th Percentile ..	4.0	7.0
90th Percentile ..	7.0	24.0
99th Percentile ..	52.0	51.0

Source: Abt Associates analysis of 100% CY 2012 Medicare Home Health claims data.

Comment: One commenter asked that CMS confirm that over 800,000 episodes fit into a category of admissions shortly following discharges with goals met because that number seemed high.

Response: In the CY 2015 HH PPS proposed rule we noted, in the Collection of Information section, that: ''we estimate that of the 6,562,856 episodes in the CY 2012 home health Datalink file, 3,096,680 SOC assessments were performed on initial home health episodes. If this proposal is implemented, an additional 830,287 episodes would require documentation of a face-to-face encounter for subsequent episodes that were initiated with a new SOC OASIS assessment'' (79 FR 38412). This includes instances where patients finished a 60-day episode of care, were discharged, and then were re-admitted before 60 days lapsed without having home health care. In addition, this estimate represents a ''worst-case'' scenario as it does not account for instances where HHAs already consider anytime a new SOC OASIS is completed as a certification and are thus already in compliance. Home Health Compare, via Medicare.gov, reports national and state-level data on how often home health patients had to be admitted to the hospital and how often patients receiving home health care needed urgent, unplanned care in the ER without being admitted. Nationally, for CY 2013, 12 percent of home health patients receiving home health care needed urgent, unplanned care in the emergency room and 16 percent of home health patients had to be admitted to the hospital. Subsequent episodes initiated with a SOC OASIS represent 12.7 percent of all home health episodes in the CY 2012 Datalink file. Most commenters focused on instances where the initial episode of care was a PEP (that is, the patient transferred to another HHA or was discharged before the end of a 60-day episode and then re-admitted during what would have been the same 60-day episode of care), which were only 2.2 percent of episodes in CY 2012.

This clarification was intended to mostly respond to instances of patients being discharged after the end of a 60-day episode of care and then re-admitted without a 60-day gap in care before the start of the next episode. For claims processing purposes (to categorize episodes into ''early'' versus ''late'' for case-mix adjustment), these episodes are considered subsequent episodes rather than initial episodes of care. Sub-regulatory guidance (face-to-face encounter Q&As on the CMS Web site at: *http://www.cms.gov/Medicare/*

Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Home-Health-Questions-Answers.pdf) stated that face-to-face encounter requirement applies to ''initial episodes''. We received several questions from the MACs and providers asking whether the face-to-face encounter was required for instances where the patient was discharged at the end of a 60-day episode of care and then re-admitted, sometimes up to 50 days later and for reasons completely unrelated to the previous episode of care. This prompted us to propose a clarification in the CY 2015 HH PPS proposed rule that would make it clear that documentation of a face-to-face encounter is required for each certification and a certification is any time a SOC OASIS is completed to initiate care.

Comment: One commenter stated that while it is understandable to categorize the completion of a SOC OASIS as a certification, thus requiring documentation of a face-to-face encounter, concerns exist that this will increase burden without any direct benefit. Several commenters stated that for subsequent episodes initiated with a SOC OASIS, a certification (which requires documentation of a face-to-face encounter) versus a recertification should be differentiated based on whether the reason for home care changed. Several commenters stated that a new face-to-face encounter should only be required when the second admission to home health services is for a wholly different reason than presented in the original admission. One commenter stated that a subsequent episode should only be considered a certification (which requires documentation of a face-to-face encounter) when a new physician is the certifying physician or if a new home health agency is providing the care.

Response: If the patient is hospitalized during a 60-day episode of care and is expected to return to home health during the same 60-day episode of care, the HHA has the option to complete a transfer OASIS without discharging the patient. If the patient returns to home heath during that same 60-day home health episode, a resumption of care OASIS would be completed upon return, and depending on when the patient returned to home health, a re-certification/follow-up OASIS would be completed during the last 5 days of the episode. The subsequent episode would be considered continuous for re-certification purposes and documentation of a face-to-face encounter would not be required. More often than not, the primary reason for home care is changing between episodes of care when the subsequent episode of care is initiated with a SOC OASIS, regardless of whether the patient remains with the same HHA or is receiving care from another HHA. As such, we are clarifying that documentation that face-to-face encounter occurred is required for every certification and that a certification (versus recertification) is considered to be any time that a new SOC OASIS is completed to initiate care.

When comparing the primary reason for home health care (the primary diagnosis (item M1020) on the OASIS) at the ICD–9–CM three-digit category level, subsequent episodes initiated with a SOC OASIS had a different primary diagnosis (primary reason for home care) than the previous episode of care approximately 73 percent of the time. The subsequent episode's primary diagnosis was different from the previous episodes' primary diagnosis approximately 70 percent of the time when the subsequent episode of care was with the same HHA, and 80 percent of the time when the subsequent episode of care with a different HHA. Just examining the subsequent episodes of care that follow a PEP, we found that subsequent episodes of care initiated with a SOC OASIS had a different primary diagnosis than the previous episode of care approximately 72 percent of the time. The subsequent episode's primary diagnosis was different from the previous PEP episodes' primary diagnosis approximately 66 percent of the time when the subsequent episode of care was with the same HHA, and 76 percent of the time when the subsequent episode of care with a different HHA.

As we noted above, for CY 2012, approximately 60 percent of the time there was a hospitalization between a PEP episode and the subsequent episode of care. Therefore, we determined whether there was an intervening hospitalization between the PEP episode and the episode that follows (observed in the 60 days prior to the subsequent episode's start) and if so, whether there were differences in the clinical and functional levels between the PEP episode and the subsequent episode of care (Table 10 and Table 11 below). Overall, clinical levels only matched in 53 percent of instances. Functional levels matched in 63 percent of instances. Clinical levels are higher in 24 percent of the episodes that follow PEP episodes and lower in 22 percent of episodes. Functional levels are higher in approximately 20 percent of episodes that follow PEP episodes and lower in 17 percent of episodes.

TABLE 10—CROSS-TABULATION OF CLINICAL LEVEL BETWEEN A PARTIAL EPISODE PAYMENT (PEP) EPISODE AND EPISODES THAT FOLLOW BY INTERVENING HOSPITALIZATION PRESENCE, CY 2012

	No intervening hospitalization [Total episodes = 81,719]			Intervening hospitalization [Total episodes = 30,416]		
	Low	Medium	High	Low	Medium	High
Low	12.3%	7.1%	5.4%	9.2%	6.9%	5.1%
Medium	7.8%	12.2%	11.4%	6.7%	12.8%	12.7%
High	4.8%	9.8%	29.1%	4.1%	10.8%	31.7%

Source: Abt Associates analysis of 100% Medicare Home Health claims, CY 2012.
Note(s): Low = Clinical level 1; Medium = Clinical level 2; High = Clinical level 3 as described in section III.C of this rule.

TABLE 11—CROSS-TABULATION OF FUNCTIONAL LEVEL BETWEEN A PARTIAL EPISODE PAYMENT (PEP) EPISODE AND EPISODES THAT FOLLOW BY INTERVENING HOSPITALIZATION PRESENCE, CY 2012

	No intervening hospitalization [Total episodes = 81,719]			Intervening hospitalization [Total episodes = 30,416]		
	Low	Medium	High	Low	Medium	High
Low	6.6%	7.8%	1.4%	6.4%	8.4%	1.4%

TABLE 11—CROSS-TABULATION OF FUNCTIONAL LEVEL BETWEEN A PARTIAL EPISODE PAYMENT (PEP) EPISODE AND EPISODES THAT FOLLOW BY INTERVENING HOSPITALIZATION PRESENCE, CY 2012—Continued

	No intervening hospitalization [Total episodes = 81,719]			Intervening hospitalization [Total episodes = 30,416]		
	Low	Medium	High	Low	Medium	High
Medium	6.9%	38.6%	10.3%	8.3%	40.6%	10.4%
High	1.1%	8.5%	18.8%	1.0%	8.1%	15.3%

Source: Abt Associates analysis of 100% Medicare Home Health claims, CY 2012.
Note(s): Low = Functional level 1; Medium = Functional level 2; High = Functional level 3 as described in section III.C of this rule.

Final Decision: In order to determine when documentation of a patient's face-to-face encounter is required under sections 1814(a)(2)(C) and 1835 (a)(2)(A) of the Act, we are clarifying that the face-to-face encounter requirement is applicable for certifications (not re-certifications), rather than initial episodes. A certification (versus recertification) is considered to be any time that a new Start of Care OASIS is completed to initiate care.

C. Recalibration of the HH PPS Case-Mix Weights

As stated in the CY 2015 proposed rule, for CY 2012, we removed two hypertension codes from our case-mix system and recalibrated the case-mix weights in a budget neutral manner. When recalibrating the case-mix weights for the CY 2012 HH PPS final rule, we used CY 2005 data in the four-equation model used to determine the clinical and functional points for a home health episode and CY 2007 data in the payment regression model used to determine the case-mix weights. We estimated the coefficients for the variables in the four-equation model using CY 2005 data to maintain the same variables we used for CY 2008 when we implemented the four-equation model, thus minimizing substantial changes. Due to a noticeable shift in the number of therapy visits provided as a result of the 2008 refinements, at the time, we decided to use CY 2007 data in the payment regression. As part of the CY 2012 recalibration, we lowered the high therapy weights and raised the low or no therapy weights to address MedPAC's concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes (March 2011 MedPAC Report to the Congress: Medicare Payment Policy, p. 176). These adjustments better aligned the case-mix weights with episode costs estimated from cost report data. The CY 2012 recalibration, itself, was implemented in a budget neutral manner. However, we noted that in the CY 2012 HH PPS final rule, we also finalized a 3.79 percent reduction to payments in CY 2012 and a 1.32 percent reduction for CY 2013 to account for the nominal case-mix growth identified through CY 2009.

For CY 2014, as part of the rebasing effort mandated by the Affordable Care Act, we reset the case-mix weights, lowering the average case-mix weight to 1.0000. To lower the case-mix weights to 1.0000, each case-mix weight was decreased by the same factor (1.3464), thereby maintaining the same relative values between the weights. This ''resetting'' of the case-mix weights was done in a budget neutral manner, inflating the national, standardized 60-day episode rate as the starting point for rebasing by the same factor (1.3464) that was used to decrease the weights. In the CY 2014 HH PPS final rule, we also finalized reductions ($80.95) to the national, standardized 60-day episode payment amount each year from CY 2014 through CY 2017 to better align payments with costs (78 FR 72293), as required by the Affordable Care Act.

For CY 2015, we proposed to recalibrate the case-mix weights, adjusting the weights relative to one another, using more current data and aligning payments with current utilization data in a budget neutral manner. We also proposed to recalibrate the case-mix weights annually in subsequent payment updates based on the methodology finalized in the 2008 refinements (72 FR 25359–25392) and the CY 2012 HH PPS final rule (76 FR 68526), with minor changes as described below. To generate the CY 2015 case-mix weights, we used CY 2013 home health claims data (as of June 30, 2014) and used the same methodology finalized in the CY 2012 HH PPS final rule, except where noted below. Similar to the CY 2012 recalibration, some exclusion criteria were applied to the CY 2013 home health claims data used to generate the CY 2015 case-mix weights. Specifically, we excluded Request for Anticipated Payment (RAP) claims, claims without a matched OASIS, claims where total minutes equal 0, claims where the payment amount equals 0, claims where paid days equal 0, claims where covered visits equal 0, and claims without a HIPPS code. In addition, the episodes used in the recalibration were normal episodes. PEP, LUPA, outlier, and capped outlier (that is, episodes that are paid as normal episodes, but would have been outliers had the HHA not reached the outlier cap) episodes were dropped from the data file.[16] We note that for the CY 2015 recalibration, a 100 percent sample of CY 2013 claims data as of June 30, 2014 with linked OASIS data was used.[17]

Similar to the CY 2012 recalibration, the first step in the CY 2015 recalibration was to re-estimate the four-equation model used to determine the clinical and functional points for an episode. The dependent variable for the CY 2015 recalibration is the same as the CY 2012 recalibration, wage-weighted minutes of care. The wage-weighted minutes of care are determined using the CY 2012 Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the minutes per visit from the claim.[18]

The CY 2012 four-equation model contained the same variables and restrictions as the four-equation model used in the CY 2008 refinements (*http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/Coleman_Final_April_2008.pdf*). The CY 2012 model was estimated using CY 2005 data, same data used in the CY 2008 refinements, thereby minimizing changes in the points for the CY 2012 four-equation model. For the CY 2015 four-equation model, we re-examined all of the four-equation or ''leg'' variables for each of the 51 grouper variables in the CY 2008 model. Therefore, a grouper variable that may have dropped out of the model

[16] At a later point, when normalizing the weights, PEP episodes are included in the analysis.

[17] Note, for the last recalibration (CY 2012 recalibration), only a 20 percent sample of data was used.

[18] Note, wage information for sub-disciplines is also used (e.g., RNs versus RNs and LPNs combined).

in one of the four equations in CY 2008 may be in the CY 2015 four-equation model and vice versa. Furthermore, the specific therapy indicator variables that were in the CY 2012 four-equation model were dropped in the CY 2015 four-equation model so that the number of therapy visits provided had less of an impact on the process used to create the case-mix weights.

The steps used to estimate the four-equation model are similar to the steps used in the CY 2008 refinements. They are as follows: [19]

(1) We estimated a regression model where the dependent variable is wage-weighted minutes of care. Independent variables were indicators for which equation or ''leg'' the episode is in. The four legs of the model are leg 1: early episodes 0–13 therapy visits, leg 2: early episodes 14+ therapy visits, leg 3: Later episodes 0–13 therapy visits, and leg 4: later episodes 14+ therapy visits.[20] Also, independent variables for each of the 51 grouper variables for each leg of the model are included.

(2) Once the four-equation model is estimated, we drop all grouper variables with a coefficient less than 5. We re-estimate the model and continue to drop variables and re-estimate until there are no grouper variables with a coefficient of 5 or less.

(3) Taking the final iteration of the model in the previous step, we drop all grouper variables with a p-value greater than 0.10. We then re-estimate the model.

(4) Taking the model in the previous step, we begin to apply restrictions to certain coefficients. Within a grouper variable we first look across the coefficients for leg1 and leg3. We performed an equality test on those coefficients. If the coefficients are not significantly different from one another (using a p-value of 0.05), we set a restriction for that grouper variable such that the coefficients are equal across leg1 and leg3. We run these tests for all grouper variables for leg1 and leg3. We also run these tests for all grouper variables for leg2 and leg4.[21] After all restrictions are set, we re-run the regression again taking those restrictions into account.

(5) Taking the model from step 4, we drop variables that have a coefficient less than 5 and re-estimate the model a final time. Using complete 2013 claims data as of June 30, 2014, there were no grouper variables with a negative coefficient at this step.

The results from the final four-equation model are used to determine the clinical and functional points for an episode and place episodes in the different clinical and functional levels. We take the coefficients from the four equation model, divide them by 10, and round to the nearest integer to determine the points associated with each variable. The points for each of the grouper variables for each leg of the model, updated with complete CY 2013 data as of June 30, 2014, are shown in Table 12. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

[19] All the regressions mentioned in steps 1–4 are estimated with robust standard errors clustered at the beneficiary ID level. This is to account for beneficiaries appearing in the data multiple times. When that occurs, the standard errors can be correlated causing the p-value to be biased downward. Clustered standard errors account for that bias.

[20] Early episodes are defined as the 1st or 2nd episode in a sequence of adjacent covered episodes. Later episodes are defined as the 3rd episode and beyond in a sequence of adjacent covered episodes. Episodes are considered to be adjacent if they are separated by no more than a 60-day period between claims.

[21] In the CY 2008 rule, there was a further step taken to determine if the coefficients of a grouper variable are equal across all 4 legs. This step was not taken at this time.

TABLE 12: Case-Mix Adjustment Variables and Scores

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
CLINICAL DIMENSION					
1	Primary or Other Diagnosis = Blindness/Low Vision				
2	Primary or Other Diagnosis = Blood disorders		6		3
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms		8		8
4	Primary Diagnosis = Diabetes		8		7
5	Other Diagnosis = Diabetes	1			
6	Primary or Other Diagnosis = Dysphagia ***AND*** Primary or Other Diagnosis = Neuro 3 – Stroke	2	16	1	9
7	Primary or Other Diagnosis = Dysphagia ***AND*** M1030 (Therapy at home) = 3 (Enteral)	2	7		7
8	Primary or Other Diagnosis = Gastrointestinal disorders				
9	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** M1630 (ostomy)= 1 or 2		6		
10	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis, ***OR*** Neuro 2 - Peripheral neurological disorders, ***OR*** Neuro 3 - Stroke, ***OR*** Neuro 4 - Multiple Sclerosis				
11	Primary or Other Diagnosis = Heart Disease OR Hypertension	1			
12	Primary Diagnosis = Neuro 1 - Brain disorders and paralysis	3	11	6	11
13	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis ***AND*** M1840 (Toilet transfer) = 2 or more				

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
14	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis ***OR*** Neuro 2 - Peripheral neurological disorders ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	2	7	1	7
15	Primary or Other Diagnosis = Neuro 3 – Stroke	3	10	2	
16	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3		4		8
17	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1860 (Ambulation) = 4 or more				
18	Primary or Other Diagnosis = Neuro 4 - Multiple Sclerosis ***AND AT LEAST ONE OF THE FOLLOWING:*** M1830 (Bathing) = 2 or more ***OR*** M1840 (Toilet transfer) = 2 or more ***OR*** M1850 (Transferring) = 2 or more ***OR*** M1860 (Ambulation) = 4 or more	3	8	7	13
19	Primary or Other Diagnosis = Ortho 1 - Leg Disorders or Gait Disorders ***AND*** M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4	8	1	8	4
20	Primary or Other Diagnosis = Ortho 1 - Leg OR Ortho 2 - Other orthopedic disorders ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	4	3	2	
21	Primary or Other Diagnosis = Psych 1 – Affective and other psychoses, depression				
22	Primary or Other Diagnosis = Psych 2 - Degenerative and other organic psychiatric disorders				
23	Primary or Other Diagnosis = Pulmonary disorders				

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
24	Primary or Other Diagnosis = Pulmonary disorders ***AND*** M1860 (Ambulation) = 1 or more				
25	Primary Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications	4	21	8	19
26	Other Diagnosis = Skin 1 - Traumatic wounds, burns, post-operative complications	6	15	7	15
27	Primary or Other Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications ***OR*** Skin 2 – Ulcers and other skin conditions ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	4		1	
28	Primary or Other Diagnosis = Skin 2 - Ulcers and other skin conditions	2	17	8	17
29	Primary or Other Diagnosis = Tracheostomy	4	19	4	11
30	Primary or Other Diagnosis = Urostomy/Cystostomy		19		14
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)		18	6	18
32	M1030 (Therapy at home) = 3 (Enteral)		15		7
33	M1200 (Vision) = 1 or more				
34	M1242 (Pain)= 3 or 4	2		1	
35	M1308 = Two or more pressure ulcers at stage 3 or 4	4	5	4	13
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	3	19	7	16
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	8	33	12	26
38	M1334 (Stasis ulcer status)= 2	4	13	8	22
39	M1334 (Stasis ulcer status)= 3	7	18	10	18
40	M1342 (Surgical wound status)= 2	1	7	6	14
41	M1342 (Surgical wound status)= 3		6	5	11
42	M1400 (Dyspnea) = 2, 3, or 4		2		3
43	M1620 (Bowel Incontinence) = 2 to 5		4		3
44	M1630 (Ostomy)= 1 or 2	4	11	3	11
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3				
FUNCTIONAL DIMENSION					
46	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	2		2	
47	M1830 (Bathing) = 2 or more	6	3	5	

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
48	M1840 (Toilet transferring) = 2 or more	1	3		3
49	M1850 (Transferring) = 2 or more	3	4	2	1
50	M1860 (Ambulation) = 1, 2 or 3	7		3	
51	M1860 (Ambulation) = 4 or more	7	8	6	8

Source: CY 2013 Medicare claims data for episodes ending on or before December 31, 2013 (as of June 30, 2014) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with SCIC or PEP adjustments were excluded.

Note(s): Points are additive; however, points may not be given for the same line item in the table more than once.

Please see Medicare Home Health Diagnosis Coding guidance at http://www.cms.hhs.gov/HomeHealthPPS/03_coding&billing.asp for definitions of primary and secondary diagnoses.

In updating the four-equation model with 2013 data (the last update to the four-equation model used 2005 data), there were a number of changes to the point values for the variables in the four-equation model. These changes reflect the change in the relationship between the grouper variables and resource use since 2005. The CY 2015 four-equation model resulted in 124 point-giving variables being used in the model (as compared to the 164 variables for the 2012 recalibration). There were 21 variables that were added to the model and 63 variables that were dropped from the model due to the absence of additional resources associated with the variable. The points for 57 variables increased in the CY 2015 four-equation model and the points for 25 variables in decreased in the CY 2015 four-equation model. There were 17 variables with the same point values.

Since there were a number of changes to the point values associated with the four-equation model, we are redefining the clinical and functional thresholds so that they would be reflective of the new points associated with the CY 2015 four-equation model. Specifically, after estimating the points for each of the variables and summing the clinical and functional points for each episode, we looked at the distribution of the clinical score and functional score, breaking the episodes into different steps. The categorizations for the steps are as follows:

- Step 1: First and second episodes, 0–13 therapy visits.
- Step 2.1: First and second episodes, 14–19 therapy visits.
- Step 2.2: Third episodes and beyond, 14–19 therapy visits.
- Step 3: Third episodes and beyond, 0–13 therapy visits.
- Step 4: Episodes with 20+ therapy visits

Similar to the methodology used in the CY 2008 refinements, we then divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.[22] Also, we looked at the average resource use associated with each clinical and functional score and used that to guide where we placed our thresholds. We tried to group scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off of the CY 2015 four-equation model, points are shown in Table 13.

[22] For Step 1, 55% of episodes were in the medium functional level (All with score 15).

For Step 2.1, 60.7% of episodes were in the low functional level (Most with score 3, some with score 0).

For Step 2.2, 58.3% of episodes were in the low functional level (All with score 0).

For Step 3, 52.1% of episodes were in the medium functional level (all with score 10).

For Step 4, 41.7% of episodes were in the medium functional level (almost all with score 3).

TABLE 13: CY 2015 Clinical and Functional Thresholds

		1st and 2nd Episodes		3rd+ Episodes		All Episodes
		0 to 13 therapy visits	14 to 19 therapy visits	0 to 13 therapy visits	14 to 19 therapy visits	20+ therapy visits
Grouping Step:		1	2	3	4	5
Equation(s) used to calculate points: (see Table 12)		1	2	3	4	(2&4)
Dimension	Severity Level					
Clinical	C1	0 to 1	0 to 1	0	0 to 5	0 to 3
	C2	2 to 3	2 to 7	1	6 to 12	4 to 16
	C3	4+	8+	2+	13+	17+
Functional	F1	0 to 14	0 to 3	0 to 9	0	0 to 2
	F2	15	4 to 13	10	1 to 7	3 to 5
	F3	16+	14+	11+	8+	6+

Once the thresholds were determined and each episode was assigned a clinical and functional level, the payment regression was estimated with an episode's wage-weighted minutes of care as the dependent variable. Independent variables in the model were indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 14 shows the regression coefficients for the variables in the payment regression model updated with complete CY 2013 data. The R-squared value for the payment regression model is 0.4680 (an increase from 0.3769 for the CY 2012 recalibration).

TABLE 14—PAYMENT REGRESSION MODEL

Variable description	New payment regression coefficients
Step 1, Clinical Score Medium	$24.36
Step 1, Clinical Score High	61.06
Step 1, Functional Score Medium	81.65
Step 1, Functional Score High	121.95
Step 2.1, Clinical Score Medium	56.47
Step 2.1, Clinical Score High	177.00
Step 2.1, Functional Score Medium	26.09
Step 2.1, Functional Score High	91.13
Step 2.2, Clinical Score Medium	91.83
Step 2.2, Clinical Score High	206.75
Step 2.2, Functional Score Medium	6.22
Step 2.2, Functional Score High	88.98
Step 3, Clinical Score Medium	11.00
Step 3, Clinical Score High	89.06
Step 3, Functional Score Medium	50.88
Step 3, Functional Score High	86.69
Step 4, Clinical Score Medium	74.96
Step 4, Clinical Score High	241.95
Step 4, Functional Score Medium	35.12
Step 4, Functional Score High	91.41
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	447.08
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	456.36
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	−65.98
Step 4, All Episodes, 20+ Therapy Visits	872.95
Intercept	378.43

Source: CY 2013 Medicare claims data for episodes ending on or before December 31, 2013 (as of June 30, 2014) for which we had a linked OASIS assessment.

The method used to derive the CY 2015 case-mix weights from the payment regression model coefficients is the same as the method used to derive the CY 2012 case-mix weights. This method is described below.

(1) We used the coefficients from the payment regression model to predict each episode's wage-weighted minutes of care (resource use). We then divided these predicted values by the mean of the dependent variable (that is, the

average wage-weighted minutes of care across all episodes used in the payment regression). This division constructs the weight for each episode, which is simply the ratio of the episode's predicted wage-weighted minutes of care divided by the average wage-weighted minutes of care in the sample. Each episode was then aggregated into one of the 153 home health resource groups (HHRGs) and the ''raw'' weight for each HHRG was calculated as the average of the episode weights within the HHRG.

(2) The weights associated with 0 to 5 therapy visits were then increased by 3.75 percent, the weights associated with 14–15 therapy visits were decreased by 2.5 percent, and the weights associated with 20+ therapy visits were decreased by 5 percent. These adjustments to the case-mix weights are the same as the ones used in the CY 2012 recalibration (76 FR 68557) and were done to address MedPAC's concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes (March 2011 MedPAC Report to the Congress: Medicare Payment Policy, p. 176). These adjustments better aligned the case-mix weights with episode costs estimated from cost report data.

(3) After the adjustments in step (2) were applied to the raw weights, the weights were further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy thresholds. Weights with the same clinical severity level, functional severity level, and early/later episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds were gradually increased. We did this by interpolating between the main thresholds on the model (from 0–5 to 14–15 therapy visits, and from 14–15 to 20+ therapy visits). We used a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0–5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) was constant. This interpolation is the identical to the process finalized in the CY 2012 final rule (76 FR 68555).

(4) The interpolated weights were then adjusted so that the average case-mix for the weights was equal to 1.[23] This last step creates the final CY 2015 case-mix weights shown in Table 15.

[23] When computing the average, we compute a weighted average, assigning a value of one to each normal episode and a value equal to the episode length divided by 60 for PEPs.

TABLE 15: CY 2015 Case-Mix Payment Weights

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5985
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.7242
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8499
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9756
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.1013
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.7277
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.8353
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9429
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0505
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1581
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7914
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.9056
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	1.0198
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.1340
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2482
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.6370
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7718
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.9066
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0413
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1761
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.7662
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8829
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9996
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.1163
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.2330
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.8299
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.9532
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	1.0765
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1998
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.3230
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6951
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.8541
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	1.0131
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.1720
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3310
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.8242
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.9651

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.1061
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.2470
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3879
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.8880
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	1.0355
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1830
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.3305
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4780
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2270
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4220
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.6171
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2657
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4649
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6640
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3624
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5565
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.7506
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3109
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.5142
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.7175
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3497
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5570
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7643
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.4463
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.6486
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.8509
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4900
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.7142
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9384
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5288
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7570
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9853
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.6255
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8487
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0718
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2407
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4312
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.6217

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2500
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4544
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6587
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3730
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5635
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.7541
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3772
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.5584
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.7396
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3865
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5815
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7766
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.5095
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.6907
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.8720
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.5480
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.7529
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9578
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5573
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7760
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9948
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.6803
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8852
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0901
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4942
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6435
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7928
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9421
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0914
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5746
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.7097
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8448
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9798
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1149
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6313
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7796
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9280
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0763

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2246
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.5116
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6847
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8578
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	1.0310
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.2041
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5920
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7509
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9098
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0687
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.2276
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6487
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.8208
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9930
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.1652
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.3373
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6350
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.8176
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	1.0002
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1828
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3654
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7155
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8839
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0522
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.2206
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3889
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7721
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.9538
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1354
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.3170
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4987
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.8122
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.8631
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.9446
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.9208
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.9717
40231	All Episodes, 20+ Therapy Visits	C2F3S1	2.0532
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.1626

Payment Group	Step (Episode and/or Therapy Visit Ranges)	Clinical and Functional Levels (1 = Low; 2 = Medium; 3= High)	CY 2015 Final Case-mix Weights
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.2135
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.2950

To ensure the changes to the case-mix weights are implemented in a budget neutral manner, we proposed to apply a case-mix budget neutrality factor to the CY 2015 national, standardized 60-day episode payment rate (see section III.D.4. of this final rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when CY 2015 case-mix weights are applied to CY 2013 utilization (claims) data to total payments when CY 2014 case-mix weights are applied to CY 2013 utilization data. This produces a final case-mix budget neutrality factor for CY 2015 of 1.0366, based on CY 2013 claims data as of June 30, 2014. The case-mix budget neutrality factor (1.0366) also takes into account the re-grouping of episodes according to the point values from the four-equation model and new clinical and functional thresholds described in section III.C, which contributes 0.0090 to the case-mix budget neutrality factor.

Section 1895(b)(3)(B)(iv) of the Act gives us the authority to implement payment reductions for nominal case-mix growth (that is, changes in case-mix that are not related to actual changes in patient characteristics over time). Previously, we accounted for nominal case-mix growth from 2000 to 2009 through case-mix reductions implemented from 2008 through 2013 (76 FR 68528–68543). In the CY 2013 HH PPS proposed rule, we stated that we found that 15.97 percent of the total case-mix change was real from 2000 to 2010 (77 FR 41553). In the CY 2014 HH PPS final rule, we used 2012 claims data to rebase payments (78 FR 72277). Since we were resetting the payment amounts with 2012 data, we did not take into account any additional nominal case-mix growth. For the proposed rule, we examined case-mix growth from CY 2012 to CY 2013 using CY 2012 and preliminary CY 2013 claims data. For this final rule, in updating our analysis with CY 2013 claims data as of June 30, 2014, we estimate that case-mix increased by 2.76 percent between CY 2012 and CY 2013. In applying the 15.97 percent estimate of real case-mix growth to the total estimated case-mix growth from CY 2012 to CY 2013 (2.76 percent), we estimate that 2.32 percent (2.76–(2.76 * 0.1597)) of the case-mix growth is nominal (that is, case-mix growth that is unrelated to changes in patient acuity).

We estimate that the case-mix budget neutrality factor of 1.0366 would have to be reduced to 1.0134 to account for nominal case-mix growth ((1.0366 − 0.0276) + (0.0276*0.1597) = 1.0134). While we considered adjusting the case-mix budget neutrality factor to take into account the growth in nominal case-mix (2.32 percent), which would result in a case-mix budget neutrality adjustment of 1.0134 rather than 1.0366, we will apply the full 1.0366 case-mix budget neutrality factor to the national, standardized 60-day episode payment rate. We will continue to monitor case-mix growth and may consider whether to propose nominal case-mix reductions in future rulemaking.

The following is a summary of the comments and our responses to comments on the CY 2015 proposed case-mix weights and methodology:

Comment: Commenters stated that CMS has not provided complete technical information on the nature and basis for the revisions to the case-mix weights and variables in the model and therefore, the recalibration of the weights cannot be sufficiently evaluated. Commenters stated that unlike previous recalibrations, CMS has not provided the technical report on the proposed recalibration of the weights and that CMS did not publish the data or the analysis used to support its conclusions. Commenters stated that a full technical report on the methodology and regression analysis would be valuable in understanding the reliability and validity of the recalibration and would allow stakeholders to conduct their own evaluations as well. A commenter recommended that CMS make all technical reports and analyses regarding the recalibration of the case-mix weights publicly available immediately in order to permit stakeholders to review the significant changes described in the proposed rule.

Response: As stated in the CY 2015 proposed rule, the methodology used to recalibrate the weights is identical to the methodology used in the CY 2012 recalibration except for the minor exceptions noted in the proposed rule. We encourage commenters to refer to the CY 2012 proposed and final rule and the CY 2012 technical report on our home page at *http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html* for additional information about the recalibration methodology.

Comment: Commenters stated that the recalibration of the high volume therapy episodes will lead to financial incentives to increase therapy visits even though CMS has indicated that therapy visit volume should have less impact on the weights. They stated that the changes to the proposed case-mix weights contradict what was said previously regarding undervalue of clinical elements and over-value of the therapy component. Commenters presented their analyses comparing the CY 2014 weights to the CY 2015 weights and payments associated with each of the HHRGs. Commenters stated that under the CY 2015 proposed case-mix weights, a majority of the HHRGs with low therapy visits will have losses and a large number of the high therapy groups and all of the 20+ therapy episodes will receive substantial increases to their weights. Commenters stated that these results seem to contradict the adjustment discussion in the CY 2015 proposed rule.

Response: We note that the CY 2015 recalibration is based on 2013 claims data, which is six to eight years more current than the claims data used in the CY 2012 recalibration. The 2013 data also reflects the 2008 refinements to the HH PPS, which included the change from one therapy threshold to multiple therapy thresholds and the change from 80 HHRGs to 153 HHRGs. Given the time difference in the data used for the

two recalibrations, one would expect differences in the resulting case-mix weights. However, comparing the CY 2015 proposed case-mix weights to the CY 2014 final weights; we observed that over 60% of normal episodes would have a case-mix weight change of 5 percent or less. Furthermore, few episodes have an increase in their case-mix weight that exceeds 5 percent (14.2 percent) and very few episodes have an increase in their case-mix weight that exceeds 10 percent (0.4 percent).

The changes in case-mix weights can be mostly attributed to shifts in utilization patterns between 2005/2007 and 2013. Over that six to eight year time period, we find a notable shift across all therapy groups away from the use of home health aides and a shift to either more nursing or more therapy care (see Tables 16 and 17 below). While some of the low therapy groups did add more skilled nursing visits, most of the therapy groups added more occupational therapy (OT) and speech-language pathology (SLP), which have substantially higher Bureau of Labor Statistics (BLS) average hourly wage values compared to skilled nursing ($39/hr for skilled nursing versus $55 for OT and $60 for SLP).

TABLE 16—SUMMARY STATISTICS—EPISODES FROM 2013

[Only normal episodes]

Therapy group	Number of episodes	Nursing	Aides	PT	OT	SLP	MSS	All therapy	All visits
0–5	2,951,379	8.9	2.1	0.6	0.1	0.0	0.1	0.7	11.8
6	224,325	6.0	1.3	5.2	0.6	0.1	0.1	6.0	13.3
7–9	664,911	6.5	1.5	6.9	0.9	0.2	0.2	7.9	16.0
10	184,871	6.8	1.7	8.5	1.3	0.2	0.2	10.0	18.6
11–13	532,875	7.1	2.0	10.0	1.7	0.3	0.2	12.0	21.2
14–15	249,627	7.3	2.4	11.6	2.4	0.4	0.2	14.5	24.3
16–17	267,500	6.5	2.5	13.5	2.5	0.4	0.2	16.4	25.6
18–19	173,769	7.0	2.6	13.8	4.0	0.6	0.2	18.4	28.2
20+	328,295	8.1	3.5	14.9	7.9	1.9	0.3	24.8	36.6
Total	5,577,552	7.9	2.1	5.1	1.2	0.2	0.1	6.5	16.7

Source: Data on episodes with a through date in 2013 using complete CY 2013 claims data as of June 30, 2014.

TABLE 17—SUMMARY STATISTICS—EPISODES FROM 2007 (FILE USED IN CY 2012 RECALIBRATION)

[Only normal episodes]

Therapy group	Number of episodes	Nursing	Aides	PT	OT	SLP	MSS	All therapy	All visits
Average number of visits for Normal episodes with a through date in 2007									
0–5	520,639	9.3	3.6	0.6	0.1	0.0	0.1	0.7	13.7
6	28,349	5.5	1.7	5.3	0.6	0.1	0.2	6.0	13.4
7–9	59,156	5.9	2.1	6.9	0.9	0.1	0.2	7.9	16.1
10	47,798	7.2	2.8	8.9	1.0	0.1	0.2	10.0	20.1
11–13	107,970	7.2	3.5	10.5	1.2	0.1	0.2	11.9	22.7
14–15	38,188	7.3	4.0	12.1	2.1	0.3	0.2	14.5	25.9
16–17	29,322	7.2	4.4	13.6	2.5	0.4	0.2	16.5	28.4
18–19	17,679	7.4	4.4	14.4	3.5	0.5	0.2	18.4	30.5
20+	39,395	7.4	5.2	16.3	7.1	1.5	0.3	24.9	37.9
Total	888,496	8.3	3.5	4.7	0.9	0.1	0.1	5.7	17.7

Source: Data on episodes ending in 2007 using a 20% sample of 2007 data from the home health Datalink file.

In addition, while the average number of total visits per episode has decreased overall, it decreased disproportionately more for the no/low therapy group (which constitute over 50 percent of all episodes) compared to the remaining groups (see Table 18 below). These utilization changes result in changes to the weights observed by the commenters, specifically, the decreases in the case-mix weights for the low or no therapy groups and increases in the case-mix weights for the high therapy groups.

TABLE 18—PERCENT CHANGE IN THE AVERAGE NUMBER OF VISITS BY THERAPY GROUP, 2007 AND 2013

Therapy group	Percent change in visits from 2007 to 2013
0–5	−13.92
6	0.18
7–9	0.32
10	−7.38
11–13	−6.63
14–15	−6.14
16–17	−9.89
18–19	−7.73
20+	−3.46

We would like to clarify that the adjustments applied to the case-mix weights are not in addition to the

adjustments applied in 2012, but rather are the same adjustments as the ones applied to the 2012 data. In other words, the 3.75 percent increases to the weights associated with 0 to 5 therapy visits, the 2.5 percent decreases to the weights associated with 14–19 therapy visits, and 5 percent decreases to the weights associated with 20+ therapy visits are applied to the raw weights resulting from 2013 claims data. We did not take the CY 2012 case-mix weights and further adjust them. Therefore, one should not expect to see higher weights for low or no therapy episodes and lower weights for high therapy episodes when comparing the CY 2015 proposed case-mix weights to the CY 2014 weights, which have the same relative values as the 2012 case-mix weights.

We note that by removing the therapy indicator variables from the four equation model and moving away from the use of therapy visits in the model that the case-mix weights for high therapy groups were lower than what they would have been if the therapy indicator variables were included in the model. We also note that the final case-mix weights for the highest therapy HHRGs (those groups of episodes with 20 or more therapy visits) slightly decreased when comparing the CY 2015 final case-mix weights, based on complete CY 2013 data as of June 30, 2014, to the CY 2015 proposed case-mix weights, based on preliminary CY 2013 data as of December 31, 2013.

Comment: One commenter was supportive of the recalibration proposal and agreed that the proposed recalibration strikes an appropriate balance between discouraging inappropriate use of therapy while addressing concerns that non-therapy services are undervalued.

Response: We thank the commenter for their support.

Comment: A commenter stated that the increase in therapy visits was due to therapists providing clinically necessary skilled care, not due to manipulating the therapy reimbursement process. Another commenter questioned whether CMS utilized multiple years of OASIS data to consider the change in functional status of those patients who receive low numbers of therapy visits versus those receiving 20 or more therapy visits and if the change noted at both ends of the spectrum of therapy utilization are appropriately reflected in the recalibration effort. Another commenter stated that CMS' proposed changes do not appear to be based on any reasoned consideration of why the visit time data is the way it is.

Response: The case-mix weights are driven by the 2013 claims data with the same adjustments finalized in CY 2012 to better align payment for high and no/low therapy episodes with cost. The proposed recalibration of the case-mix weights used the methodology proposed and finalized in CY 2012, with a few noted differences outlined above and in the CY 2015 HH PPS proposed rule. We did not set the weights based on what levels of services we thought were appropriate. Any changes in the case-mix weights for CY 2015 are driven by utilization patterns observed in CY 2013 claims data.

Comment: A commenter stated that the case-mix weights appear to decrease payments for third or later episodes of care. The commenter stated that many home health providers serve patients with multiple chronic conditions and that the patients often have significant medical issues. The commenter stated that reducing payments for such episodes of care will likely have an impact on how home health providers will treat patients with chronic conditions. The commenter asked for more clarifications regarding what practice or utilization changes we are trying to achieve and if we could explain if there are particular types of patients we believe should not be receiving third episodes of home health care and/or if there are certain patients who should receive a different approach to care that would be less costly than the care delivered at present.

Response: We reiterate that CY 2015 the case-mix weights are reflective of the utilization patterns observed in the CY 2013 claims data. We have not manipulated the case-mix weights to encourage certain patterns of care for the third or later episodes. The case-mix weights are driven by the mix of services provided, the costs of services provided as determined by the BLS hourly rates, the length of the visits, and the number of visits provided. Any decreases in the case-mix weights for third or later episodes of care reflect less average resources associated with those episodes using 2013 claims data than the average resources associated with third and later episodes using 2007 data, which was the data used in the 2012 recalibration.

We note that when comparing the visit distribution in 2013 versus 2007 for third and later episodes, we observe large decreases in the total visit count in 2013 versus 2007 for these episodes (see Table 19 and Table 20). As shown in Table 21, the number of total visits for the third and later episodes, on average, decreased significantly, ranging from −8.30 percent to −19.01 percent, for the various therapy groups. The decreases in the case-mix weights for third or later episode episodes for CY 2015 versus CY 2014 may be due to the decrease in total visits for these episodes between 2007 and 2013.

TABLE 19—AVERAGE NUMBER OF VISITS FOR THIRD AND LATER EPISODES OF CARE (NOT INCLUDING 20+ THERAPY VISIT EPISODES WHICH MAY BE EARLY OR LATE), CY 2013

Therapy group	Number of episodes	Nursing	Aides	PT	OT	SLP	MSS	All therapy	All visits
0–5	1,424,148	9.2	3.2	0.2	0.0	0.0	0.1	0.3	12.7
6	38,406	7.8	2.6	4.9	0.8	0.2	0.1	6.0	16.5
7–9	125,743	8.2	2.9	6.7	1.0	0.3	0.1	7.9	19.1
10	37,482	8.4	2.9	8.5	1.2	0.3	0.1	10.0	21.4
11–13	120,115	8.4	3.2	10.2	1.5	0.3	0.1	12.0	23.7
14–15	68,540	8.3	3.5	12.1	1.9	0.5	0.1	14.5	26.3
16–17	77,730	7.2	3.6	13.9	2.0	0.4	0.1	16.4	27.3
18–19	41,557	7.6	3.6	14.2	3.5	0.6	0.1	18.3	29.7
Total	1,933,721	8.9	3.2	2.8	0.5	0.1	0.1	3.3	15.5

Source: Data on normal episodes of care with a through date in 2013 using complete CY 2013 claims data as of June 30, 2014.

TABLE 20—AVERAGE NUMBER OF VISITS FOR THIRD AND LATER EPISODES OF CARE (NOT INCLUDING 20+ THERAPY VISIT EPISODES WHICH MAY BE EARLY OR LATE), CY 2007

Therapy group	Number of episodes	Nursing	Aides	PT	OT	SLP	MSS	All therapy	All visits
0–5	227,934	9.6	5.9	0.2	0.0	0.0	0.1	0.2	15.7
6	3,068	7.7	4.1	5.0	0.8	0.2	0.1	6.0	18.0
7–9	7,458	8.1	4.6	6.7	1.1	0.2	0.2	8.0	20.8
10	9,510	9.0	5.2	8.7	1.1	0.2	0.1	10.0	24.3
11–13	21,620	9.0	5.8	10.4	1.3	0.2	0.1	11.9	26.8
14–15	7,736	8.6	6.4	12.4	1.8	0.3	0.1	14.5	29.6
16–17	6,481	8.2	7.0	14.1	1.9	0.4	0.1	16.5	31.8
18–19	2,982	8.8	6.7	14.9	3.0	0.5	0.2	18.4	34.0
Total	292,873	9.4	5.9	2.6	0.4	0.1	0.1	3.1	18.4

Source: Data on normal episodes of care ending in 2007 using a 20% sample of 2007 data from the home health Datalink file.

TABLE 21—PERCENT CHANGE IN THE AVERAGE NUMBER OF VISITS BY THERAPY GROUP FOR THIRD AND LATER EPISODES OF CARE, 2007 AND 2013

Therapy group	Percent change in visits from 2007 to 2013
0–5	−19.01
6	−8.38
7–9	−8.30
10	−11.75
11–13	−11.44
14–15	−11.28
16–17	−14.18
18–19	−12.72

Comment: A commenter stated that the points for the case-mix variables seem to be decreasing for the low therapy episodes and increasing for the high therapy episodes, motivating agencies to provide more therapy visits to boost reimbursement. The commenter stated that the data used to determine the case-mix points was swayed by the payment system which rewards high therapy utilization. Other commenters stated that many diagnosis codes are losing case-mix points and that there doesn't seem to be a reason behind the loss of points. Another commenter implied that there doesn't seem to be a balance in the shift in points and was concerned with the impact of the scoring variables being eliminated and others decreasing or increasing points. Another commenter stated that there is not sufficient detail to explain the Agency's rationale for the large scale changes to the case-mix point values in the proposed rule and questioned what message CMS is sending to agencies based on the changes to the case-mix variable table. The commenter stated that there is no longer an emphasis on diabetes, heart failure, COPD, or depression, but that there seems to be an emphasis on orthopedic and neurological diagnoses, particularly when 14 or more therapy visits are ordered. A commenter stated that the change in the case-mix points sends a message that there is little or no benefit to home health agencies in caring for chronically ill patients with common medical diagnoses unless those patients are receiving 14 or more therapy visits and urged CMS to reconsider adoption and implementation of the proposed case-mix point tables and new thresholds until CMS has sought more input from clinicians and agencies and has re-evaluated the messages the new case-mix table will send to the home health community.

Response: We reiterate that the points for the case-mix variables are driven by the utilization patterns observed in the CY 2013 claims data. The changes to the weights are not surprising given the different data used for the CY 2012 recalibration versus the data used for the CY 2015 recalibration. We used 2005 data to estimate the four equation model for the CY 2012 recalibration and we used 2013 data to estimate the four equation model for the CY 2015 recalibration. (The 2012 payment regression was based on a 2007 sample that was assigned to severity levels based on the point values from a 4-equation model using 2005 data that eliminated certain hypertension codes). The different point estimates across the two models indicate that the case-mix variables have a different relationship to resource use in 2013 compared to 2005. A decrease in the number of points (for 2013 compared to 2005) for a variable means that the variable is associated with less resource use on average in 2013 compared to 2005. An increase in the number of points for a variable means that the variable is associated with more resource use on average in 2013 compared to 2005. Certain variables did drop out of the 4-equation model in in the CY 2015 recalibration versus the CY 2012 recalibration. For many of those variables, the CY 2012 recalibration estimated only a small number of points associated with the variables and therefore those variables were already on the verge of being dropped from the model in CY 2012. While some variables did drop out of the model, the potential change in points associated with those variables was not very large, so that individually those variables had minimal impact on episodes' resource use. Some of the variables that dropped out of the model experienced increases in the number of episodes with the variable reported on OASIS between 2005 and 2013. The increase in episodes reporting a particular variable may have decreased the difference in resources for episodes that coded the variable versus those that did not and, therefore, may have caused the variable to become insignificant or to have minimal impact on resource costs, leading to its elimination from the model.

When evaluating the points associated with each leg of the model, it is important to examine the thresholds for each leg. For example, the clinical thresholds described in the proposed rule have fewer points associated with them for the 0 to 13 therapy visit episodes. Therefore, while there may be fewer points associated with some of the variables within the 0 to 13 therapy visit legs, there is also a lower threshold for the clinical levels. In order to determine the thresholds, we put episodes into five groups (early episodes, 0 to 13 therapy visits, early episodes, 14–19 therapy visits, late episodes, 0 to 13 therapy visits, late episodes, 14–19 therapy visits, and 20+ therapy visit episodes) for both the clinical and the functional dimensions. We then attempt to divide the episodes within each group into thirds in order to set the thresholds. Therefore, regardless of the points, on average, the most resource-intensive episodes will be placed in the highest clinical or functional level. It is also

worth noting that, with the CY 2015 recalibration, additional variables received points in the estimation of the 4-equation model that did not receive points in the CY 2012 recalibration. Again, the outcomes of the models are guided by the data and reflect recent (2013) utilization patterns. This approach increases payments for the HHRGs where resources are being provided where they were not previously and decreases payment for the HHRGs where resources are not being provided where they were previously. The intent is to create payments that more accurately reflect the costs that agencies incur.

Comment: A commenter also stated that this is the third year in a row that the HH PPS has had different case-mix weights and that this may be an indicator of uncertainty by CMS. Another commenter stated that the recalibration of the weights is being recommended after having just recently been changed the prior year and that there is no consistency in the change.

Response: We would like to clarify that fundamentally we have not changed the weights since CY 2012. We previously recalibrated the case-mix weights in 2012 and did not change the weights in CY 2013. For CY 2014, while we lowered the case-mix weights to an average case-mix weight of 1.0000, we did not adjust the weights relative to one another. We instead decreased each case-mix weight by the same factor (1.3464). In the CY 2015 proposed rule, we proposed to recalibrate the case-mix weights with more current data, adjusting the weights relative to one another. To the greatest extent possible, we are attempting to use recent data to calibrate the payment models to ensure payments accurately reflect current resource use in home health episodes.

Comment: A commenter found the data CMS is basing its proposals on to be puzzling and mentioned that the payment system does not allow for reporting of time devoted to patient care that is not visit time. The commenter stated that dementia and brain disorders involve significant time outside of the visit.

Response: Section 1861(m) of the Act defines home health services as ''items and services furnished to an individual [. . .] provided on a visiting basis *in a place of residence used as such individual's home . . .*'' (emphasis added). Under certain circumstances, services may be provided via a telecommunications system, but these services do not substitute for in-person home health services and are not considered a home health visit for purposes of home health eligibility or payment (see section 1895(e)(1) of the Act). In addition, the commenter provided no supporting data explaining why home health services for patients suffering from dementia and brain disorders would require reimbursement exceeding the typical case management/care coordination functions that are inherent in managing patients in the home. We also note that while the case-mix recalibration does not include time outside of the visit, the base rate should capture other expenses related to patient care, such as travel costs, etc. An assumption since the original development of the HH PPS, supported by internal studies of cost report data, has been that visit time is approximately proportional to the total cost of caring for a patient during an episode.

Comment: Commenters expressed concerns with the effects the recalibrated weights will have when coupled with the rebasing reductions. A commenter stated that the combination of the recalibrated case-mix weights and the change in base rate brings about the equivalent of about a three point reduction in payments. A commenter stated that it makes sense to update case-mix points when statistical analyses warrant it but that it seems that most adjustments in recent years were done to reduce payments to home health agencies. A commenter stated that the changes in the case-mix points and thresholds for scoring the episode constitute a further reduction in payment beyond the required reduction and recalibration of the case-mix weights for CY 2015.

Response: The CY 2015 case-mix recalibration is done in a budget neutral manner. While we recalibrated the CY 2015 case-mix weights to an average case-mix weight of 1.00, we also proposed an increase to the base rate of 2.37 percent in order to ensure that there are no changes in aggregate payments due to the recalibration. The weights are only changing relative to one another and do not result in an overall reduction in HH PPS payments due to the recalibration of the case-mix weights.

Comment: A commenter stated that case-mix weights are continuing to be recalibrated to 1.000 but that many payments to home health do not result in the episodic payment including Partial Episode Payments, payments for low utilization payment adjustment episodes, outliers, and others.

Response: We believe the commenter is implying that the case-mix recalibration is not budget neutral given that LUPA, outlier episodes, etc. are not included in the case-mix weight recalibration. We note the LUPA episodes are paid on a per-visit basis and are not paid using the case-mix weights. Therefore, they were not included when performing the recalibration. We note that all episodes, including partial episode payment episodes and outlier episodes, are included when calculating the budget neutrality factor in order to ensure that total payments would be the same when comparing the CY 2015 weights to the CY 2014 weights. However, outliers are not included in the data when doing the case-mix recalibration because outlier episodes contain utilization patterns that are atypical. The outliers' utilization presumably reflects unusually high patient need for services that is not easily predictable in statistical data. In addition, due to the concentration of outlier episodes in suspect billing areas, we question some of the utilization data for outlier episodes. We would also like to note that outlier episodes receive additional payment when the imputed cost exceeds a certain threshold and therefore, receive additional payment outside of the case-mix system.

Comment: A commenter stated that the R-squared value of the payment regression model has increased from the 2012 payment regression model even though variables were dropped from the four-equation model. The commenter stated that less variables in the four-equation model should weaken the R-squared value.

Response: We do note that while the R-squared value for the payment regression increased for the CY 2015 payment regression model when compared to the CY 2012 payment regression model, the R-squared value for the CY 2015 four-equation model did decrease when compared to the R-squared value for the CY 2012 four-equation model, from 0.462 to 0.427. However, we point out that for the CY 2015 four-equation model and payment regression model, we used 2013 data. For the CY 2012 four-equation model, we used 2005 data and for the CY 2012 payment regression model, we used data from 2007. R-squared values will change depending on what data are used and cannot be directly compared.

Comment: Commenters supported the idea of recalibrating the weights with newer data but expressed concerns with the resulting proposed weights. Commenters stated their concerns with the continued use of therapy thresholds in the case-mix system. Commenters recommended that the therapy thresholds be eliminated from the payment system and that home health services be paid solely based on patient characteristics. A commenter stated that

though CMS has made efforts to reduce payments for therapy episodes, the incentives of the therapy thresholds, with more visits receiving higher payments, still remain in effect. The commenter stated that the adjustments to the case-mix weights would not be necessary if the therapy thresholds were eliminated.

Response: We recognize the issues around the use of the therapy thresholds and the use of therapy utilization in the payment system. We are currently looking into findings of the home health study authorized by section 3131(d) of the Affordable Care Act and payment reform options, including alternate ways to explain the amount of therapy resources without using therapy utilization variables. Further research is needed to find alternatives that will compensate for some of the loss of the explanatory power associated with the removal of the therapy utilization variables.

Comment: Several commenters were concerned about the implications for agencies of adjusting to several successive recalibrations. Commenters said recalibrations cause instability for HHAs, with one saying recalibrations were inconsistent with one another. A commenter was concerned that multiple recalibrations make calculations with the case mix weights useless as a comparative tool over time. This commenter also cited problems with calculations from including therapy utilization and by the constant annual revision to the various OASIS items or diagnoses included/excluded.

Response: We note that other post-acute payment systems, such as the inpatient rehabilitation facility PPS and acute inpatient PPS, recalibrate their case-mix weights annually. The differences in the recalibration results for the CY 2012 recalibration and the CY 2015 recalibration largely result from the six to eight year difference in the data used. We expect future annual recalibrations to have less significant changes in the case-mix points and values. With regard to the use of therapy utilization in our methodology, as stated in our response above, we are looking into alternate ways to explain the amount of therapy resources. Since the 2008 refinements, there have been no changes to the payment items on the OASIS. In addition, besides last year's changes to the ICD–9–CM codes included into the case-mix system (effective January 1, 2014 and therefore not reflected in the CY 2013 data used to recalibration the CY 2015 case-mix weights) and the removal of the hypertension codes in 2012, we did not make significant changes to the diagnoses included or excluded in the case-mix system. We also note in 2013, changes in the rules for using the payment diagnosis field were simulated and the simulations showed impacts in payment of less than one percent.

Comment: A commenter stated that to the extent that CMS is pursuing the adjustments to the weights for 2015, the agency should analyze the payment-to-cost ratios for the proposed payment weights before and after the manual adjustment, similar to the analysis conducted during the CY 2012 recalibration. The commenter stated that this additional analysis would allow CMS to assess whether these adjustments equalize the financial incentives for therapy and non-therapy episodes. Another commenter urged CMS to adjust the CY 2015 case-mix weights to ensure appropriate use of therapy visits and move reimbursement for therapy-based episodes towards actual costs incurred. Commenters recommended that CMS conduct a thorough validation review of the proposed case-mix weight recalibration and evaluate the potential impact on utilization, spending, access to care, and other relevant matters. Other commenters urged CMS to re-examine the case-mix recalibration and refine it to control for variables that might skew outcomes and ensure that the end result does not create rewards for high therapy resource use that may be inappropriate. A commenter suggested that CMS revisit the case-mix weight recalibration to accomplish its stated intention or alternatively provide a detailed explanation how the recalibrated case-mix weights are consistent with its intent. The commenter also stated that there has been no testing to determine whether the adjustments will achieve the desired outcomes. The commenter recommended that CMS retain the current case-mix weights until an approach to recalibration that actually achieves the desired outcomes can be developed and tested. The commenter stated that the changes to the payment system don't seem to have achieved the desired impact.

Response: We performed an analysis of the payment-to-cost ratio for episodes with varying levels of therapy visits. This analysis used cost report data to estimate episode cost and showed that the payment to cost ratios across the varying levels of therapy visits for the recalibrated weights were similar to the payment to cost ratios for the current weights. The analysis also justified the need for the continued adjustments (finalized in CY 2012) to be applied to the raw weights to lower the case-mix weights for high therapy episodes. The payment-to-cost ratios across the individual therapy visits were all relatively similar to each other, with some exceptions in the tails of the distribution, and indicated that there may not be a strong incentive to provide unnecessary amounts of therapy visits. The goal of the recalibration is to better align payment with current costs and we believe the recalibration achieves this.

Comment: Commenters expressed their support for CMS' decision to apply a full case-mix budget neutrality factor rather than a reduced case-mix budget neutrality factor which would take into account nominal case-mix growth. However, they expressed concern about the uncertainty for providers in planning for projected rates in CY 2015 and beyond given the possibility of case-mix reductions in the future. Commenters urged CMS to closely collaborate with the industry and stakeholders to ensure that the appropriate analysis is conducted in evaluating case-mix growth before proposing case-mix reductions in the future. Another commenter suggested that CMS perform a comprehensive study of individual patient clinical records before asserting that case-mix growth has occurred by anything other than necessary clinical care being provided. Another commenter urged CMS to use their enforcement authority to conduct targeted claims reviews and deny payment for claims where the case-mix weight is not supported by the plan of care rather than cut the national standardized episode rate for all agencies. Yet another commenter stated that case-mix change should not be measured using 1999 data as a baseline and that HHAs are providing better care for a more needy clinical population. Other commenters questioned the methodology used to determine real and nominal case-mix.

Response: While we appreciate the commenters' suggestion about the clinical record review, we note that our resources are not sufficient to conduct a review of patient records and/or claims on a scale that would be required to counteract the broad-based uptrend in case-mix weights; therefore, we cannot perform the review as suggested. However, we note that the MACs, in conjunction with supplemental review contractors, perform medical review of claims. When they perform medical review, they review the plan of care and OASIS and make adjustments to HHRGs if they deem that the documentation is not sufficient to support what was billed by the agency. Furthermore, we note that our statistical methods using available administrative data are

feasible and sufficiently reliable to utilize for the purpose of case-mix reductions.

With regard to the comments about patient severity, as stated in the CY 2012 proposed rule, a detailed analysis of Medicare Expenditure Panel Survey (MEPS) data (which is independent of our real case-mix model) was performed to examine the severity of the Medicare home health population. The trends in health status from 2000 to 2008 were analyzed. The analysis showed a slight increase in the overall health status of the Medicare home health population, and in particular, the percent of home health Medicare beneficiaries experiencing ''extreme'' or ''quite a bit'' of work-limiting pain decreased substantially, from 56.6 percent in 2000 to 45.4 percent in 2008 ($p = 0.039$). While we recognize that there are some limitations to this analysis, we conclude that the results of this analysis provide no evidence of an increase in patient severity from 2000 to 2008.

In addition, we would like to note that during the CY 2012 rulemaking, we incorporated HCC data, which is used by CMS to risk-adjust payments to managed care organization in the Medicare program, in our model to assess real case-mix growth. Our findings of real and nominal case-mix growth, even when incorporating HCC data, were consistent with past results. Most of the case-mix change was identified as nominal case-mix change. We will continue to solicit suggestions for other data that can be incorporated into our analysis of real and nominal growth and solicit suggestions on possible ways to improve our models. We plan to continue to monitor real and nominal case-mix growth and may propose additional case-mix reductions as necessary.

Comment: One commenter stated that CMS has adjusted payments in 2008 to 2013 based on an analysis of changes in coding not related to changes in patient severity, but that CMS has not proposed a coding adjustment for 2015. The commenter stated that given the history of coding increases not attributable to severity, CMS should analyze the nominal case-mix change in the reported average case-mix for more recent years and implement additional payment reductions as warranted.

Response: We agree and we will continue to monitor nominal case-mix growth and propose case-mix adjustments, as necessary. We also note that annually recalibrating (and normalizing the weights to 1.00) may minimize nominal case-mix growth in future years.

Comment: Another commenter stated that CMS should address and eliminate fraudulent activities in a targeted manner that does not burden the whole industry for the actions of a small number of bad actors. The commenter stated that CMS should target bad actors rather than continue to implement across the board reductions that could reduce the number and quality of home health providers.

Response: For a variety of reasons, as we have noted in previous regulations, we have not proposed targeted reductions for nominal case-mix change. Many agencies have small patient populations, which would make it practically impossible to reliably measure nominal case-mix change at the agency level. Further, we believe changes and improvements in coding practices have been widespread, making it difficult to clearly categorize agencies into high and low coding-change groups. As discussed in the CY 2012 final rule, when performing an independent review of our case-mix measurement methodology, Dr. David Grabowski and his team at Harvard University agreed with our reasons for not proposing targeted reductions, stating their concerns about the small sample size of many agencies and their findings of significant nominal case-mix increases across different classes of agencies.

We note that although we have stated in past regulations that a targeted system would be administratively burdensome, the reasons we have just presented go beyond administrative complexity. We do not agree that agency-specific case-mix levels can precisely differentiate agencies with inappropriate coding practices from other agencies that are coding appropriately. System wide, case-mix levels have risen over time while data on patient characteristics indicate little change in patient severity over time. That is, the main problem is not the level of case-mix reached over a period of time, but the amount of change in the billed case-mix not attributable to underlying changes in actual patient severity. We will continue to monitor nominal case-mix growth and determine whether case-mix reductions are needed.

Comment: Commenters questioned why CMS has not expanded the recalibration analysis to include additional variables that impact the cost of home health services to Medicare beneficiaries, such as those examined in the home health study and associated with low-income beneficiaries, beneficiaries in medically underserved areas, and those with varying levels of severity of illness. Commenters urged CMS to incorporate findings from the access study into the case-mix system for CY 2015. A commenter expressed disappointment that CMS continued to rely on the current case-mix system rather than testing and implementing new models. The commenter stated that the current case-mix system and proposed adjustments have reached a level of complexity that make it challenging to determine the accuracy of the proposed technical refinements. The commenter stated that the inaccuracies in the current system, resulting from the limitations of the current OASIS variables and the use of average costs that do not represent the full costs of treating more complex patients, continue to result in underpayment for patients whose resource use and cost of care are not fully captured in the case-mix weights. Another commenter suggested that CMS work with the industry to develop the case-mix methodology.

Response: We are currently doing follow-on work to the home health study to explore findings and recommendations from the home health study on access to care for vulnerable populations. Under this contract, we are also exploring payment reform options to better capture costs associated with the various types of home health patients. However, the project is in its preliminary stages and will take some time to complete. We plan to provide updates on the follow on study and payment reform work in future rulemaking and plan to consult with stakeholders once further progress has been made.

Comment: While outside the scope of the rule, some commenters provided suggestions for our payment reform work.

Response: We thank the commenter for their input. We will take their comments into consideration for our payment reform work.

Final Decision: We are finalizing the points for the case-mix variables, the revised thresholds for the clinical and functional levels, and the case-mix weights for CY 2015 shown in the tables above. We are also finalizing our proposal to recalibrate the case-mix weights every year with more current data. We will continue to monitor case-mix growth and may consider whether to propose nominal case-mix reductions in future rulemaking.

D. CY 2015 Home Health Rate Update

1. CY 2015 Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2015 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. The home health market basket percentage increase for CY 2015 is based on IHS Global Insight Inc.'s (IGI) third quarter 2014 forecast with historical data through the second quarter of 2014. The home health market basket percentage increase for CY 2015 is 2.6 percent. The HH market basket was rebased and revised in CY 2013. A detailed description of how we derive the HH market basket is available in the CY 2013 HH PPS final rule (77 FR 67080, 67090).

For CY 2015, section 3401(e) of the Affordable Care Act, requires that, in CY 2015 (and in subsequent calendar years), the market basket percentage under the HH prospective payment system as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. The statute defines the productivity adjustment, described in section 1886(d)(3)(B)(xi)(II) of the Act, to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period)(the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data. We note that the proposed methodology for calculating and applying the MFP adjustment to the HHA payment update is similar to the methodology used in other Medicare provider payment systems as required by section 3401 of the Affordable Care Act. Please refer to the CY 2015 HH PPS proposed rule (79 FR 38384 through 38386) for more detailed information regarding the computation of the MFP adjustment.

We did not receive any comments on our proposal related to the computation of the statutorily-required productivity adjustment. Therefore, we are finalizing our proposal to adjust the HH market basket percentage increase by the MFP adjustment as discussed in the proposed rule. The CY 2015 HH market basket percentage of 2.6 percent will be reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending December 31, 2015) of 0.5 percent, which is based on IGI's third quarter 2014 forecast. The resulting MFP-adjusted HH market basket update is equal to 2.1 percent, or 2.6 percent less 0.5 percentage point.

Section 1895(b)(3)(B) of the Act requires that the home health market basket percentage increase be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2015, the home health market basket update will be 0.1 percent (2.1 percent minus 2.0 percentage points).

2. Home Health Care Quality Reporting Program (HH QRP)

a. General Considerations Used for Selection of Quality Measures for the HH QRP

The successful development of the Home Health Quality Reporting Program (HH QRP) that promotes the delivery of high quality healthcare services is one of our paramount concerns in administering the home health program. We seek to adopt measures for the HH QRP that promote more efficient and safer care. Our measure selection activities for the HH QRP take into consideration input we receive from the Measure Applications Partnership (MAP), convened by the National Quality Forum (NQF) as part of a pre-rulemaking process that we have established and are required to follow under section 1890A of the Act. The MAP is a public-private partnership comprised of multi-stakeholder groups convened for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890A(a)(3) of the Act. By February 1st of each year, the NQF must provide that input to CMS.

More details about the pre-rulemaking process can be found at *http://www.qualityforum.org/map.*

MAP reports to view and download are available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.*

Our measure development and selection activities for the HH QRP take into account national priorities, such as those established by the National Priorities Partnership (*http://www.qualityforum.org/Setting_Priorities/NPP/National_Priorities_Partnership.aspx*), the Department of Health & Human Services (HHS) Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html,* the National Quality Strategy (NQS) (*http://www.ahrq.gov/workingforquality/reports.htm*), and the CMS Quality Strategy (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html*). To the extent practicable, we have sought to adopt measures that have been endorsed by the national consensus organization under contract to endorse standardized healthcare quality measures under section 1890 of the Act, recommended by multi-stakeholder organizations, and developed with the input of patients, providers, purchasers/payers, and other stakeholders. At this time, the NQF is the national consensus organization that is under contract with HHS to provide review and endorsement of quality measures.

b. Background and Quality Reporting Requirements

Section 1895(b)(3)(B)(v)(II) of the Act states that ''each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause.''

In addition, section 1895(b)(3)(B)(v)(I) of the Act states that ''for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points.'' This requirement has been codified in regulations at § 484.225(i). HHAs that meet the quality data reporting requirements are eligible for the full home health (HH) market basket percentage increase. HHAs that do not meet the reporting requirements are subject to a 2 percentage point reduction to the HH market basket increase.

Section 1895(b)(3)(B)(v)(III) of the Act further states that ''[t]he Secretary shall establish procedures for making data submitted under subclause (II) available to the public. Such procedures shall ensure that a home health agency has the opportunity to review the data that is to be made public with respect to the agency prior to such data being made public.''

Medicare home health regulations, as codified at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of

Healthcare Providers and Systems Survey® (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. We provide quality measure data to HHAs via the Certification and Survey Provider Enhanced Reports (CASPER reports) which are available on the CMS Health Care Quality Improvement System (QIES). A subset of the HH quality measures has been publicly reported on the Home Health Compare (HH Compare) Web site since 2003. The CY 2012 HH PPS final rule (76 FR 68576), identifies the current HH QRP measures. The selected measures that are made available to the public can be viewed on the HH Compare Web site located at *http://www.medicare.gov/HHCompare/Home.asp.* As stated in the CY 2012 and CY 2013 HH PPS final rules (76 FR 68575 and 77 FR 67093, respectively), we finalized that we will also use measures derived from Medicare claims data to measure HH quality.

In the CY 2014 HH PPS final rule, we finalized a proposal to add two claims-based measures to the HH QRP, and also stated that we would begin reporting the data from these measures to HHAs beginning in CY 2014. These claims based measures are: (1) Rehospitalization during the first 30 days of HH; and (2) Emergency Department Use without Hospital Readmission during the first 30 days of HH. Also in this rule, we finalized our proposal to reduce the number of process measures reported on the CASPER reports by eliminating the stratification by episode length for 9 process measures. While no timeframe was given for the removal of these measures, we have scheduled their removal from the CASPER folders in October 2014. In addition, five short stay measures which had previously been reported on HH Compare were recently removed from public reporting and replaced with non-stratified ''all episodes of care'' versions of these measures.

Comment: One commenter urged CMS to only adopt quality measures that have been endorsed by the Measure Applications Partnership (MAP) and National Quality Forum (NQF).

Response: To the extent practicable, we seek to adopt measures that have been endorsed by a consensus based entity, such as NQF. We also intend to continue seeking input from the MAP as part of the pre-rulemaking process.

Comment: One commenter asked CMS to comment on the timeframe for the public release of the two ''post-acute 30 day measures.''

Response: We believe the commenter is requesting information about the status of public reporting for the two HH claims based measures titled ''Rehospitalization during the First 30 Days of HH'' and ''Emergency Department Use without Readmission during the First 30 Days of HH'' that were finalized in the CY 2014 HH PPS final rule (78 FR 72256). In the CY 2014 HH PPS final rule, we stated that ''these measures will be added to HH Compare for public reporting in CY 2015'' (78 FR 72298.).

c. OASIS Data Submission and OASIS Data for Annual Payment Update

(1) Regulatory Authority

The HH conditions of participation (CoPs) at § 484.55(d) require that the comprehensive assessment must be updated and revised (including the administration of the OASIS) no less frequently than: (1) The last 5 days of every 60 days beginning with the start of care date, unless there is a beneficiary-elected transfer, significant change in condition, or discharge and return to the same HHA during the 60-day episode; (2) within 48 hours of the patient's return to the home from a hospital admission of 24-hours or more for any reason other than diagnostic tests; and (3) at discharge.

It is important to note that to calculate quality measures from OASIS data, there must be a complete quality episode, which requires both a Start of Care (initial assessment) or Resumption of Care OASIS assessment and a Transfer or Discharge OASIS assessment. Failure to submit sufficient OASIS assessments to allow calculation of quality measures, including transfer and discharge assessments, is a failure to comply with the CoPs.

HHAs do not need to submit OASIS data for those patients who are excluded from the OASIS submission requirements. As described in the December 23, 2005 Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies final rule (70 FR 76202), we define the exclusion as those patients:

- Receiving only non-skilled services;
- For whom neither Medicare nor Medicaid is paying for HH care (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement);
- Receiving pre- or post-partum services; or
- Under the age of 18 years.

As set forth in the CY 2008 HH PPS final rule (72 FR 49863), HHAs that become Medicare-certified on or after May 31 of the preceding year are not subject to the OASIS quality reporting requirement nor any payment penalty for quality reporting purposes for the following year. For example, HHAs certified on or after May 31, 2013 are not subject to the 2 percentage point reduction to their market basket update for CY 2014. These exclusions only affect quality reporting requirements and do not affect the HHAs' reporting responsibilities as announced in the December 23, 2005 final rule, ''Medicare and Medicaid Programs; Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies'' (70 FR 76202).

(2) HH QRP Requirements for CY 2015 Payment and Subsequent Years

In the CY 2014 HH PPS Final rule (78 FR 72297), we finalized a proposal to consider OASIS assessments submitted by HHAs to CMS in compliance with HH CoPs and Conditions for Payment for episodes beginning on or after July 1, 2012, and before July 1, 2013 as fulfilling one portion of the quality reporting requirement for CY 2014. In addition, we finalized a proposal to continue this pattern for each subsequent year beyond CY 2014. OASIS assessments submitted for episodes beginning on July 1st of the calendar year 2 years prior to the calendar year of the Annual Payment Update (APU) effective date and ending June 30th of the calendar year 1 year prior to the calendar year of the APU effective date fulfill the OASIS portion of the HH QRP requirement.

(3) Establishing a ''Pay-for-Reporting'' Performance Requirement for Submission of OASIS Quality Data

Section 1895(b)(3)(B)(v)(I) of the Act states that ''for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points.'' This ''pay-for-reporting'' requirement was implemented on January 1, 2007. However, to date, the quantity of OASIS assessments each HHA must submit to meet this requirement has never been proposed and finalized through rulemaking or through the sub-regulatory process. We believe that this matter should be addressed for several reasons.

We believe that defining a more explicit performance requirement for

the submission of OASIS data by HHAs would better meet section 5201(c)(2) of the Deficit Reduction Act of 2005 (DRA), which requires that ''each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause.''

In February 2012, the Department of Health & Human Services Office of the Inspector General (OIG) performed a study to: (1) Determine the extent to which HHAs met federal reporting requirements for the OASIS data; (2) to determine the extent to which states met federal reporting requirements for OASIS data; and (3) to determine the extent to which the CMS was overseeing the accuracy and completeness of OASIS data submitted by HHAs. In a report entitled, ''Limited Oversight of Home Health Agency OASIS Data,''[24] the OIG stated their finding that ''CMS did not ensure the accuracy or completeness of OASIS data.'' The OIG recommended that we ''identify all HHAs that failed to submit OASIS data and apply the 2 percent payment reduction to them''. We believe that establishing a performance requirement for submission of OASIS quality data would be responsive to the recommendations of the OIG.

In response to these requirements and the OIG report, we designed a pay-for-reporting performance system model that could accurately measure the level of an HHA's submission of OASIS data. The performance system is based on the principle that each HHA is expected to submit a minimum set of two ''matching'' assessments for each patient admitted to their agency. These matching assessments together create what is considered a ''quality episode of care'', consisting ideally of a Start of Care (SOC) or Resumption of Care (ROC) assessment and a matching End of Care (EOC) assessment. However, it was determined that there are several scenarios that could meet this ''matching assessment requirement'' of the new pay-for-reporting performance requirement. These scenarios or ''quality assessments,'' are defined as assessments that create a quality episode of care during the reporting period or could create a quality episode if the reporting period were expanded to an earlier reporting period or into the next reporting period.

Seven types of assessments submitted by an HHA fit this definition of a quality assessment. These are:

- A Start of Care (SOC) or Resumption of Care (ROC) assessment that has a matching End of Care (EOC) assessment. EOC assessments are assessments that are conducted at transfer to an inpatient facility (with or without discharge), death, or discharge from HH care. These two assessments (the SOC or ROC assessment and the EOC assessment) create a regular quality episode of care and both count as quality assessments.
- A SOC/ROC assessment that could begin an episode of care, but occurs in the last 60 days of the performance period. This is labeled as a ''Late SOC/ROC'' quality assessment.
- An EOC assessment that could end an episode of care that began in the previous reporting period, (that is, an EOC that occurs in the first 60 days of the performance period.) This is labeled as an ''Early EOC'' quality assessment.
- A SOC/ROC assessment that is followed by one or more follow-up assessments, the last of which occurs in the last 60 days of the performance period. This is labeled as an ''SOC/ROC Pseudo Episode'' quality assessment.
- An EOC assessment is preceded by one or more follow-up assessments, the last of which occurs in the first 60 days of the performance period. This is labeled an ''EOC Pseudo Episode'' quality assessment.
- A SOC/ROC assessment that is part of a known one-visit episode. This is labeled as a ''One-Visit episode'' quality assessment.
- SOC, ROC, and EOC assessments that do not meet any of these definitions are labeled as ''Non-Quality'' assessments.
- Follow-up assessments (that is, where the M0100 Reason for Assessment = '04' or '05') are considered ''Neutral'' assessments and do not count toward or against the pay for reporting performance requirement.

Compliance with this performance requirement can be measured through the use of an uncomplicated mathematical formula. This pay for reporting performance requirement metric has been titled as the ''Quality Assessments Only'' (QAO) formula because only those OASIS assessments that contribute, or could contribute, to creating a quality episode of care are included in the computation. The formula based on this definition is as follows:

$$\text{QAO} = \frac{(\text{\# of Quality Assessments})}{(\text{\# of Quality Assessments} + \text{\# of NonQuality Assessments})} * 100$$

Our ultimate goal is to require all HHAs to achieve a pay-for-reporting performance requirement compliance rate of 90 percent or more, as calculated using the QAO metric illustrated above. However, we proposed to implement this performance requirement in an incremental fashion over a 3 year period. We proposed to require each HHA to reach a compliance rate of 70 percent or better during the first reporting period[25] that the new pay-for-reporting performance requirement is implemented. We further proposed to increase the pay-for-reporting performance requirement by 10 percent in the second reporting period, and then by an additional 10 percent in the third reporting period until a pay-for-reporting performance level of 90 percent is reached.

To summarize, we proposed to implement the pay-for-reporting performance requirement beginning with all episodes of care that occur on or after July 1, 2015, in accordance with the following schedule:

- For episodes beginning on or after July 1st, 2015 and before June 30th, 2016, HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance or be subject to a 2 percentage point reduction to their market basket update for CY 2017.
- For episodes beginning on or after July 1st, 2016 and before June 30th, 2017, HHAs must score at least 80 percent on the QAO metric of pay-for-reporting performance or be subject to a 2 percentage point reduction to their market basket update for CY 2018.

[24] *http://oig.hhs.gov/oei/reports/oei-01-10-00460.asp*

[25] The term ''reporting period'' is defined as the submission of OASIS assessments for episodes between July 1 (of the calendar year two years prior to the calendar year of the APU effective date) through the following June 30th (of the calendar year one year prior to the calendar year of the APU effective date) each year.

• For episodes beginning on or after July 1st, 2017, and thereafter, and before June 30th, 2018 and thereafter, HHAs must score at least 90 percent on the QAO metric of pay-for-reporting performance or be subject to a 2 percentage point reduction to their market basket update for CY 2019, and each subsequent year thereafter.

We solicited public comment on our proposal to implement the pay-for-reporting performance requirement, as described previously, for the HH QRP. We received the following comments in response to our proposal:

Comment: MedPAC submitted a comment in which they expressed full support for the proposal to establish a minimum requirement for submission of OASIS assessments. MedPAC stated that ''the requirement for submission of OASIS data to receive a full payment update has been in effect for many years, and agencies should have many years of experience with the transmission of this data'' and suggested that CMS consider phasing in the requirement at a faster rate, given the familiarity of HHAs with these processes. MedPAC recommended raising the threshold to 90 percent in the second year. Another commenter, who stated support for this proposal, suggested increasing the compliance thresholds to 75 percent, 85 percent and 95 percent (instead of the 70 percent, 80 percent and 90 percent threshold that were proposed). Another commenter suggested that CMS should carefully monitor compliance rates over the next two years to determine if a 90 percent compliance rate is a realistic goal.

Several commenters supported our proposal to establish a minimum requirement for submission of OASIS assessments for a variety of reasons. One commenter stated a belief that this proposal demonstrates CMS' efforts to obtain more complete patient data sets. Another commenter expressed an opinion that the proposed OASIS minimum reporting requirement is a program integrity reform and cost cutting measure that is preferable to the across the board payment cuts established by CMS in previous HH PPS rules.

Response: We thank MedPAC and other commenters who support our proposal to establish a pay-for-reporting performance requirement for the HH QRP. We agree that the requirements for OASIS reporting have been in effect for many years. The HH CoPs which are codified at 42 CFR 484.55 and mandate use of the OASIS data set when evaluating adult non-maternity patients receiving skilled services were established in 1999 (64 FR 3764 through 3784). OASIS reporting was first implemented on July 19, 1999 and in 2007, OASIS reporting became mandatory for quality reporting purposes under section 1895(b)(3)(B)(v)(I) of the Act. HHAs have been required to submit OASIS data as a condition of payment of their Medicare claims since 2010. As HHAs have been required to report OASIS data for the past 15 years as a CoP in the Medicare program and as a condition of payment of their Medicare claims for the past 4 years, our establishment of a minimum threshold for OASIS reporting should not place any new or additional burden on HHAs.

Our ultimate goal is to require all HHAs to achieve a pay-for-reporting performance requirement compliance rate of 90 percent or more, as calculated using the QAO metric described and in this section. In the proposed rule, we proposed to require each HHA to reach a compliance rate of 70 percent or better during the first reporting period that the new pay-for-reporting performance requirement is implemented. We believe that use of the 70 percent standard is one that is attainable by any HHA, whether it is a large corporate entity or very small family run business. We had further proposed to increase the performance requirement by 10 percent in the second reporting period, and then by an additional 10 percent in the third reporting period until a pay-for-reporting performance requirement of 90 percent is reached, because we believed that this schedule would promote successful performance by all HHAs.

However, after carefully considering the comments submitted, we have reconsidered our proposal for implementation of a ''pay-for-performance'' performance requirement over a 3 year period. MedPAC suggested that CMS consider phasing in the OASIS reporting requirement at a faster rate, given the familiarity that HHAs have with the OASIS process. MedPAC recommended raising the threshold to 90 percent in the second year.

We agree with MedPAC's contention that HHAs have been statutorily required to report OASIS for a number of years and therefore should have many years of experience with the collection of OASIS data and transmission of this data to CMS. Given the length of time that HHAs have been mandated to report OASIS data, we believe that HHAs will adapt quickly to the implementation of the ''pay-for-reporting'' performance requirement, if phased in over a 2 year period. On the other hand, the ''pay-for-reporting'' performance requirement is a new reporting requirement that can have a significant financial impact any HHA that is not able to meet the requirements.

We believe that it is best to proceed with the establishment of the 70 percent reporting requirement during the first reporting period (that is, July 1, 2015 through June 30, 2016) and will finalize this part of our proposal. However, we will not finalize our proposal to increase the reporting requirement in 10 percent increments over a 2 year period until the maximum rate of 90 percent is reached. In consideration of the recommendations made, we plan to monitor provider performance under the ''pay-for-reporting'' performance requirement during the time period of July 1, 2014 through June 30, 2015. We will then use such information, as available, to make a determination about what the ''pay-for-reporting'' performance requirement will be set at in the 2nd and subsequent years. For example, we will review OASIS data from a recent reporting period simulating the ''pay-for reporting'' performance 70 percent submission requirement to determine the ''hypothetical performance'' of each HHA ''as if'' the ''pay for reporting'' performance requirement were in effect during the reporting period preceding its implementation. We will provide a report to each HHA of their ''hypothetical performance'' under the ''pay for reporting'' performance requirement during the 2014–2015 ''pre-implementation reporting period.'' We will also consider provider performance during the first part of the first year of the ''pay for reporting'' performance requirement as data are available in determining the OASIS reporting requirement for the 2nd and subsequent years.

Comment: A commenter expressed agreement with our proposal to implement the OASIS minimum reporting requirements over a 3 year period, but strongly recommended that such requirements be limited to the OASIS data sets collected for Medicare PPS episodes only. This commenter stated a belief that it would be too burdensome if HHAs were required to complete OASIS assessments for patients on other payment programs.

Response: Patients receiving care under a Medicare or Medicaid managed care plan are not excluded from the OASIS reporting requirements, and HHAs are required to submit OASIS assessments for these patients. OASIS reporting is mandated for all Medicare beneficiaries (under 42 CFR 484.250(a), 484.225(i), and 484.55). The HH CoPs require that the Home Health Registered

Nurse (HH RN) or qualified therapist perform an initial assessment within 48 hours of referral, within 48 hours of the patient's return home, or on the physician-ordered start of care date. The HH RN or qualified therapist must also complete a comprehensive assessment within 5 days from the start of care. During these assessments, the HH RN or qualified therapist must determine the patient's eligibility for the Medicare HH benefit, including homebound status (42 CFR 484.55(a)(1) and 42 CFR 484.55 (b)). In addition, the requirement for OASIS reporting on Medicare and Medicaid Managed Care patients was established in a final rule titled ''Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies Final Rule'' dated December 23, 2005 (70 FR 76202), which stated the following:

In the January 25, 1999, interim final rule with comment period (64 FR 3749), we generally mandated that all HHAs participating in Medicare and Medicaid (including managed care organizations providing home health services to Medicare and Medicaid beneficiaries) report their OASIS data to the database we established within each State via electronic transmission. (76 FR 76200).

We do not believe that there is more burden associated with the collection of OASIS assessment data for a Medicare Managed Care patient than there is for a HH patient that receives traditional Medicare PPS benefits. The requirements for the HH RN or qualified therapist to perform an initial and comprehensive assessment and complete all required OASIS assessments is the same for all Medicare patients regardless of the type of Medicare benefits they receive. The completion of these activities is a condition of payment of both Medicare PPS and managed care claims.

Comment: A commenter, while in general agreement with the establishment of a minimum reporting requirement for OASIS reporting, expressed disagreement with implementation of this requirement on July 1, 2015. This commenter voiced the opinion that HHAs should first be informed of their current OASIS submission compliance rate, so they have an opportunity to improve, if below the 70 percent threshold. Another commenter suggested that CMS provide each HHA with their current OASIS reporting compliance rates to allow them to assess and understand their compliance levels and create a benchmark against which they can seek to improve over time. Another commenter requested that CMS publish the current rate of HHA compliance with OASIS reporting and recommended that the new compliance standard be based on incremental increases from those rates.

Response: HHAs have been required to report OASIS data on 100 percent of their Medicare beneficiary patients for the past 15 years as a CoP and as a condition of payment of their Medicare claims. Also, since 2007, HHAs have been required to report OASIS quality data on 100 percent of their Medicare beneficiary patients in order to receive their full yearly market basket update.

We do not agree that revealing sub-par provider compliance rates will be helpful to providers as several commenters have requested. Our establishment of the pay-for reporting performance requirement is a means by which we can measure HHA compliance with the established and long standing OASIS reporting requirements, while allowing HHAs a 2 year period to bring their performance up to the 90 percent compliance level. As the OASIS reporting requirements have been in existence for 15 years, HHAs should already possess knowledge of these requirements and know what they need to do to bring their agency into compliance. Furthermore, as OASIS reporting on each Medicare beneficiary is a requirement for payment of Medicare billing claims and also a HH CoP, our establishment of a minimum threshold for OASIS reporting should not place any new or additional burden on HHAs.

Comment: Several commenters, while in general agreement with this proposal, requested that CMS provide clarification of the term ''submission'' and inquired whether this requires both submission and acceptance of OASIS data by the state agency. Another commenter sought assurance that HHAs will not be penalized for delayed acceptance of OASIS data by state agency due to CMS server/IT issues.

Response: The pay-for reporting performance requirements will go into effect on July 1, 2015. However, on January 1, 2015, the data submission process for OASIS will convert from the current state-based OASIS submission system to a new national OASIS submission system known as the Assessment Submission and Processing (ASAP) System.[26] Therefore, the commenter's question about whether successful submission requires both submission and acceptance of OASIS data by the state agency is moot because the state-based OASIS submission system will not be in existence.

On July 1, 2015, when the pay-for reporting performance requirement of 70 percent goes into effect, providers will be required to submit their OASIS assessment data into the ASAP system. Successful submission of an OASIS assessment will consist of the submission of the data into the ASAP system with a receipt of no fatal error messages. Error messages received during submission can be an indication of a problem that occurred during the submission process and could also be an indication that the OASIS assessment was rejected. Successful submission can be verified by ascertaining that the submitted assessment data resides in the national database after the assessment has met all of the quality standards for completeness and accuracy during the submission process.

Should one or more OASIS assessments submitted by a HHA be rejected due to an IT/servers issue cause by CMS, we may, at our discretion, excuse the non-submission of OASIS data. We anticipate that such a scenario would rarely, if ever, occur. In the event that a HHA believes they were unable to submit OASIS assessments due to an IT/server issue on the part of CMS, the HHA should be prepared to provide any documentation or proof available which demonstrates that no fault on their part contributed to the failure of the OASIS records to transmit to CMS.

Comment: Several commenters suggested that CMS provide comprehensive education on the new OASIS minimum reporting requirements for at least 6 months before it is effective. One commenter stated a belief that provider education is especially necessary since the failure to meet the submission threshold would result in a 2 percent reduction in payment for an entire calendar year.

Response: We agree that educating HH providers about the new OASIS data submission requirements is very important and necessary. The initial performance period for the pay-for-reporting performance requirement will consist of July 1, 2015 through June 30, 2016. Prior to and during this performance period, we will schedule multiple Open Door Forums and webinars to educate HHA personnel about the pay-for-reporting performance requirement program and the pay-for-

[26] The state-based OASIS submission system is scheduled to shut down permanently at 6:00 p.m. on December 26, 2014. Beginning at 12:00 a.m. midnight on January 1, 2015, HHAs must begin to submit their OASIS assessment via the national ASAP system. With the implementation of the ASAP system, HHAs will no longer submit OASIS assessment data to CMS via their state databases.

reporting performance QAO metric. Additionally, OASIS Education Coordinators (OECs) will be trained to provide state-level instruction on this program and metric. We have already posted a report which provides a detailed explanation of the methodology for this pay-for-reporting QAO methodology. To view this report, go to: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html.* Training announcements and additional educational information related to the pay-for-reporting Performance Requirement will be provided in the near future on the HH Quality Initiatives Web page (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/index.html*).

Comment: Another commenter expressed an opinion that the terms of our proposed ''pay-for reporting performance requirement'' reporting are not clear. This commenter states the opinion that the definitions of both the numerator and the denominator in the proposed ratio are not clear.

Response: We have posted a technical report which provides a detailed explanation of the methodology used for the pay-for-reporting QAO methodology. This report provides a detailed definition of both the numerator and denominator of the QAO metric, and also addresses the definition of quality vs. non quality assessments. In addition, this report provides an extensive analysis of the pay-for reporting methodology using 2012–2013 OASIS assessment data. To view this report, go to: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Pay-for-Reporting-Quality-Assessments-Only-Methodology.pdf.*

Comment: A commenter believes that it is not necessary for CMS to establish a minimum threshold for the submission of OASIS quality data because state surveyors have access to the OASIS data and, therefore, have ways to ensure HHAs are in compliance with OASIS data submission requirements.

Response: We respectfully disagree with this commenter. State surveyors would not be able to ensure compliance with the OASIS data submission requirements for several reasons. First, state surveyors have limited access to the OASIS data. Second, state surveyors do not have access to the claims/billing information that is necessary to determine if complete quality episodes have been submitted for each patient. Third, compliance with OASIS quality reporting requirements must be assessed on an annual basis in order to determine whether an HHA will receive their full market basket update or the 2 percentage point reduction for non-compliance. Therefore, use of state surveyors to perform this task is not possible.

Comment: A commenter recommended that CMS provide HHAs with a 30-day period in which to review CMS's assessment of their compliance and submit corrections if necessary.

Response: Such a process has been in place for the HH QRP for some time. This process is referred to as the ''reconsideration process.''

The OASIS data collection period runs from July 1st each year to June 30th of the following year. At the conclusion of each reporting period, we will assess the type and amount of OASIS data submitted by each HHA during the reporting period to determine whether each provider met the quality reporting requirements. HHAs that do not meet the requirements for that reporting period will be sent a ''notice of non-compliance'' letter by their Medicare Administrative Contractor (MAC). A HHA will have 30 days from the date of the ''notice of non-compliance'' letter to file a request for reconsideration to us. The HHA must tell us why they think the finding of non-compliance was incorrect and provide any documentation that proves they did meet the reporting requirements for that reporting period.

The reconsideration process can also serve to provide notice to HHAs who fall below the pay-for-reporting performance requirement for a given reporting period of their OASIS compliance score for the reporting period. The HHA will then have 30 days to submit a request for reconsideration if they disagree with the compliance score provided by us. The HHA will also have the opportunity to submit evidence on their behalf of a higher compliance score.

Comment: A commenter suggested that CMS should include an exemption from the OASIS minimum reporting requirements for small agencies similar to that given with the HH–CAHPS requirements.

Response: Small HHAs are exempt from reporting HHCAHPS for several reasons. First, the data is not collected using OASIS, but is instead collected by the HHCAHPS, which is a non-payment related data collection instrument. Second, HHCAHPS data are collected for the purpose for quality monitoring. If data were collected from very small HHAs, there is a high probability that protected patient information or confidential information could be identified simply because of the small number of responses. Therefore, the granting of an exemption to small HHAs is done to protect the integrity of the data.

However, the reporting of OASIS assessment data on each patient by HHAs is mandated by section 1895(b)(3)(B)(v)(II) of the Act. This statute required that ''each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause.'' Section 1895(b)(3)(B)(v)(I) of the Act states that ''for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with sub clause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points.''

None of the statutes or Medicare regulations related to OASIS reporting exempt small HHAs from the OASIS reporting requirements. In fact, we would not be able to provide such an exemption, as submission of OASIS assessments is a condition of payment and condition of participation in the Medicare program. Any HHA (regardless of size) that wants to bill for HH care of a Medicare patient must submit the proper OASIS assessments in order to file valid claims. Also, any HHA (regardless of size) that wants to participate in the Medicare program, must submit the required type and amount of OASIS assessments for their Medicare patients.

Comment: One commenter, though in agreement with the timeframes and the minimum scores proposed by CMS, expressed a belief that CMS should establish a disaster/exceptional circumstances policy to address situations beyond the control of the HHA that could result in the inability to submit OASIS data in a timely manner. This commenter noted that such a policy has been established in other post-acute care settings.

Response: We thank this commenter for their support of our proposal to establish a pay-for-reporting performance requirement. However, the commenter's suggestion that CMS establish an exceptional circumstances/disaster waiver policy for the HH QRP is outside the scope of the proposals that made in the proposed rule and

therefore, we are unable to comment on this suggestion. We will however take this suggestion under advisement.

Comment: One commenter expressed concern that the proposal to establish a ''pay-for-reporting'' performance requirement for OASIS reporting is actually based on a ''pay for performance'' model.

Response: The ''pay-for-reporting performance requirement'' discussed above is not a pay-for-performance model. This performance requirement simply sets a standard for the type and minimum number of OASIS assessments that each HHA must submit during a 12 month reporting period. If a HHA submits the required number of OASIS assessments during the 12 month reporting period, they will receive their full market basket update for the following calendar year.

Final Decision: After consideration of the public comments received, we are adopting as final, our proposal to establish a pay-for-reporting performance requirement, with the modifications stated below:

- For episodes beginning on or after July 1st, 2015 and before June 30th, 2016, HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance requirement or be subject to a 2 percentage point reduction to their market basket update for CY 2017.
- We defer for now from setting a minimum OASIS reporting requirement for the 2nd and subsequent years of the OASIS ''pay-for-reporting'' performance requirement program. However, we will consider increasing the requirement in subsequent years. We anticipate rates of at least 80 percent or higher, not exceed 90 percent, in years 2 and 3.

d. Updates to HH QRP Measures Which Are Made as a Result of Review by the NQF Process

In the proposed rule, we noted that section 1895(b)(3)(B)(v)(II) of the Act generally requires the Secretary to adopt measures that have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the NQF. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process.[27]

The NQF undertakes to: (1) Review new quality measures and national consensus standards for measuring and publicly reporting on performance; (2) provide for annual measure maintenance updates to be submitted by the measure steward for endorsed quality measures; (3) provide for measure maintenance endorsement on a 3-year cycle; (4) conduct a required follow-up review of measures with time limited endorsement for consideration of full endorsement; and (5) conduct ad hoc reviews of endorsed quality measures, practices, consensus standards, or events when there is adequate justification for a review. In the normal course of measure maintenance, the NQF solicits information from measure stewards for annual reviews to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to the NQF on an annual basis. As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence for review by a NQF Technical Expert panel which, in turn, provides input to the Consensus Standards Approval Committee which then makes a decision on endorsement status and/or specification changes for the measure, practice, or event.

Through the NQF's measure maintenance process, the NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. With respect to what constitutes a substantive versus a non-substantive change, we expect to make this determination on a measure-by-measure basis. Examples of such non-substantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and changes to exclusions for a measure. We believe that non-substantive changes may include updates to measures based upon changes to guidelines upon which the measures are based. These types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

We proposed that, in the event that the NQF makes updates to an endorsed measure that we have adopted for the HH QRP in a manner that we consider to not substantially change the nature of the measure, we will use a sub-regulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we stated that we would revise the information that is posted on the CMS Home Health Quality Initiatives Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html* so that it clearly identifies the updates and provides links to where additional information on the updates can be found. We also stated that we would refer HHAs to the NQF Web site for the most up-to date information about the quality measures (*http://www.qualityforum.org/*). In addition, we stated that we would provide sufficient lead time for HHAs to implement the changes where changes to the data collection systems would be necessary.

We further proposed to use the traditional ''notice and comment'' rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent, such as changes in acceptable timing of medication, procedure/process, test administration, or expansion of the measure to a new setting. We believed that our proposal adequately balances our need to incorporate NQF updates to NQF endorsed measures used in the HH QRP in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted.

We noted that a similar policy was adopted for the Hospital IQR Program, the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program, the Long-Term Care Hospital Quality Reporting (LTCHQR) Program, the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) and the Inpatient Psychiatric Facility (IPF) Quality Reporting Program.

We invited public comment on our proposal to adopt a policy in which NQF changes to a measure that are non-substantive in nature will be adopted using a sub-regulatory process and NQF

[27] For more information about the NQF Consensus Development Process, please visit the NQF Web site using the following link: *http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx.*

changes that are substantive in nature will be adopted through the rulemaking process. We received the following public comments in response to this proposal:

Comment: One commenter was opposed to our proposal to use sub-regulatory guidance to incorporate NQF updates to previously endorsed measures unless NQF itself, in communication accompanying such updates, affirms that such updates do not substantially change the nature of the measure.

Response: We believe it unlikely that NQF will undertake to make a determination as to whether a change to a measure is substantive or non-substantive. This is a policy determination that NQF is likely to leave to the discretion of the measure steward. In the event that a measure that has been previously adopted for use in the HH QRP is updated in a manner that we determine to be non-substantive in nature, we will ensure that stakeholders are fully informed about these changes and that they have been afforded adequate lead time to make any necessary changes. The NQF process requires an ad-hoc review of any measures that undergo substantive changes, and any party may request such an ad hoc review. If stakeholders believe a change to measures is substantive, they are encouraged to participate in the NQF process.

Comment: Several commenters expressed a concern that the definition of what changes are considered to substantive and what changes are non-substantive is not clear.

Response: As noted above, with respect to what constitutes a substantive versus a non-substantive change, we expect to make this determination on a measure-by-measure basis. Examples of such non-substantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and changes to exclusions for a measure. We believe that non-substantive changes may include updates to measures based upon changes to guidelines upon which the measures are based. These types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

Comment: One commenter expressed the opinion that CMS should develop a more comprehensive list of substantive and non-substantive change in a measure, and further suggested that stakeholders should be given the opportunity to submit comments on the list for CMS to consider.

Response: We appreciate the commenters request for a more comprehensive list of substantive and non- substantive change in a measure, and the opportunity to submit comments on such lists. However, as noted above, we believe that our proposal adequately balances our need to incorporate NQF updates to NQF endorsed measures used in the HH QRP in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We noted that a similar policy was adopted for the Hospital Inpatient Quality Reporting (IQR) Program, the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program, the Long-Term Care Hospital Quality Reporting (LTCHQR) Program, the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) and the Inpatient Psychiatric Facility (IPF) Quality Reporting Program.

Comment: A commenter expressed concern that most HH providers are not aware of the NQF Consensus Development process, and therefore may not have the opportunity to comment on changes to measures.

Response: The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in updates to the NQF-endorsed measures. HHAs can go to the NQF Web page for information about the measure endorsement process. The NQF process is open to the public and transparent and incorporates an opportunity for public comment and engagement in the measure maintenance process.

In the event that any measure that has been previously adopted for use in the HH QRP is updated through the NQF process, we will ensure that stakeholders are fully informed about these changes and that they have been afforded adequate lead time to make any necessary changes. Some of the methods that we will use to keep our stakeholders informed include: (1) Posting of information on the HH Quality Initiatives Web page; (2) holding special open door forums; (3) posting information in the CMS weekly E-News publication; and (4) responding to provider questions. While we expect to provide notice to stakeholders when we intend to seek NQF's review of measures, the NQF process also incorporates an opportunity for public comment and engagement in the measure maintenance process.

Comment: Another commenter recommended that CMS notify HH providers when NQF, in their Consensus Development Process, is asking for input on NQF-endorsed measures used by HHAs, in order to give them an opportunity to comment on a change in the measure.

Response: We anticipate that in most cases such changes will occur, not during the measure development process, but after a measure has already been endorsed by NQF and has been adopted for use in the HH QRP. Changes to adopted measures could take place during yearly measure maintenance or during the 3 year measure review process.

We acknowledge that the NQF post-endorsement reviews may provide limited opportunity for provider engagement in the process. Therefore, we will make every effort to keep stakeholders informed about reviews to HH quality measures. Some of the methods that we will use to keep our stakeholders informed include: (1) Posting of information on the HH Quality Initiatives Web page; (2) holding special open door forums; (3) posting information in the CMS weekly E-News publication; and (4) responding to provider questions.

Comment: One commenter expressed the concern about whether changes labeled as non-substantive changes are truly ''non-substantive''. This commenter proposed that CMS convene a panel of HH experts, drawn from individuals representing various regions of the country and types of agencies (urban, rural, profit, non-profit, governmental, etc.) with experience in the industry, to offer their opinion on whether changes to a measure are truly ''non-substantive'' in nature. The commenter further suggested that the panel be allowed to consider the changes for ''two cycles of consideration'' and if the panel supports the changes, then the sub-regulatory could be used.

Response: In the proposed rule, we proposed to establish a policy that ''in the event that the NQF makes updates to an endorsed measure that we have adopted for the HH QRP in a manner that we consider to not substantially change the nature of the measure, we will use a sub-regulatory process to incorporate those updates to the measure specifications that apply to the program.'' It is our intent that this policy apply to existing NQF-endorsed quality measures that have already been adopted for use in the HH QRP. These measures have undergone the measure

development and endorsement process which typically includes multiple opportunities for input from stakeholders. Examples of stakeholder involvement include, but are not limited to: (1) Expert opinions obtained from a technical expert panel consisting of experts drawn from the HH community, (2) public comments solicited during the measure development process, and (3) multiple opportunities to provide input during the NQF endorsement process. HHAs will have multiple opportunities to become familiar with and provide their input related to the existing HH quality measures by the time they come up for the NQF one year measure maintenance review or the 3 year re-endorsement review.

Because the NQF process is open and transparent and readily available to HHAs, they can learn of possible changes existing HH quality measure as a result of the NQF process and provide their input should they choose to do so. Furthermore, the NQF process provides for a comprehensive and in-depth review of all quality measures under review (including changes to these measures) by a highly qualified panel of experts in the field of home health care. For these reasons, we do not believe it is necessary to convene another panel of home health experts, as suggested by this commenter, to seek an opinion on whether changes to a measure are truly ''non-substantive'' in nature.

This commenter further suggested that the expert panel be allowed to consider the changes for ''two cycles of consideration'' and if the panel supports the changes, then the sub-regulatory process should be used. It is not clear how this commenter defines ''two cycles of consideration'', however, it is not feasible for CMS to allow a decision regarding changes to an existing quality measure to go unresolved for a prolonged period of time. It is necessary for CMS to immediately assess any changes made to existing quality measures to determine if changes to the data collection process, data collection instrument, or technical specifications must be made. In addition CMS must determine if provider training or educational materials are required.

Final Decision: After consideration of the public comments we received, we are adopting final a policy to: (1) Utilize a sub-regulatory process to incorporate updates to the HH QRP quality measures that are not substantive in nature; and (2) continue use of the rulemaking process to adopt changes to measures that we consider to be substantive in nature.

e. Home Health Care CAHPS® Survey (HHCAHPS)

In the CY 2014 HH PPS final rule (78 FR 72294), we stated that the HH quality measures reporting requirements for Medicare-certified agencies includes the Home Health Care CAHPS® (HHCAHPS) Survey for the CY 2014 APU. We are continuing to maintain the stated HHCAHPS data requirements for CY 2015 that have been set out in CY 2014 and in previous rules. We note that home health agencies and HHCAHPS survey vendors sometimes refer to the Home Health Care CAHPS® Survey as ''HH–CAHPS'' rather than ''HHCAHPS''.

(1) Background and Description of HHCAHPS

As part of the HHS Transparency Initiative, we implemented a process to measure and publicly report patient experiences with home health care, using a survey developed by the Agency for Healthcare Research and Quality's (AHRQ's) Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program and endorsed by the NQF in March 2009 (NQF Number 0517). The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The Home Health Care CAHPS® (HHCAHPS) survey presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care.

Prior to this survey, there was no national standard for collecting information about patient experiences that will enable valid comparisons across all HHAs. The history and development process for HHCAHPS has been described in previous rules and is also available on the official HHCAHPS Web site at *https://homehealthcahps.org* and in the annually-updated *HHCAHPS Protocols and Guidelines Manual,* which is downloadable from *https://homehealthcahps.org.*

For public reporting purposes, we report five measures from the HHCAHPS Survey—three composite measures and two global ratings of care that are derived from the questions on the HHCAHPS survey. The publicly reported data are adjusted for differences in patient mix across HHAs. We update the HHCAHPS data on Home Health Compare on *www.medicare.gov* quarterly. Each HHCAHPS composite measure consists of four or more individual survey items regarding one of the following related topics:

- Patient care (Q9, Q16, Q19, and Q24);
- Communications between providers and patients (Q2, Q15, Q17, Q18, Q22, and Q23); and
- Specific care issues on medications, home safety, and pain (Q3, Q4, Q5, Q10, Q12, Q13, and Q14).

The two global ratings are the overall rating of care given by the HHA's care providers (Q20), and the patient's willingness to recommend the HHA to family and friends (Q25).

The HHCAHPS survey is currently available in English, Spanish, Chinese, Russian, and Vietnamese. The OMB number on these surveys is the same (0938–1066). All of these surveys are on the Home Health Care CAHPS® Web site, *https://homehealthcahps.org.* We continue to consider additional language translations of the HHCAHPS in response to the needs of the home health patient population.

All of the requirements about home health patient eligibility for the HHCAHPS survey and conversely, which home health patients are ineligible for the HHCAHPS survey are delineated and detailed in the *HHCAHPS Protocols and Guidelines Manual,* which is downloadable at *https://homehealthcahps.org.* Home health patients are eligible for HHCAHPS if they received at least two skilled home health visits in the past 2 months, which are paid for by Medicare or Medicaid.

Home health patients are ineligible for inclusion in HHCAHPS surveys if one of these conditions pertains to them:

- Are under the age of 18;
- Are deceased prior to the date the sample is pulled;
- Receive hospice care;
- Receive routine maternity care only;
- Are not considered survey eligible because the state in which the patient lives restricts release of patient information for a specific condition or illness that the patient has; or
- No Publicity patients, defined as patients who on their own initiative at their first encounter with the HHAs make it very clear that no one outside of the agencies can be advised of their patient status, and no one outside of the HHAs can contact them for any reason.

We stated in previous rules that Medicare-certified HHAs are required to contract with an approved HHCAHPS survey vendor. This requirement continues, and Medicare-certified agencies also must provide on a monthly basis a list of their patients served to their respective HHCAHPS survey vendors. Agencies are not allowed to influence at all how their patients respond to the HHCAHPS survey.

As previously required, HHCAHPS survey vendors are required to attend introductory and all update trainings conducted by CMS and the HHCAHPS Survey Coordination Team, as well as to pass a post-training certification test. We have approximately 30 approved HHCAHPS survey vendors. The list of approved HHCAHPS survey vendors is available at *https://homehealthcahps.org.*

(2) HHCAHPS Oversight Activities

We stated in prior final rules that all approved HHCAHPS survey vendors are required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. The purpose of the oversight activities is to ensure that approved HHCAHPS survey vendors follow the *HHCAHPS Protocols and Guidelines Manual.* As stated in previous HH PPS final rules, all HHCAHPS approved survey vendors must develop a Quality Assurance Plan (QAP) for survey administration in accordance with the *HHCAHPS Protocols and Guidelines Manual.* An HHCAHPS survey vendor's first QAP must be submitted within 6 weeks of the data submission deadline date after the vendor's first quarterly data submission. The QAP must be updated and submitted annually thereafter and at any time that changes occur in staff or vendor capabilities or systems. A model QAP is included in the *HHCAHPS Protocols and Guidelines Manual.* The QAP must include the following:

- Organizational Background and Staff Experience;
- Work Plan;
- Sampling Plan;
- Survey Implementation Plan;
- Data Security, Confidentiality and Privacy Plan; and
- Questionnaire Attachments

As part of the oversight activities, the HHCAHPS Survey Coordination Team conducts on-site visits to all approved HHCAHPS survey vendors. The purpose of the site visits is to allow the HHCAHPS Survey Coordination Team to observe the entire HHCAHPS Survey implementation process, from the sampling stage through file preparation and submission, as well as to assess data security and storage. The HHCAHPS Survey Coordination Team reviews the HHCAHPS survey vendor's survey systems, and assesses administration protocols based on the *HHCAHPS Protocols and Guidelines Manual* posted at *https://homehealthcahps.org.* The systems and program site visit review includes, but is not limited to the following:

- Survey management and data systems;
- Printing and mailing materials and facilities;
- Telephone call center facilities;
- Data receipt, entry and storage facilities; and
- Written documentation of survey processes.

After the site visits, HHCAHPS survey vendors are given a defined time period in which to correct any identified issues and provide follow-up documentation of corrections for review. HHCAHPS survey vendors are subject to follow-up site visits on an as-needed basis.

In the CY 2013 HH PPS final rule (77 FR 67094, 67164), we codified the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

(3) HHCAHPS Requirements for the CY 2015 APU

In the CY 2014 HH PPS final rule (78 FR 72294), we stated that for the CY 2015 APU, we require continued monthly HHCAHPS data collection and reporting for 4 quarters. The data collection period for CY 2015 APU includes the second quarter 2013 through the first quarter 2014 (the months of April 2013 through March 2014). Although these dates are past, we included them in the proposed rule so that HHAs were reminded of what months constituted the requirements for the CY 2015 APU. HHAs were required to submit their HHCAHPS data files to the HHCAHPS Data Center for the HHCAHPS data from the first quarter of 2014 data by 11:59 p.m., e.d.t. on July 16, 2014.

(4) HHCAHPS Requirements for the CY 2016 APU

For the CY 2016 APU, we require continued monthly HHCAHPS data collection and reporting for 4 quarters. The data collection period for the CY 2016 APU includes the second quarter 2014 through the first quarter 2015 (the months of April 2014 through March 2015). We are in this data collection period now. HHAs are required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2014 by 11:59 p.m., e.d.t. on October 16, 2014; for the third quarter 2014 by 11:59 p.m., e.s.t. on January 15, 2015; for the fourth quarter 2014 by 11:59 p.m., e.d.t. on April 16, 2015; and for the first quarter 2015 by 11:59 p.m., e.d.t. on July 16, 2015. These deadlines are firm; no exceptions are permitted.

We exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count (April 1, 2013 through March 31, 2014) on or after April 1, 2014, from the full HHCAHPS reporting requirement for the CY 2016 APU, because these HHAs are not Medicare-certified throughout the period of April 1, 2013, through March 31, 2014. These HHAs do not need to complete a HHCAHPS Participation Exemption Request form for the CY 2016 APU.

We require that all HHAs that had fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2013 through March 31, 2014 request an exemption from the HHCAHPS data collection and submission requirements for the CY 2016 APU by completing the CY 2016 HHCAHPS Participation Exemption Request form. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2013, through March 31, 2014, are required to submit their patient counts on the HHCAHPS Participation Exemption Request form for the CY 2016 APU posted on *https://homehealthcahps.org* from April 1, 2014, to 11:59 p.m., e.s.t. on March 31, 2015. This deadline for the exemption form is firm, as are all of the quarterly data submission deadlines.

(5) HHCAHPS Requirements for the CY 2017 APU

For the CY 2017 APU, we require continued monthly HHCAHPS data collection and reporting for 4 quarters. The data collection period for the CY 2017 APU includes the second quarter 2015 through the first quarter 2016 (the months of April 2015 through March 2016). HHAs are required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2015 by 11:59 p.m., e.d.t. on October 15, 2015; for the third quarter 2015 by 11:59 p.m., e.s.t. on January 21, 2016; for the fourth quarter 2015 by 11:59 p.m., e.d.t. on April 21, 2016; and for the first quarter 2016 by 11:59 p.m., e.d.t. on July 21, 2016. These deadlines are firm; no exceptions are permitted.

We exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count (April 1, 2014 through March 31, 2015) on or after April 1, 2015, from the full HHCAHPS reporting requirement for the CY 2016 APU, because these HHAs are not Medicare-certified throughout the period of April 1, 2014, through March 31, 2015. These HHAs do not need to complete a CY 2017 HHCAHPS Participation Exemption Request form.

We require that all HHAs that had fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the

period of April 1, 2014, through March 31, 2015 request an exemption from the HHCAHPS data collection and submission requirements for the CY 2017 APU by completing the CY 2017 HHCAHPS Participation Exemption Request form. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2014, through March 31, 2015, are required to submit their patient counts on the CY 2017 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2015, to 11:59 p.m., e.s.t. on March 31, 2016. This deadline for the exemption form is firm, as are all of the quarterly data submission deadlines.

(6) HHCAHPS Reconsiderations and Appeals Process

HHAs should always monitor their respective HHCAHPS survey vendors to ensure that vendors submit their HHCAHPS data on time, by accessing their HHCAHPS Data Submission Reports on *https://homehealthcahps.org.* This helps HHAs ensure that their data are submitted in the proper format for data processing to the HHCAHPS Data Center.

We continue HHCAHPS oversight activities as finalized in the previous rules. In the CY 2013 HH PPS final rule (77 FR 6704, 67164), we codified the current guideline that all approved HHCAHPS survey vendors must fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

We continue the HHCAHPS reconsiderations and appeals process that we have finalized and that we have used for all prior periods cited in the previous rules, and utilized in the CY 2012 through CY2014 annual payment update recommendations and determinations. We have described the HHCAHPS reconsiderations and appeals process requirements in the Technical Direction Letter that we send to the affected HHAs annually in September. HHAs have 30 days from their receipt of the Technical Direction Letter informing them that they did not meet the HHCAHPS requirements to reply to CMS with documentation that supports their requests for reconsideration of the annual payment update to CMS. It is important that the affected HHAs send in comprehensive information in their reconsideration letter/package because we will not contact the affected HHAs to request additional information or to clarify incomplete or inconclusive information. If clear evidence to support a finding of compliance is not present, then the 2 percent reduction in the APU will be upheld. If clear evidence of compliance is present, then the 2 percent reduction for the APU will be reversed. We will notify affected HHAs by December 31st of the decisions that affect payments in the annual year beginning on January 1st. If we determine to uphold the 2 percent reduction for the annual payment update, the affected HHA may further appeal the 2 percent reduction via the Provider Reimbursement Review Board (PRRB) appeals process, which is described in the December letter.

The following is a summary of the comments we received regarding HHCAHPS:

Comment: A commenter stated that HHCAHPS is an unfunded administrative mandate that entails financial and resource burdens to HHAs.

Response: This comment is outside the scope of the proposed rule. We finalized the collection of HHCAHPS in the CY2014 HH PPS Final Rule published in the **Federal Register** on December 2, 2013 (78 FR 72256). Please see the comments received and our responses on pages 72295 and 72296.

Comment: A commenter stated that a more timely way of collecting and publicly reporting the HHCAHPS survey data needs to be developed.

Response: We understand this concern to collect the data in a timely manner. This is why the patients are sampled in the month following the two months of their care. We have a very strict timetable for how the 42-day survey data collection period is to be implemented, as described in the HHCAHPS Protocols and Guidelines Manual that is posted on *https://homehealthcahps.org.* We also allow time for the data received in from thousands of home health agencies to be processed and analyzed to ensure comparisons that are reliable and valid. We apply patient mix adjustment to the HHCAHPS data to allow for national comparisons. The best way to understand the reasons for our detailed survey implementation procedures is to examine the relevant sections in the *HHCAHPS Protocols and Guidelines Manual* which is posted on *https://homehealthcahps.org.*

HHAs may always request their respective HHCAHPS survey vendors to provide continual feedback on particular questions of the survey so that they are kept apprised of any issues that their patients are reporting on the HHCAHPS surveys. When HHAs contract with their vendors about the terms of their HHCAHPS data collection and processing processes, they may arrange for ways to receive survey feedback information in real-time.

Final Decision: We are not recommending any changes as a result of comments we received.

(7) For Further Information on the HHCAHPS Survey

We strongly encourage HHAs to learn about the HHCAHPS Survey and to view the official Web site for HHCAHPS at *https://homehealthcahps.org.* For further information, HHAs may also send email correspondence to the HHCAHPS Survey Coordination Team at *HHCAHPS@rti.org;* or telephone toll-free (1–866–354–0985) for more information about HHCAHPS.

3. CY 2015 Home Health Wage Index

a. Background

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We proposed to continue this practice for CY 2015, as we continue to believe that, in the absence of HH-specific wage data, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. Specifically, we proposed to continue to use the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2015, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2010 and before October 1, 2011 (FY 2011 cost report data).

We will apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence). Previously, we determined each HHA's labor market area based on definitions of metropolitan statistical areas (MSAs) issued by the Office of Management and Budget (OMB). In the CY 2006 HH PPS final rule (70 FR 68132), we adopted revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of micropolitan statistical areas and core-based statistical areas (CBSAs). The bulletin is available online at *www.whitehouse.gov/omb/bulletins/b03–04.html.* In adopting the CBSA

geographic designations, we provided a one-year transition in CY 2006 with a blended wage index for all sites of service. For CY 2006, the wage index for each geographic area consisted of a blend of 50 percent of the CY 2006 MSA-based wage index and 50 percent of the CY 2006 CBSA-based wage index. We referred to the blended wage index as the CY 2006 HH PPS transition wage index. As discussed in the CY 2006 HH PPS final rule (70 FR 68132), since the expiration of this one-year transition on December 31, 2006, we have used the full CBSA-based wage index values.

In the CY 2015 HH PPS proposed rule, we proposed to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2015 HH PPS wage index. For rural areas that do not have inpatient hospitals, we would use the average wage index from all contiguous CBSAs as a reasonable proxy. For FY 2015, there are no rural geographic areas without hospitals for which we would apply this policy. For rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we would continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we would use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2015, the only urban area without inpatient hospital wage data is Hinesville, Georgia (CBSA 25980).

A summary of the comments we received regarding the wage index and our responses to those comments appears below. Comments on the specific proposal to use revised OMB delineations as part of the wage index are discussed further below.

Comment: A commenter is concerned about the policy for imputing a rural wage index in instances where there is no hospital. The commenter is concerned about the impact for Texas and sizable rural areas, where some rural geographic areas that almost certainly do not have an inpatient hospital, but are significant metropolitan areas such as Dallas and Houston. The commenter asserts that wage rates vary considerably in Texas between these urban and rural areas and urges CMS to be extremely cautious in this pursuit and analyze the effects of such assumptions in the methodology.

Response: As stated previously, there are currently no rural areas without hospitals. Therefore, the wage index proxy is not applicable for any rural area in CY 2015. We appreciate the comment and assure the commenter that if the need for a rural wage index proxy should arise, we would re-evaluate the policy in order to avoid possible unintended consequences. As such, we would propose any potential revision to this policy through rulemaking.

Comment: Commenters stated that hospitals have a competitive advantage in being able to apply for geographic reclassification to other CBSAs and being able to apply for the rural floor and that this creates a competitive advantage for hospitals in recruiting and retaining nurses and therapists. Commenters stated that the wage index can be very volatile with large decreases and increases in an area index value from one year to the next. Commenters stated that all provider sectors should use the same index with the same rights of reclassification, exceptions, and appeals. Commenters urged us to work with home health providers to develop regulatory and legislative remedies to the continuing problem of wage index disparity. One commenter stated that the same MSAs continue to be rewarded with higher wage indexes, while MSAs like Asheville, NC and rural NC continue to be penalized with lower wage indexes. This commenter states that the current system rewards MSAs that have inefficient and inappropriate hospital costs, and is very volatile with large decreases and increases in an MSA from one year to the next. One commenter noted that CMS is reviewing the entire wage index system and considering a move to a Commuting-Based Wage Index that would set hospital-specific wage indices. The commenter urges CMS to expedite that review and implement a system that not only recognizes variations between localities, but also treats all provider types within a local market equitably. In the meantime, commenters urge CMS to implement an immediate policy to limit the wage index variations among provider types within CBSA's and adjacent markets. Another stated that unexpected increases and decreases in wage index values should be spread over two or more years to reduce the rapid escalation or decline in wage index values and thus create more payment stability in a budget neutral fashion. The commenter specifically requests CMS respond to this broader recommendation. One commenter urged CMS to adjust the 2015 home health agency wage index to reflect a policy to limit the wage index disparity between provider types within a given CBSA to no more than 10%.

Response: Consistent with our previous responses to these recurring comments (most recently published in the CY 2014 HH PPS final rule (78 FR 72302)), the regulations that govern the HH PPS do not provide a mechanism for allowing HHAs to seek geographic reclassification or to utilize the rural floor provisions that exist for IPPS hospitals. The rural floor provision in section 4410 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) is specific to hospitals. The reclassification provision found in section 1886(d)(10) of the Act is also specific to hospitals. CMS is exploring opportunities to reform the wage index. We refer readers to the CMS Web site at: *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*). We do not believe it would be appropriate to limit wage index differences or changes which are above or below a given level or to spread changes in wage index values over multiple years. The wage index values are updated annually and applying these types of changes would make the area wage index less reflective of the geographic area's wages.

Comment: A commenter believes that linking home health wage index adjustments to the pre-floor, pre-reclassified hospital wage index may have been acceptable when this index only impacted the home health payment caps under cost reimbursement that most providers never reached. However, the commenter believes that this measure is imprecise to adjust every home health payment under HHPPS and creates clear and meaningful inaccuracies. Previously, CMS responded to this comment by citing a historical precedent of 20 years ago when a home health specific wage index was proposed by CMS as part of the payment capping mechanism and was opposed by many home health agencies. The commenter requests that CMS agree to collaborate with the home health community to develop a home health specific wage index based on current data on the wage categories used in home health care today and the related costs of this labor. An additional commenter also suggested that CMS pursue a home health specific wage index. Another commenter suggested that a new wage system could be

considered for non-hospital provider sectors.

Response: Developing a wage index that utilizes data specific to HHAs would require us to engage resources in an audit process. In order to establish a home health specific wage index, we would need to collect data that is specific to home health services. This is not currently feasible due to the volatility of existing home health wage data and the significant amount of resources that would be required to improve the quality of that data. Furthermore, we believe the collection of home health specific wage data would place a significant amount of additional burden on HHAs. As discussed above, we continue to believe that in the absence of home health specific wage data, using the pre-floor, pre-reclassified hospital wage data is appropriate and reasonable for the HH PPS.

Comment: A commenter expressed concern that when a hospital appeals or requests exceptions to what they believe are errors in the wage data, that corrections are not granted. The commenter asked us to reconsider this matter and believes that all providers should have the right to appeal or request exceptions when they suspect that there are errors in the data on which their rates will be based.

Response: When a hospital submits an appeal of its wage data, CMS ensures that the appeal goes through the proper protocol and is given consideration. Not every appeal will warrant being granted. When appeals are valid, CMS take immediate action to correct the wage data and publish corrections to the wage indices for all provider types.

Comment: A commenter is concerned that the home health wage index is based on inpatient hospital wage data, which in some cases contains errors that can result in significant fluctuations in the HHA wage index. Based on the Hospital Wage Index Development Timetable, there are specific deadlines for hospitals to report errors in the wage data to their MAC, CMS emphasizes that data that is incorrect in the preliminary hospital wage index data PUFs, but for which no correction request was received by the deadline, will not be changed for inclusion in the wage index. Another commenter stated that the inaction of a hospital or a mishandling of data by CMS or the MAC should not result in the lowering of an area's wage index value and, therefore, lowering Medicare payments for all HHAs in the area. Other commenters stated that inaccurate cost report data results in unpredictable year to year swings in the wage index values. Commenters are concerned that HHAs are subject to a wage index database that they have no control over. As such, HHAs are at the mercy of hospital data submission and have no means to correct erroneous data or avoid the impact of any unusual compensation changes in a hospital.

Response: We believe that the mechanisms we employ ensure the accuracy of the hospital cost report data and resulting wage index. Our contractors perform desk reviews of all hospital cost report Worksheet S–3 wage data. In addition, we perform edits on the wage data to further ensure the accuracy and validity of the wage data. Any provider may submit comments on the hospital wage index during the annual IPPS rulemaking. We believe that our review processes result in an accurate collection of wage data.

Comment: A commenter requested that CMS remove six specific counties in New Jersey from the New York City wage index.

Response: We believe that the OMB standards for delineating Metropolitan and Micropolitan Statistical Areas are appropriate for determining wage area differences. We do not believe it would be appropriate to make exceptions and carve out specific areas from the OMB delineations. The 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas were published in a **Federal Register** Notice on June 28, 2010 (75 FR 37246).

Final Decision: After considering the comments received, for the reasons discussed above and in the CY 2015 HH PPS proposed rule (79 FR 38366), we are finalizing our proposal to continue to use the pre-floor, pre-reclassified hospital inpatient wage index data to develop the HH PPS wage index. For CY 2015, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2010 and before October 1, 2011 (FY 2011 cost report data).

b. Update

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. This bulletin is available online at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.* This bulletin states that it ''provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246–37252) and Census Bureau data.''

While the revisions OMB published on February 28, 2013 are not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2006, the February 28, 2013 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart.

As discussed in the CY 2014 HH PPS final rule (78 FR 72302), the changes made by the bulletin and their ramifications required extensive review by CMS before using them for the HH PPS wage index. We completed our assessment and in the FY 2015 IPPS final rule (79 FR 49854), and stated that we will use the most recent labor market area delineations issued by OMB for payments for inpatient stays at general acute care and long-term care hospitals (LTCHs). In addition, in the FY 2015 Skilled Nursing Facility (SNF) PPS final rule (79 FR 45628), we made a final decision to use the new labor market delineations issued by OMB for payments for SNFs.

c. Implementation of New Labor Market Delineations

We believe it is important for the HH PPS to use the latest OMB delineations available to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. While CMS and other stakeholders have explored potential alternatives to the current CBSA-based labor market system (we refer readers to the CMS Web site at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*), no consensus has been achieved regarding how best to implement a replacement system. As discussed in the FY 2005 IPPS final rule (69 FR 49027), ''While we recognize that MSAs are not designed specifically to define labor market areas, we believe they do represent a useful proxy for this purpose.'' We further believe that using the most current OMB delineations will increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. We have reviewed our findings and impacts relating to the new OMB delineations, and have concluded that there is no compelling reason to further delay implementation.

We proposed to incorporate the new CBSA delineations into the CY 2015 HH PPS wage index in the same manner in

which the CBSAs were first incorporated into the HH PPS wage index in CY 2006 (70 FR 68138). We proposed to use a one-year blended wage index for CY 2015. We referred to this blended wage index as the CY 2015 HH PPS transition wage index. The proposed transition wage index would consist of a 50/50 blend of the wage index values using OMB's old area delineations and the wage index values using OMB's new area delineations. That is, for each county, a blended wage index would be calculated equal to fifty percent of the CY 2015 wage index using the old labor market area delineation and fifty percent of the CY 2015 wage index using the new labor market area delineation (both using FY 2011 hospital wage data). This ultimately results in an average of the two values.

The comments we received on the proposal to include the newest OMB area delineations into the HH PPS wage index and the proposed wage index transition methodology and our responses to these comments, appear below:

Comment: Some commenters have reservations about CMS's proposal to adopt revisions to the CBSAs developed by the Census Bureau and OMB. Commenters strongly support a phased-in approach to provide a more uniform and equitable transition for providers impacted by the CBSA revisions. Commenters believe that a phased-in approach will mitigate short-term financial instability and better align OMB's labor market areas with the actual labor costs of provider organizations.

Response: While CMS and other stakeholders have explored potential alternatives to the current CBSA-based labor market system (we refer readers to the CMS Web site at: *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*), no consensus has been achieved regarding how best to implement a replacement system. As stated in the FY 2005 IPPS final rule (69 FR 49027), while we recognize that MSAs are not designed specifically to define labor market areas, we believe they do represent a useful proxy for this purpose. We believe that using the most current OMB delineations would increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. We believe that the most current OMB delineations accurately reflect the local economies and wage levels of the areas in which hospitals are currently located. In the CY 2015 HH PPS proposed rule, we proposed a transition period of one year, during which a 50/50 blended wage index would be used for all providers in CY 2015, in order to mitigate the resulting short-term instability and negative impacts on certain providers and to provide time for providers to adjust to their new labor market delineations. Under this proposal, providers would receive 50 percent of their FY 2015 wage index based on the new OMB delineations and 50 percent of their FY 2015 wage index based on the labor market delineations for CY 2014 (both using FY 2011 hospital wage data).

Comment: Most commenters support using a 50/50 blend of the current CBSA areas with the new CBSA areas as a way of easing the transition to the new geographic area designations. A commenter supports the budget neutrality adjustment to account for changes in the wage indices.

Response: We thank the commenters for their support of these two policies.

Comment: While a commenter commends CMS on the proposed wage index phase-in, which should afford home health providers time to adjust their budgets, expenses and operations, the commenter also recommends that home health providers that have been negatively impacted in such reclassified areas be permitted to seek a hardship exception or additional phase-in period. Such measures could be used in the event providers find that the characteristics of their operating areas remain representative of rural communities. This will help ensure that beneficiary access to home health services in such areas is not stifled or significantly negatively impacted.

Response: We do not believe that the adoption of the OMB's new area delineations will impact HHAs that provide care to beneficiaries who are located in areas whose delineations have changed to such an extent that the HHAs will no longer be able to provide care in their current locale. As always, we continue to monitor home health utilization to determine if there are any problems related to beneficiary access to care.

Comment: A commenter states that CMS' one-year transition policy of using a 50/50 blend of the previous and updated CBSA values is inconsistent with CMS' policy published in the Inpatient Prospective Payment System (IPPS) and Long- Term Acute Care Hospital-Prospective Payment System (LTCH–PPS) final rule. That rule applies a one-year 50/50 blending of the previous and updated CBSA values, respectively, only to facilities whose payments will decrease based on the use of the updated CBSAs. This inconsistency unfairly penalizes home health agencies that would benefit from applying the new CBSA delineations exclusively. Consequently, the commenter recommends that CMS apply the one-year 50/50 blend to any agencies experiencing a decrease in their payments, but utilize the new CBSA delineations for those agencies that will experience an increase in their Medicare payments. In contrast, another commenter stated that while the current requirement to maintain budget neutrality means that some agencies will not immediately see the full increases in their wage index values to reduce the impact of those with decreases, the commenter believes this is a worthwhile trade-off to assure that those agencies who would otherwise suffer sudden and significant payment declines.

Response: The implementation of the revised OMB delineations, which we are finalizing in this rule, sets home health payments at a level that more accurately reflects the costs of labor in a geographic area. Accordingly, under this policy, HHAs will experience a decrease from their current wage index only to the extent that their current wage index value actually exceeds what the latest area wage data warrants using the revised OMB delineations, and they will experience an increase from their current wage index value to the extent that their current wage index value is less than what the latest area wage data warrants using the revised OMB delineations. As discussed in the CY 2015 HH PPS proposed rule (79 FR 38416), we considered whether or not the blended wage index should be used for all HHAs or for only a subset of HHAs, such as those HHAs that would experience a decrease in their respective wage index values due to implementation of the revised OMB delineations. If we were to apply the transition policy only to those HHAs that would experience a decrease in their respective wage index values due to implementation of the revised OMB delineations, the wage index budget neutrality factor, discussed in section III.D.4, would result in reduced base rates for all HHAs as compared to the budget neutrality factor that results from applying the blended wage index to all HHAs. We believe that our proposal to apply a one-year blended wage index in CY 2015 for all geographic areas appropriately balances the interests of all HHAs and would best achieve our objective of providing relief to negatively impacted HHAs.

Final Decision: For the reasons previously discussed, we are finalizing our proposal to include changes to the

HH PPS wage index based on the newest OMB area delineations and to apply a one-year blended wage index in CY 2015 for all geographic areas to assist providers in adapting to these changes. This transition policy will be in effect for a one-year period, beginning January 1, 2015, and continuing through December 31, 2015. Thus, beginning January 1, 2016, the wage index for all HH PPS payments will be fully based on the new OMB delineations.

The wage index Addendum provides a crosswalk between the CY 2015 wage index using the current OMB delineations in effect in CY 2014 and the CY 2015 wage index using the revised OMB delineations. Addendum A shows each state and county and its corresponding transition wage index along with the previous CBSA number, the new CBSA number and the new CBSA name. Due to the calculation of the blended transition wage index, some CBSAs may have more than one transition wage index value associated with that CBSA. However, each county will have only one transition wage index. Therefore, for counties located in CBSAs that correspond to more than one transition wage index, a number other than the CBSA number will need to be input on the claim for CY 2015 only. These numbers are shown in the last column of Addendum A. The final CY 2015 transition wage index as set forth in Addendum A is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html*

4. CY 2015 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS is a national, standardized 60-day episode payment rate. As set forth in 42 CFR 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary.

To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. The labor-related share of the case-mix adjusted 60-day episode rate will continue to be 78.535 percent and the non-labor-related share will continue to be 21.465 percent as set out in the CY 2013 HH PPS final rule (77 FR 67068). The CY 2015 HH PPS rates will use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and adjusted as described in section III.C. of this rule. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode rate:

(1) Multiply the national 60-day episode rate by the patient's applicable case-mix weight.

(2) Divide the case-mix adjusted amount into a labor (78.535 percent) and a non-labor portion (21.465 percent).

(3) Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.

(4) Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments.

In accordance with section 1895(b)(3)(B) of the Act, this document constitutes the annual update of the HH PPS rates. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus two percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and § 484.205(b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare will use to pay the claim.

We may also adjust the 60-day case-mix and wage-adjusted episode payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in § 484.205(c) and § 484.230.
- A partial episode payment (PEP) adjustment as set forth in § 484.205(d) and § 484.235.
- An outlier payment as set forth in § 484.205(e) and § 484.240.

b. CY 2015 National, Standardized 60-Day Episode Payment Rate

Section 1895(3)(A)(i) of the Act required that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2015 national, standardized 60-day episode payment rate, we will apply a wage index standardization factor, a case-mix budget neutrality factor described in section III.C, the rebasing adjustment described in section II.C, and the MFP-adjusted home health market basket update discussed in section III.D.1 of this final rule.

To calculate the wage index standardization factor, henceforth referred to as the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the 2015 wage index and compared it to our simulation of total payments for non-LUPA episodes using the 2014 wage index. By dividing the total payments for non-LUPA episodes using the 2015 wage index by the total payments for non-LUPA episodes using the 2014 wage index, we obtain a wage index budget neutrality factor of 1.0024. We will apply the wage index budget neutrality factor of 1.0024 to the CY 2015 national, standardized 60-day episode rate.

As discussed in section III.C of this final rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we will apply a case-mix weights budget neutrality factor to the CY 2015 national, standardized 60-day episode payment rate. The case-mix weights budget neutrality factor is calculated as the ratio of total payments when CY 2015 case-mix weights are applied to CY 2013 utilization (claims) data to total payments when CY 2014 case-mix weights are applied to CY 2013 utilization data. The case-mix budget neutrality factor for CY 2015 will be 1.0366 as described in section III.C of this final rule.

Then, we will apply the −$80.95 rebasing adjustment finalized in the CY 2014 HH PPS final rule (78 FR 72256) and discussed in section II.C. Lastly, we will update the payment rates by the CY 2015 HH payment update percentage of 2.1 percent (MFP-adjusted home health market basket update) as described in section III.D.1 of this final rule. The CY 2015 national, standardized 60-day episode payment rate will be $2,961.38 as calculated in Table 22.

TABLE 22—CY 2015 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2014 National, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage	CY 2015 National, standardized 60-day episode payment
$2,869.27	×; 1.0024	×; 1.0366	−$80.95	×; 1.021	= $2,961.38

The CY 2015 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2015 HH payment update (2.1 percent) minus 2 percentage points and is shown in Table 23.

TABLE 23—FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA—CY 2015 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2014 National, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage minus 2 percentage points	CY 2015 National, standardized 60-day episode payment
$2,869.27	×; 1.0024	×; 1.0366	−$80.95	×; 1.001	= $2,903.37

c. National Per-Visit Rates

The national per-visit rates are used to pay LUPAs (episodes with four or fewer visits) and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide);
- Medical Social Services (MSS);
- Occupational therapy (OT);
- Physical therapy (PT);
- Skilled nursing (SN); and
- Speech-language pathology (SLP).

To calculate the CY 2015 national per-visit rates, we start with the CY 2014 national per-visit rates. We then apply a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments and increase each of the six per-visit rates by the maximum rebasing adjustments described in section II.C. of this rule. We calculate the wage index budget neutrality factor by simulating total payments for LUPA episodes using the 2015 wage index and comparing it to simulated total payments for LUPA episodes using the 2014 wage index. By dividing the total payments for LUPA episodes using the 2015 wage index by the total payments for LUPA episodes using the 2014 wage index, we obtain a wage index budget neutrality factor of 1.0012. We will apply the wage index budget neutrality factor of 1.0012 to the CY 2015 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, there is no case-mix weights budget neutrality factor needed to ensure budget neutrality for LUPA payments. Finally, the per-visit rates for each discipline are updated by the CY 2015 HH payment update percentage of 2.1 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2015 national per-visit rates are shown in Tables 24 and 25.

TABLE 24—CY 2015 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH Discipline type	CY 2014 Per-visit payment	Wage index budget neutrality factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage	CY 2015 Per-visit payment
Home Health Aide	$54.84	×; 1.0012	+ $1.79	×; 1.021	$57.89
Medical Social Services	194.12	×; 1.0012	+ $6.34	×; 1.021	204.91
Occupational Therapy	133.30	×; 1.0012	+ $4.35	×; 1.021	140.70
Physical Therapy	132.40	×; 1.0012	+ $4.32	×; 1.021	139.75
Skilled Nursing	121.10	×; 1.0012	+ $3.96	×; 1.021	127.83
Speech-Language Pathology	143.88	×; 1.0012	+ 4.70	×; 1.021	151.88

The CY 2015 per-visit payment rates for an HHA that does not submit the required quality data are updated by the CY 2015 HH payment update (2.1 percent) minus 2 percentage points and is shown in Table 25.

TABLE 25—CY 2015 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline type	CY 2014 Per-visit rates	Wage index budget neutrality factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage minus 2 percentage points	CY 2015 Per-visit rates
Home Health Aide	$54.84	×; 1.0012	+ $1.79	×; 1.001	$56.75
Medical Social Services	194.12	×; 1.0012	+ $6.34	×; 1.001	200.89
Occupational Therapy	133.30	×; 1.0012	+ $4.35	×; 1.001	137.95
Physical Therapy	132.40	×; 1.0012	+ $4.32	×; 1.001	137.02
Skilled Nursing	121.10	×; 1.0012	+ $3.96	×; 1.001	125.33
Speech-Language Pathology	143.88	×; 1.0012	+ 4.70	×; 1.001	148.90

d. Low-Utilization Payment Adjustment (LUPA) Add-On Factors

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule, we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP (78 FR 72306). We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount. For example, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit will be $235.86 (1.8451 multiplied by $127.83), subject to area wage adjustment.

e. Non-Routine Medical Supply (NRS) Conversion Factor Update

Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the CY 2015 NRS conversion factor, we start with the 2014 NRS conversion factor ($53.65) and apply the −2.82 percent rebasing adjustment described in section II.C. of this rule (1 − 0.0282 = 0.9718). We then update the conversion factor by the CY 2015 HH payment update percentage (2.1 percent). We do not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The NRS conversion factor for CY 2015 is shown in Table 26.

TABLE 26—CY 2015 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2014 NRS Conversion factor	CY 2015 Rebasing adjustment	CY 2015 HH Payment update percentage	CY 2015 NRS Conversion factor
$53.65	×; 0.9718	×; 1.021	= $53.23

Using the CY 2015 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 27.

TABLE 27—CY 2015 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2015 NRS Payment amounts
1	0	0.2698	$14.36
2	1 to 14	0.9742	51.86
3	15 to 27	2.6712	142.19
4	28 to 48	3.9686	211.25
5	49 to 98	6.1198	325.76
6	99+	10.5254	560.27

For HHAs that do not submit the required quality data, we again begin with the CY 2014 NRS conversion factor ($53.65) and apply the −-2.82 percent rebasing adjustment discussed in section II.C of this final rule (1 − 0.0282 = 0.9718). We then update the NRS conversion factor by the CY 2015 HH payment update percentage (2.1 percent) minus 2 percentage points. The CY 2015 NRS conversion factor for

HHAs that do not submit quality data is shown in Table 28.

TABLE 28—CY 2015 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2014 NRS conversion factor	CY 2015 rebasing adjustment	CY 2015 HH payment update percentage minus 2 percentage points	CY 2015 NRS conversion factor
$53.65	×; 0.9718	×; 1.001	$52.19

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not submit quality data are calculated in Table 29.

TABLE 29—CY 2015 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2015 NRS payment amounts
1	0	0.2698	$ 14.08
2	1 to 14	0.9742	50.84
3	15 to 27	2.6712	139.41
4	28 to 48	3.9686	207.12
5	49 to 98	6.1198	319.39
6	99+	10.5254	549.32

f. Rural Add-On

Section 421(a) of the MMA required, for HH services furnished in a rural areas (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise will have been made under section 1895 of the Act for the services by 5 percent.

Section 5201 of the DRA amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006 and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 421 of the MMA, as amended, waives budget neutrality related to this provision, as the statute specifically states that the Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Act applicable to HH services furnished during a period to offset the increase in payments resulting in the application of this section of the statute.

The comments we received regarding the rural add-on, along with our responses, appear below:

Comment: One commenter questioned why the rural add-on will not apply after CY 2015. Several commenter urged CMS to not eliminate the rural add-on scheduled to sunset on December 31, 2015. A commenter stated that CMS should conduct a separate and comprehensive impact analysis on what the impact of elimination of the rural-add would have in the availability of home health services in rural areas. Another commenter asked if CMS would encourage the continuation of the rural add-on for the indefinite future beyond 2016.

Response: The rural add-on is a legislative provision, mandated by the Affordable Care Act, and CMS does not have the authority to revise the date at which the rural add-on expires. Since the inception of the HH PPS, at various points in time, rural add-ons have been applied to home health payments due to legislation. These rural add-ons have not been subject to budget neutrality. If CMS were to propose a regulatory policy change to provide a rural add-on payment, we would have to apply the add-on in a budget neutral manner and adjust (decrease) other components of the payment rates.

Comment: A commenter suggests that CMS should investigate the impact of a applying a population density adjustment factor to the rates. This adjustment factor would increase payments in less densely populated areas (primarily rural) to offset higher costs of providing care in rural areas. These costs include increases in transportation costs and the scarcity of skilled professionals in rural areas. The commenter states that an increase to rural payments rates is necessary as rural wage indices are uniformly lower than urban wage indices.

Response: We do not have evidence that a population density adjustment is appropriate. While rural HHAs cite the added cost of long distance travel to provide care for their patients, urban HHAs cite added costs associated with needed security measures and traffic congestion. In regard to the commenters assertion that rural wage indices are uniformly lower than urban wage indices, our analysis shows that almost 18 percent of urban wage index values are less than the rural wage index in the corresponding state.

Comment: Commenters recommend that the rural add-on should apply for at least one year for services provided to beneficiaries in counties that are transitioning from rural to urban status for wage index purposes. Other commenters requested that CMS clarify which areas qualify for the rural add-on on as numerous areas lose rural status under the new CBSAs. Some commenters state that in 2006 when CMS blended MSA and CBSA regions as

part of a comparable wage index transition policy, CMS applied the rural add-on for both patients residing in a non-MSA and non-CBSA area. In other words, the rural add-on applied in the rural areas under the old MSA designations as well as the new CBSA designations during the transition year.

Response: When we implemented OMB revised delineations in CY 2006, we applied the rural add-on to counties in non-CBSA areas. If a county had been previously classified as rural but changed to urban classification under the new CBSAs, the rural add-on was not applied. The commenters who stated that CMS applied the rural add-on for patients residing in non-MSA areas and patients residing in non-CBSA areas are mistaken. This policy was implemented in CMS Transmittal 887 which was published on March 10, 2006. In order to remain consistent with our previous policy for applying the rural add-on, we would implement the rural add-on in the same manner for CY 2015. That is, only counties that are classified as rural under the new area delineations would receive the rural add-on. As stated previously, we believe that this method of adopting the most current OMB delineations would increase the integrity of the wage index as it is a more accurately represents geographic variation in wage levels.

Comment: One commenter recommended that CMS adopt the same definition of a ''rural'' area that is used by the Federal Office of Rural Health (ORH). The commenter states that the ORH explicitly recognizes that ''the New England states require special consideration as ''their geographic divisions are different than typical counties.'' There are many towns within Massachusetts that are very rural, yet they lie within large counties that are designated a CBSA based on the fact that there is a small city within that county. The commenter recommended that CMS modify the CBSA approach to recognize rural census tracts within large counties.

Response: In the CY 2015 HH PPS proposed rule, we did not propose alternatives to the use of CBSAs, which were adopted in the CY 2006 HH PPS final rule, to classify areas as ''rural'' for wage adjustment purposes. In the CY 2006 HH PPS final rule (70 FR 68132), we proposed and finalized the adoption of revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of micropolitan statistical areas and core-based statistical areas (CBSAs).

Comment: A commenter requested that CMS disclose the areas that would lose their rural status under the new CBSAs.

Response: We provided several tables in the CY 2015 HH PPS proposed rule (79 FR 38392–38395) which display the counties whose status will change if we finalize our proposal to adopt the new OMB delineations. Table 13 shows the 37 counties that would change from urban to rural status. Table 14 shows the 105 counties that would change from rural to urban status. Lastly, Table 15 displays the 46 urban counties that would move from one urban CBSA to another urban CBSA.

Final Decision: For CY 2015, home health payment rates for services provided to beneficiaries in areas that are defined as rural under the new OMB delineations will be increased by 3 percent as mandated by section 3131(c) of the Affordable Care Act. The 3 percent rural add-on is applied to the national, standardized 60-day episode payment rate, national per visit rates, and NRS conversion factor when HH services are provided in rural (non-CBSA) areas. Refer to Tables 30 through 33 for these payment rates.

TABLE 30—CY 2015 PAYMENT AMOUNTS FOR 60-DAY EPISODES FOR SERVICES PROVIDED IN A RURAL AREA

For HHAs that DO submit quality °Data			For HHAs that DO NOT submit quality data		
CY 2015 national, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	CY 2015 rural national, standardized 60-day pisode payment rate	CY 2015 national, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	CY 2015 rural national, standardized 60-day episode payment rate
$2,961.38	×; 1.03	$3,050.22	$2,903.37	×; 1.03	$2,990.47

TABLE 31—CY 2015 PER-VISIT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

HH Discipline type	For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
	CY 2015 per-visit rate	Multiply by the 3 percent rural add-on	CY 2015 rural per-visit rates	CY 2015 per-visit rate	Multiply by the 3 percent rural add-on	CY 2015 rural per-visit rates
HH Aide	$57.89	×; 1.03	$59.63	$56.75	×; 1.03	$58.45
MSS	204.91	×; 1.03	211.06	200.89	×; 1.03	206.92
OT	140.70	×; 1.03	144.92	137.95	×; 1.03	142.09
PT	139.75	×; 1.03	143.94	137.02	×; 1.03	141.13
SN	127.83	×; 1.03	131.66	125.33	×; 1.03	129.09
SLP	151.88	×; 1.03	156.44	148.90	×; 1.03	153.37

TABLE 32—CY 2015 NRS CONVERSION FACTOR FOR SERVICES PROVIDED IN RURAL AREAS

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
CY 2015 conversion factor	Multiply by the 3 percent rural add-on	CY 2015 rural NRS conversion factor	CY 2015 Conversion factor	Multiply by the 3 percent rural add-on	CY 2015 rural NRS conversion factor
$53.23	×; 1.03	$54.83	$52.19	×; 1.03	$53.76

TABLE 33—CY 2015 NRS PAYMENT AMOUNTS FOR SERVICES PROVIDED IN RURAL AREAS

Severity level	Points (scoring)	For HHAs that DO submit quality data (CY 2015 NRS Conversion Factor = $54.83)		For HHAs that DO NOT submit quality data (CY 2015 NRS Conversion Factor = $53.76)	
		Relative weight	CY 2015 NRS Payment amounts for rural areas	Relative weight	CY 2015 NRS Payment amounts for rural areas
1	0	0.2698	$14.79	0.2698	$14.50
2	1 to 14	0.9742	53.42	0.9742	52.37
3	15 to 27	2.6712	146.46	2.6712	143.60
4	28 to 48	3.9686	217.60	3.9686	213.35
5	49 to 98	6.1198	335.55	6.1198	329.00
6	99+	10.5254	577.11	10.5254	565.85

E. Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the national, standardized 60-day case-mix and wage-adjusted episode payment amounts in the case of episodes that incur unusually high costs due to patient care needs. Prior to the enactment of the Affordable Care Act, section 1895(b)(5) of the Act stipulated that projected total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. In the Medicare Program; Prospective Payment System for Home Health Agencies final rule (65 FR 41188 through 41190), we described the method for determining outlier payments. Under this system, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each HH Resource Group (HHRG). The episode's estimated cost is the sum of the national wage-adjusted per-visit payment amounts for all visits delivered during the episode. The outlier threshold for each case-mix group or PEP adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost beyond the wage-adjusted threshold. The threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

In the CY 2010 HH PPS final rule (74 FR 58080 through 58087), we discussed excessive growth in outlier payments, primarily the result of unusually high outlier payments in a few areas of the country. Despite program integrity efforts associated with excessive outlier payments in targeted areas of the country, we discovered that outlier expenditures still exceeded the 5 percent, target and, in the absence of corrective measures, would continue do to so. Consequently, we assessed the appropriateness of taking action to curb outlier abuse. To mitigate possible billing vulnerabilities associated with excessive outlier payments and adhere to our statutory limit on outlier payments, we adopted an outlier policy that included a 10 percent agency-level cap on outlier payments. This cap was implemented in concert with a reduced FDL ratio of 0.67. These policies resulted in a projected target outlier pool of approximately 2.5 percent. (The previous outlier pool was 5 percent of total HH expenditure). For CY 2010, we first returned 5 percent of these dollars back into the national, standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor. Then, we reduced the CY 2010 rates by 2.5 percent to account for the new outlier pool of 2.5 percent. This outlier policy was adopted for CY 2010 only.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act. As amended, ''Adjustment for outliers,'' states that ''The Secretary shall reduce the standard prospective payment amount (or amounts) under this paragraph applicable to HH services furnished during a period by such proportion as will result in an aggregate reduction in payments for the period equal to 5 percent of the total payments estimated to be made based on the prospective payment system under this subsection for the period.'' In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by re-designating the existing language as section 1895(b)(5)(A) of the Act, and revising it to state that the Secretary, ''subject to [a 10 percent program-specific outlier cap], may provide for an addition or adjustment to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. The total amount of the additional payments or payment adjustments made under this paragraph for a fiscal year or year may not exceed 2.5 percent of the total payments projected or estimated to be made based on the prospective payment system under this subsection in that year.''

As such, beginning in CY 2011, our HH PPS outlier policy is that we reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we target up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10 percent agency-level outlier cap.

2. Fixed Dollar Loss (FDL) Ratio and Loss-Sharing Ratio

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount.

In the CY 2011 HH PPS final rule (75 FR 70398), in targeting total outlier payments as 2.5 percent of total HH PPS payments, we implemented an FDL ratio of 0.67, and we maintained that ratio in CY 2012. Simulations based on CY 2010 claims data completed for the CY 2013 HH PPS final rule showed that outlier payments were estimated to comprise approximately 2.18 percent of total HH PPS payments in CY 2013, and as such, we lowered the FDL ratio from 0.67 to 0.45. We stated that lowering the FDL ratio to 0.45, while maintaining a loss-sharing ratio of 0.80, struck an effective balance of compensating for high-cost episodes while allowing more episodes to qualify as outlier payments (77 FR 67080). The national, standardized 60-day episode payment amount is multiplied by the FDL ratio. That amount is wage-adjusted to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare will pay 80 percent of the additional estimated costs.

For this final rule, simulating payments using more complete CY 2013 claims data (as of June 30, 2014 rather than preliminary data as of December 31, 2013) and the CY 2014 payment rates (78 FR 72304 through 72308), we estimate that outlier payments in CY 2014 would comprise 2.00 percent of total payments. Based on simulations using CY 2013 claims data and the CY 2015 payments rates in section III.D.4 of this final rule, we estimate that outlier payments will comprise approximately 2.25 percent of total HH PPS payments in CY 2015.

Given the increases to the CY 2015 national per-visit payment rates and the national, standardized 60-day episode payment rate as a result of making the case-mix recalibration in section III.C budget neutral, our analysis estimates an additional 0.25 percentage point increase in outlier payments as a percent of total HH PPS payments each year that we phase-in the rebasing adjustments described in the background (section II.C). We estimate that by CY 2016 outlier payments as a percent of total HH PPS payments will be approximately 2.5 percent. We did not propose a change to the FDL ratio or loss-sharing ratio for CY 2015 as we believed that maintaining an FDL of 0.45 and a loss-sharing ratio of 0.80 are appropriate given the percentage of outlier payments is estimated to increase as a result of the increasing the national per-visit amounts through the rebasing adjustments. We will continue to monitor the percent of total HH PPS payments paid as outlier payments to determine if future adjustments to either the FDL ratio or loss-sharing ratio are warranted.

Although we did not propose any changes to the outlier policy, the following is a summary of the comments we received regarding outlier payments.

Comment: Several commenters stated that estimated outlier payments as a percent of total payments for CY 2015 is below the 'budgeted' amount of 2.5 percent, which has 'deprived' an appropriate level of payment for those HHAs that field high-cost cases (including cases for beneficiaries in very rural areas). These commenters further suggest that the FDL ratio and/or loss-sharing ratio should be modified so that estimated outlier payments as a percent of total payments would reach 2.5 percent.

Response: We did not propose a change to the FDL ratio for CY 2015 given the finalized increases to the CY 2015 national per-visit payment rates, which our analysis estimates will yield an additional 0.25 percentage point increase in estimated outlier payments as a percent of total HH PPS payments each year that we phase-in the rebasing adjustments described in section II.C. We estimate that for CY 2016, estimated outlier payments as a percent of total HH PPS payments will increase to 2.5 percent. We note that per section 1895(b)(5)(A) of the Act, outlier payments as a percent of total HH PPS payments ''may not exceed 2.5 percent of the total payments projected or estimated to be made based on the prospective payment system under this subsection in that year''. The statute does not require us to pay out 2.5 percent of total HH PPS payments as outlier payments; it requires us to pay no more than 2.5 percent of total HH PPS payments as outlier payments.

Additionally, we noted that these estimates do not take in to account any changes in utilization that may have occurred in CY 2014, and will continue to occur in CY 2015. We are concerned that if we decreased the FDL ratio we could potentially pay more than 2.5 percent of estimated total payments as outlier payments and that episodes without unusual variations in the type or amount of medically-necessary care will qualify for outlier payments, which is contrary to the intent of the policy. Moreover, we remain committed to addressing potentially fraudulent activities, especially those in areas where we suspect suspicious outlier payments (74 FR 58085). We believe that maintaining the current thresholds supports our prudent approach in light of such studies as those conducted by the Office of Inspector General (August 2013 Management Implications Report). We continue to examine potential revisions to the outlier payment methodology through the current contract with Abt Associates and will make recommendations and revisions if necessary.

Consequently, for the above stated reasons, we believe that we should not make any changes/revisions to our outlier payment methodology at this time.

Comment: One commenter recommended that CMS eliminate outlier payments in their entirety and return the 2.5 percent withhold to the base payment rates.

Response: We believe that section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS. We plan to continue investigating whether or not an outlier policy remains appropriate as well as ways to maintain an outlier policy for episodes that incur unusually high costs due to patient care needs without qualifying episodes of care that do not meet that criteria or are potentially fraudulent. We recently awarded a contract to Abt Associates to address any findings from the home health study required by section 3131(d) of the Affordable Care Act, monitor the potential impact of the rebasing adjustments and other recent payment changes, and develop payment options to ensure ongoing access to care for vulnerable populations. The work may include potential revisions to the outlier payment methodology to better reflect costs of treating Medicare beneficiaries with high levels of severity of illness.

Comment: Several commenters stated that CMS's oversight and monitoring of insulin injection-based outlier episodes will drive outlier payments down as well as cause incorrect projections for future outlier payment.

Response: As we have noted in the past (74 FR 58085), we are committed to addressing potentially fraudulent activities, especially those in areas where we see suspicious outlier

payments. As we noted above, we plan to examine potential revisions to the outlier payment methodology through ongoing studies and analysis of home health claims and other utilization data. Monitoring of potentially fraudulent activity will be captured in this analysis, and we will make policy and other adjustments as necessary in light of the new data and outcomes.

Comment: One commenter recommended that CMS calculate outlier payments based on actual costs rather than imputed costs.

Response: Currently, an HHA episode's estimated cost is the sum of the national wage-adjusted per-visit payment amounts for all visits delivered during the episode, and the outlier payment is defined to be an estimate of the proportion of the wage-adjusted cost beyond the wage-adjusted threshold. We believe that this estimate serves as a valid proxy for the additional costs incurred by providers. However, in an effort to further the agency's mission of providing accurate payment, we continue to evaluate the effectiveness of the current outlier payment policy approach and are considering the investigation of alternative, cost-oriented mechanisms for determining the outlier payment amount for HHA providers for those episodes that incur unusually high costs due to patient care needs.

Comment: One commenter questioned CMS's current outlier approach, which removes 5 percent from the payment rates, and then pays out 2.5 percent in outlier payments. Additionally, the commenter wanted to understand what was done with the other 2.5 percent that is no longer being paid to providers.

Response: Per section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act, CMS is required to reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. This provision is a statutory requirement and thus we do not have the authority to rescind this policy. Consequently, to implement this particular Affordable Care Act provision, CMS reduced the standardized 60-day episode payment amount by 5 percent, and set the FDL ratio such that it would target up to 2.5 percent of total estimated HH PPS payments as outlier payments.

Final Decision: We are finalizing no change to the FDL ratio or loss sharing ratio for CY 2015. However, we will continue to monitor outlier payments and continue to explore ways to maintain an outlier policy for episodes that incur unusually high costs due to patient care needs without qualifying episodes of care that do not meet that criteria.

F. Medicare Coverage of Insulin Injections Under the HH PPS

Home health policy regarding coverage of home health visits for the sole purpose of insulin injections is limited to patients that are physically or mentally unable to self-inject and there is no other person who is able and willing to inject the patient.[28] However, the Office of Inspector General concluded in August 2013 that some previously covered home health visits for the sole purpose of insulin injections were unnecessary because the patient was physically and mentally able to self-inject.[29] In addition, results from analysis in response to public comments on the CY 2014 HH PPS final rule found that episodes that qualify for outlier payments in excess of $10,000 had, on average, 160 skilled nursing visits in a 60-day episode of care with 95 percent of the episodes listing a primary diagnosis of diabetes or long-term use of insulin (78 FR 72310). Therefore, we conducted a literature review regarding generally accepted clinical management practices for diabetic patients and conducted further analysis of home health claims data to investigate the extent to which episodes with visits likely for the sole purpose of insulin injections are in fact limited to patients that are physically or mentally unable to self-inject.

As generally accepted by the medical community, older patients (age 65 and older) are more likely to have impairments in dexterity, cognition, vision, and hearing.[30] While studies have shown that most elderly patients starting or continuing on insulin can inject themselves, these conditions may affect the elderly individual's ability to self-inject insulin. It is clinically essential that there is careful assessment prior to the initiation of home care, and throughout the course of treatment, regarding the patient's capacity for self-injection. There are multiple reliable and validated assessment tools that may be used to assess the elderly individual's ability to self-inject. These tools assess the individual's ability to perform activities of daily living (ADLs), as well as, cognitive, functional, and behavioral status.[31] These assessment tools have also proved valid for judging patients' ability to inject insulin independently and to recognize and deal with hypoglycemia.[32]

Another important consideration with regard to insulin administration in the elderly population is the possibility of dosing errors.[33] Correct administration and accurate dosing is important in order to prevent serious complications, such as hypoglycemia and hyperglycemia. The traditional vial and syringe method of insulin administration involves several steps, including injecting air into the vial, drawing an amount out of the vial into a syringe with small measuring increments, and verifying the correct dose visually.[34] In some cases, an insulin pen can be used as an alternative to the traditional vial and syringe method.

Insulin pens are designed to facilitate easy self-administration, the possession of which would suggest the ability to self-inject. Additionally, insulin pens often come pre-filled with insulin or must be used with a pre-filled cartridge thus potentially negating the need for skilled nursing for the purpose of calculating and filling appropriate doses. It is recognized that visual impairment, joint immobility and/or pain, peripheral neuropathy, and cognitive issues may affect the ability of elderly patients to determine correct insulin dosing and injection. Our literature review indicates that insulin pen devices may be beneficial in terms of safety for elderly patients due to these visual or physical disabilities.[35] To determine whether to use a traditional vial and syringe method of insulin administration versus an insulin pen, the physician must consider and understand the advantages these devices offer over traditional vials and syringes. These advantages include:

- Convenience, as the insulin pen eliminates the need to draw up a dose;

[28] Medicare Coverage Benefit Policy Manual (Pub. 100–02), Section 40.1.2.4.B.2 ''Insulin Injections.''

[29] Levinson, Daniel R. Management Implication Report 12–0011, Unnecessary Home Health Care for Diabetic Patients.

[30] Strategies for Insulin Injection Therapy in Diabetes Self-Management. (2011). American Association of Diabetes Educators.

[31] Hendra, T.J. Starting insulin therapy in elderly patients. (2012). Journal of the Royal Society of Medicine. 95(9), 453–455.

[32] Sinclair AJ, Turnbull CJ, Croxson SCM. Document of care for older people with diabetes. Postgrad Med J 1996;72: 334–8.

[33] Coscelli C, Lostia S, Lunetta M, Nosari I, Coronel GA. Safety, efficacy, acceptability of a pre-filled insulin pen in diabetic patients over 60 years old. Diabetes Research and Clinical Practice. 1995;38:173–7.[PubMed].

[34] Flemming DR. Mightier than the syringe. Am J Nurs. 2000;100:44–8.[PubMed].

[35] Wright, B., Bellone, J., McCoy, E. (2010). A review of insulin pen devices and use in elderly, diabetic population. Clinical Medicine Insights: Endocrinology and Diabetes. 3:53–63. Doi: 10.4137/CMED.S5534.

• Greater dose accuracy and reliability, especially for low doses which are often needed in the elderly;
• Sensory and auditory feedback associated with the dial mechanism on many pens may also benefit those with visual impairments;
• Pen devices are also more compact, portable and easier to grip, which may benefit those with impairments in manual dexterity; and
• Less painful injections and overall ease of use.[36]

Although pen devices are often perceived to be more costly than vialed insulin, study results indicate that elderly diabetic patients are more likely to accept pen devices and adhere to therapy, which leads to better glycemic control that decreases long-term complications and associated healthcare costs.[37] The significantly improved safety profiles of pen devices also avert costly episodes of hypoglycemia.[38] It also should be noted that most insurance plans, including Medicare Part D plans, charge the patient the same amount for a month supply of insulin in the pen device as insulin in the vial.[39] Additionally, in some cases the individual with coverage for insulin pens may have one co-pay, resulting in getting more insulin than if purchasing a vial. And, there is less waste with pens because insulin vials should be discarded after 28 days after opening. However, there may be clinical reasons for the use of the traditional vial and insulin syringe as opposed to the insulin pen, including the fact that not all insulin preparations are available via insulin pen. In such circumstances, there are multiple assistive aids and devices to facilitate self-injection of insulin for those with cognitive or functional limitations. These include: nonvisual insulin measurement devices; syringe magnifiers; needle guides; prefilled insulin syringes; and vial stabilizers to help ensure accuracy and aid in insulin delivery.[40] It is expected that providers will assess the needs, abilities, and preference of the patient requiring insulin to facilitate patient autonomy, efficiency, and safety in diabetes self-management, including the administration of insulin.

Further research regarding self-injection of insulin, whether via a vial and syringe method or insulin pen, shows that education for starting insulin and monitoring should be provided by a diabetes nurse specialist, and typically entails 5 to 10 face-to-face contacts either in the patient's home or at the diabetes clinic; these are in addition to telephone contacts to further reinforce teaching and to answer patient questions.[41] This type of assessment and education allows for patient autonomy and self-efficiency and is often a preferred mode for diabetes self-management.

In the CY 2014 HH PPS final rule (78 FR 72256), we noted that the Office of Inspector General (OIG) released a ''Management Implications Report'' in August of 2013 that concluded that there was a ''systemic weakness that results in Medicare coverage of unnecessary home health care for diabetic patients''. The OIG report noted that investigations show that the majority of beneficiaries involved in fraudulent schemes have a primary diagnosis of diabetes. The report noted that OIG Special Agents found falsified medical records documenting patients having hand tremors and poor vision preventing them from drawing insulin into a syringe, visually verifying the correct dosage, and injecting the insulin themselves, when the patients did not in fact suffer those symptoms.

In light of the OIG report, we conducted analysis and performed simulations using CY 2012 claims data and described our findings in the CY 2014 Home Health PPS Final Rule (78 FR 72310). We found that nearly 44 percent of the episodes that would qualify for outlier payments had a primary diagnosis of diabetes and 16 percent of episodes that would quality for outlier payments had a primary diagnosis of ''Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled.'' Qualifying for outlier payments should indicate an increased resource and service need. However, uncomplicated and controlled diabetes typically would be viewed as stable without clinical complications and would not warrant increased resource and service needs nor would it appear to warrant outlier payments. Our simulations estimated that approximately 81 percent of outlier payments would be paid to proprietary HHAs and that approximately two-thirds of outlier payments would be paid to HHAs located in Florida (27 percent), Texas (24 percent) and California (15 percent). We also conducted additional analyses on episodes in our simulations that would have resulted in outlier payments of over $10,000. Of note, 95 percent of episodes that would have resulted in outlier payments of over $10,000 were for patients with a primary diagnosis of diabetes or long-term use of insulin, and most were concentrated in Florida, Texas, New York, California, and Oklahoma. On average, these outlier episodes had 160 skilled nursing visits in a 60-day episode of care.[42]

Based upon the initial data analysis described above and the information found in the literature review, we conducted further data analysis with more recent home health claims and OASIS data (CY 2012 and CY 2013) to expand our understanding of the diabetic patient in the home health setting. Specifically, we investigated the extent to which beneficiaries with a diabetes-related principal diagnosis received home health services likely for the primary purpose of insulin injection assistance and whether such services were warranted by other documented medical conditions. We also analyzed the magnitude of Medicare payments associated with home health services provided to this population of interest. The analysis was conducted by Acumen, LLC because of their capacity to provide real-time claims data analysis across all parts of the Medicare program (that is, Part A, Part B, and Part D).

Our analysis began with identifying episodes for the home health diabetic population based on claims and OASIS assessments most likely to be associated with insulin injection assistance. We used the following criteria to identify the home health diabetic population of interest: (1) A diabetic condition listed as the principal/primary diagnosis on the home health claim; (2) Medicare Part A or Part B enrollment for at least three months prior to the episode and during the episode; and (3) episodes with at least 45 skilled visits. This threshold was determined based on the

[36] Wright, B., Bellone, J., McCoy, E. (2010). A review of insulin pen devices and use in elderly, diabetic population. Clinical Medicine Insights: Endocrinology and Diabetes. 3:53–63. Doi: 10.4137/CMED.S5534.

[37] Strategies for Insulin Injection Therapy in Diabetes Self-Management. (2011). American Association of Diabetes Educators.

[38] Strategies for Insulin Injection Therapy in Diabetes Self-Management. (2011). American Association of Diabetes Educators.

[39] Wright, B., Bellone, J., McCoy, E. (2010). A review of insulin pen devices and use in elderly, diabetic population. Clinical Medicine Insights: Endocrinology and Diabetes. 3:53–63. Doi: 10.4137/CMED.S5534.

[40] Strategies for Insulin Injection Therapy in Diabetes Self-Management. (2011). American Association of Diabetes Educators.

[41] Hendra, T.J. Starting insulin therapy in elderly patients. (2012). Journal of the Royal Society of Medicine. 95(9), 453–455. *http://www.ncbi.nlm.nih.gov.*

[42] This analysis simulated payments using CY 2012 claims data and CY 2012 payment rates. The simulations did not take into account the 10-percent outlier cap. Some episodes may have qualified for outlier payments in the simulations, but were not paid accordingly if the HHA was at or over its 10 percent cap on outlier payments as a percent of total payments.

distribution in the average number and length of skilled nursing visits for episodes meeting criteria 1 and 2 above using CY 2013 home health claims data. The average number of skilled nursing visits for beneficiaries who receive at least one skilled nursing visit appeared to increase from 20 visits at the 90th percentile, to 50 visits at the 95th percentile. Additionally, the average length of a skilled nursing visit for episodes between the 90th and 95th percentiles was 37 minutes, less than half the length of visits for episode between the 75th and 90th percentiles.

Approximately 49,100 episodes met the study population criteria described above, accounting for approximately $298 million in Medicare home health payments in CY 2013. Of the 49,100 episodes of interest, 71 percent received outlier payments and, on average, there were 86 skilled nursing visits per episode. In addition, 12 percent of the episodes in the study population were for patients prescribed an insulin pen to self-inject and more than half of the episodes billed (27,439) were for claims that listed ICD–9–CM 2500x, ''Diabetes Mellitus without mention of complication'', as the principal diagnosis code. ICD–9–CM describes the code 250.0x as diabetes mellitus without mention of complications (complications can include hypo- or hyperglycemia, or manifestations classified as renal, ophthalmic, neurological, peripheral circulatory damage or neuropathy). Clinically, this code generally means that the diabetes is being well-controlled and there are no apparent complications or symptoms resulting from the diabetes. Diabetes that is controlled and without complications does not warrant intensive intervention or daily skilled nursing visits; rather, it warrants knowledge of the condition and routine monitoring.

As discussed above in this section, the traditional vial and syringe method of insulin administration is one of two methods of insulin administration (excluding the use of insulin pumps). The alternative to the traditional vial and syringe method is the use of insulin pens. It would seem to be a reasonable assumption that the possession of a prescribed insulin pen would suggest the ability to self-inject. Since insulin pens often come pre-filled with insulin or must be used with a pre-filled cartridge, we believe there would not be a need for skilled nursing for the purpose of insulin injection assistance. We expect providers to assess the needs, abilities, and preference of the patient requiring insulin to facilitate patient autonomy, efficiency, and safety in diabetes self-management, including the administration of insulin. As noted above, approximately 12 percent of the episodes in the study population with visits likely for the purpose of insulin injection assistance were for patients prescribed an insulin pen to self-inject, which would seem to not conform to our current policy that home health visits for the sole purpose of insulin injection assistance is limited to patients that are physically or mentally unable to self-inject and there is no other person who is able and willing to inject the patient.

Furthermore, we recognize that our current sub-regulatory guidance may not adequately address the method of delivery. We are considering additional guidance that may be necessary surrounding insulin injection assistance provided via a pen based upon our analyses described above. We have found that literature supports that insulin pens may reduce expenses for the patient in the form of co-pays and may increase patient adherence to their treatment plan. Therefore, we encourage physicians to consider the potential benefits derived in prescribing insulin pens, when clinically appropriate, given the patient's condition.

We also investigated whether secondary diagnosis codes listed on home health claims support that the patient, either for physical or mental reasons, cannot self-inject. Our contractor, Abt Associates, with review and clinical input from CMS clinical staff and experts, created a list of ICD–9–CM codes that indicate a patient has impairments in dexterity, cognition, vision, and/or hearing that may cause the patient to be unable to self-inject insulin. We found that 49 percent of home health episodes in our study population did not have a secondary diagnosis from that ICD–9–CM code list on the home health claim that supported that the patient was physically or mentally unable to self-inject. When examining only the initial home health episodes of our study population, we found that 67 percent of initial home health episodes with skilled nursing visits likely for insulin injections did not have a secondary diagnosis on the home health claim that supported that the patient was physically or mentally unable to self-inject. Using the same list of ICD–9–CM diagnosis codes, we examined both the secondary diagnoses on the home health claim and diagnoses on non-home health claims in the three months prior to starting home health care for initial home health episodes. We found that for initial home health episodes in our study population that the percentage of episodes that did not have a secondary diagnosis to support that the patient cannot self-inject would decrease from 67 percent to 47 percent if the home health claim included diagnoses found in other claim types during the three months prior to entering home care. We do recognize that, in spite of all of the education, assistive devices and support, there may still be those who are unable to self-inject insulin and will require ongoing skilled nursing visits for insulin administration assistance. However, there is an expectation that the physician and the HHA would clearly document detailed clinical findings and rationale as to why an individual is unable to self-inject, including the reporting of an appropriate secondary condition that supports the inability of the patient to self-inject.

As described above, a group of CMS clinicians and contractor clinicians developed a list of conditions that would support the need for ongoing home health skilled nursing visits for insulin injection assistance for instances where the patient is physically or mentally unable to self-inject and there is no able or willing caregiver to provide assistance. We expect the conditions included in Table 34 to be listed on the claim and OASIS to support the need for skilled nursing visits for insulin injection assistance.

Table 34: ICD–9–CM Diagnosis Codes That Indicate a Potential Inability to Self-Inject Insulin

TABLE 34—ICD–9–CM DIAGNOSIS CODES THAT INDICATE A POTENTIAL INABILITY TO SELF-INJECT INSULIN

ICD–9–CM Code	Description
Amputation	
V49.61	Thumb Amputation Status.
V49.63	Hand Amputation Status.

TABLE 34—ICD–9–CM DIAGNOSIS CODES THAT INDICATE A POTENTIAL INABILITY TO SELF-INJECT INSULIN—Continued

ICD–9–CM Code	Description
V49.64	Wrist Amputation Status.
V49.65	Below elbow amputation status.
V49.66	Above elbow amputation status.
V49.67	Shoulder amputation status.
885.0	Traumatic amputation of thumb w/o mention of complication.
885.1	Traumatic amputation of thumb w/mention of complication.
886.0	Traumatic amputation of other fingers w/o mention of complication.
886.1	Traumatic amputation of other fingers w/mention of complication.
887.0	Traumatic amputation of arm and hand, unilateral, below elbow w/o mention of complication.
887.1	Traumatic amputation of arm and hand, unilateral, below elbow, complicated.
887.2	Traumatic amputation of arm and hand, unilateral, at or above elbow w/o mention of complication.
887.3	Traumatic amputation of arm and hand, unilateral, at or above elbow, complicated.
887.4	Traumatic amputation of arm and hand, unilateral, level not specified, w/o mention of complication.
887.5	Traumatic amputation of arm and hand, unilateral, level not specified, complicated.
887.6	Traumatic amputation of arm and hand, bilateral, any level, w/o mention of complication.
887.7	Traumatic amputation of arm and hand, bilateral, any level, complicated.
	Vision
362.01	Background diabetic retinopathy.
362.50	Macular degeneration (senile) of retina unspecified.
362.51	Nonexudative senile macular degeneration of retina.
362.52	Exudative senile macular degeneration of retina.
362.53	Cystoid macular degeneration of retina.
362.54	Macular cyst hole or pseudohole of retina.
362.55	Toxic maculopathy of retina.
362.56	Macular puckering of retina.
362.57	Drusen (degenerative) of retina.
366.00	Nonsenile cataract unspecified.
366.01	Anterior subcapsular polar nonsenile cataract.
366.02	Posterior subcapsular polar nonsenile cataract.
366.03	Cortical lamellar or zonular nonsenile cataract.
366.04	Nuclear nonsenile cataract.
366.09	Other and combined forms of nonsenile cataract.
366.10	Senile cataract unspecified.
366.11	Pseudoexfoliation of lens capsule.
366.12	Incipient senile cataract.
366.13	Anterior subcapsular polar senile cataract.
366.14	Posterior subcapsular polar senile cataract.
366.15	Cortical senile cataract.
366.16	Senile nuclear sclerosis.
366.17	Total or mature cataract.
366.18	Hypermature cataract.
366.19	Other and combined forms of senile cataract.
366.20	Traumatic cataract unspecified.
366.21	Localized traumatic opacities.
366.22	Total traumatic cataract.
366.23	Partially resolved traumatic cataract.
366.8	Other cataract.
366.9	Unspecified cataract.
366.41	Diabetic cataract.
366.42	Tetanic cataract.
366.43	Myotonic cataract.
366.44	Cataract associated with other syndromes.
366.45	Toxic cataract.
366.46	Cataract associated with radiation and other physical influences.
366.50	After-cataract unspecified.
369.00	Impairment level not further specified.
369.01	Better eye: total vision impairment; lesser eye: total vision impairment.
369.10	Moderate or severe impairment, better eye, impairment level not further specified.
369.11	Better eye: severe vision impairment; lesser eye: blind not further specified.
369.13	Better eye: severe vision impairment; lesser eye: near-total vision impairment.
369.14	Better eye: severe vision impairment; lesser eye: profound vision impairment.
369.15	Better eye: moderate vision impairment; lesser eye: blind not further specified.
369.16	Better eye: moderate vision impairment; lesser eye: total vision impairment.
369.17	Better eye: moderate vision impairment; lesser eye: near-total vision impairment.
369.18	Better eye: moderate vision impairment; lesser eye: profound vision impairment.
369.20	Moderate to severe impairment; Low vision both eyes not otherwise specified.
369.21	Better eye: severe vision impairment; lesser eye; impairment not further specified.
369.22	Better eye: severe vision impairment; lesser eye: severe vision impairment.
369.23	Better eye: moderate vision impairment; lesser eye: impairment not further specified.

TABLE 34—ICD–9–CM DIAGNOSIS CODES THAT INDICATE A POTENTIAL INABILITY TO SELF-INJECT INSULIN—Continued

ICD–9–CM Code	Description
369.24	Better eye: moderate vision impairment; lesser eye: severe vision impairment.
369.25	Better eye: moderate vision impairment; lesser eye: moderate vision impairment.
369.3	Unqualified visual loss both eyes.
369.4	Legal blindness as defined in U.S.A.
377.75	Cortical blindness.
379.21	Vitreous degeneration.
379.23	Vitreous hemorrhage.
Cognitive/Behavioral	
290.0	Senile dementia uncomplicated.
290.3	Senile dementia with delirium.
290.40	Vascular dementia, uncomplicated.
290.41	Vascular dementia, with delirium.
290.42	Vascular dementia, with delusions.
290.43	Vascular dementia, with depressed mood.
294.11	Dementia in conditions classified elsewhere with behavioral disturbance.
294.21	Dementia, unspecified, with behavioral disturbance.
300.29	Other isolated or specific phobias.
331.0	Alzheimer's disease.
331.11	Pick's disease.
331.19	Other frontotemporal dementia.
331.2	Senile degeneration of brain.
331.82	Dementia with lewy bodies.
Arthritis	
715.11	Osteoarthrosis localized primary involving shoulder region.
715.21	Osteoarthrosis localized secondary involving shoulder region.
715.31	Osteoarthrosis localized not specified whether primary or secondary involving shoulder region.
715.91	Osteoarthrosis unspecified whether generalized or localized involving shoulder region.
715.12	Osteoarthrosis localized primary involving upper arm.
715.22	Osteoarthrosis localized secondary involving upper arm.
715.32	Osteoarthrosis localized not specified whether primary or secondary involving upper arm.
715.92	Osteoarthrosis unspecified whether generalized or localized involving upper arm.
715.13	Osteoarthrosis localized primary involving forearm.
715.23	Osteoarthrosis localized secondary involving forearm.
715.33	Osteoarthrosis localized not specified whether primary or secondary involving forearm.
715.93	Osteoarthrosis unspecified whether generalized or localized involving forearm.
715.04	Osteoarthrosis generalized involving hand.
715.14	Osteoarthrosis localized primary involving hand.
715.24	Osteoarthrosis localized secondary involving hand.
715.34	Osteoarthrosis localized not specified whether primary or secondary involving hand.
715.94	Osteoarthrosis unspecified whether generalized or localized involving hand.
716.51	Unspecified polyarthropathy or polyarthritis involving shoulder region.
716.52	Unspecified polyarthropathy or polyarthritis involving upper arm.
716.53	Unspecified polyarthropathy or polyarthritis involving forearm.
716.54	Unspecified polyarthropathy or polyarthritis involving hand.
716.61	Unspecified monoarthritis involving shoulder region.
716.62	Unspecified monoarthritis involving upper arm.
716.63	Unspecified monoarthritis involving forearm.
716.64	Unspecified monoarthritis involving hand.
716.81	Other specified arthropathy involving shoulder region.
716.82	Other specified arthropathy involving upper arm.
716.83	Other specified arthropathy involving forearm.
716.84	Other specified arthropathy involving hand.
716.91	Unspecified arthropathy involving shoulder region.
716.92	Unspecified arthropathy involving upper arm.
716.93	Unspecified arthropathy involving forearm.
716.94	Unspecified arthropathy involving hand.
716.01	Kaschin-Beck disease shoulder region.
716.02	Kaschin-Beck disease upper arm.
716.04	Kaschin-Beck disease forarm.
716.04	Kaschin-beck disease involving hand.
719.81	Other specified disorders of joint of shoulder region.
719.82	Other specified disorders of upper arm joint.
719.83	Other specified disorders of joint, forearm.
719.84	Other specified disorders of joint, hand.
718.41	Contracture of joint of shoulder region.
718.42	Contracture of joint, upper arm.
718.43	Contracture of joint, forearm.

TABLE 34—ICD–9–CM DIAGNOSIS CODES THAT INDICATE A POTENTIAL INABILITY TO SELF-INJECT INSULIN—Continued

ICD–9–CM Code	Description
718.44	Contracture of hand joint.
714.0	Rheumatoid arthritis.
Movement Disorders	
332.0	Paralysis agitans (Parkinson's).
332.1	Secondary parkinsonism.
333.1	Essential and other specified forms of tremor.
736.05	Wrist drop (acquired).
After Effects from Stroke/Other Disorders of the Central Nervous System/Intellectual Disabilities	
438.21	Hemiplegia affecting dominant side.
438.22	Hemiplegia affecting nondominant side.
342.01	Flaccid hemiplegia and hemiparesis affecting dominant side.
342.02	Flaccid hemiplegia and hemiparesis affecting nondominant side.
342.11	Spastic hemiplegia and hemiparesis affecting dominant side.
342.12	Spastic hemiplegia and hemiparesis affecting nondominant side.
438.31	Monoplegia of upper limb affecting dominant side.
438.32	Monoplegia of upper limb affecting nondominant side.
343.3	Congenital monoplegia.
344.41	Monoplegia of upper limb affecting dominant side.
344.42	Monoplegia of upper limb affecting nondominant side.
344.81	Locked-in state.
344.00	Quadriplegia unspecified.
344.01	Quadriplegia c1–c4 complete.
344.02	Quadriplegia c1 c4 incomplete.
344.03	Quadriplegia c5–c7 complete.
344.04	Quadriplegia c5–c7 incomplete.
343.0	Congenital diplegia.
343.2	Congenital quadriplegia.
344.2	Diplegia of upper limbs.
318.0	Moderate intellectual disabilities.
318.1	Severe intellectual disabilities.
318.2	Profound intellectual disabilities.

Although we did not propose any policy changes at this time, we solicited public comments on whether the conditions in Table 34 represent a comprehensive list of codes that appropriately indicate that a patient may not be able to self-inject and solicited comments on the use of insulin pens in home health. We plan to continue monitoring claims that are likely for the purpose of insulin injection assistance. Historical evidence in the medical record must support the clinical legitimacy of the secondary condition(s) and resulting disability that limit the beneficiary's ability to self-inject.

The following is a summary of the comments we received regarding our discussion of Medicare Coverage of Insulin Injections under HH PPS.

Comment: A few commenters provided additional ICD–9–CM codes that CMS should consider as supporting the need for insulin injections because a patient cannot self-inject.

Response: We thank the commenters for identifying additional ICD–9–CM codes for us to consider. The ICD–9–CM codes that were identified by the commenters will be reviewed by our clinical staff and our contractors and will be taken into consideration in developing any future sub-regulatory guidance on insulin injections.

Comment: Many commenters noted their general support of a comprehensive list of codes that appropriately indicate that a patient may not be able to self-inject. However, several commenters also suggested that CMS develop guidelines that are evidenced-based along with clinical and practical reasoning. A few commenters suggested that the evidence-based guidelines should be developed through the National Coverage Determination process, with presumptive eligibility or ineligibility, and an opportunity for the patient or HHA to rebut the presumption of ineligibility prior to denial of coverage.

Response: The list of codes included in the proposed rule was not designed to provide guidelines for determining eligibility for insulin injections during a home health episode. Rather, the list of codes was designed to identify conditions that support the need for home health skilled nursing visits for insulin injection assistance when the patient is physically or mentally unable to self-inject and there is no able or willing caregiver to provide assistance. The National Coverage Determination process describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. Under current policy, insulin injection assistance can be paid for under the Medicare home health benefit. Therefore, a National Coverage Determination is not necessary for insulin injections provided within a home health episode of care.

Comment: One commenter stated that it is sometimes difficult to specify a single condition that describes why the patient cannot self-inject. The commenter also stated that the list of codes was developed using ICD–9–CM codes, which will be obsolete in the future given the expansion of codes available under ICD–10–CM. One commenter suggested that we convene stakeholders after ICD–10–CM is implemented to determine a comprehensive list based on ICD–10–CM codes.

Response: The list of codes that appropriately indicate that a patient may not be able to self-inject was developed based on codes currently available and is aimed at assisting providers and contractors in identifying diabetic patients who may not be able self-inject insulin. The list of codes is not designed to limit the provider's ability to demonstrate the necessity for insulin injections based on other information in the medical record. We agree that there may be more codes available under ICD–10–CM and plan to appropriately crosswalk the list of ICD–9–CM codes to ICD–10-Codes. We would like to note that the ICD–9–CM codes are listed in this rule because they are currently the official code set for home health claims. In addition, convening a stakeholder panel to create a comprehensive list of ICD–10–CM codes is not necessary. Any sub-regulatory guidance issued would include this list of ICD–9–CM codes appropriately translated into ICD–10–CM codes developed using the general equivalency mapping software and the clinical judgment of our clinicians and contractor clinicians.

Comment: One commenter noted that CMS should not consider a future proposal to use a list of conditions as the single means of establishing coverage eligibility for insulin injections. Many commenters stated that any sub-regulatory guidance that identifies conditions that support a patient's inability to self-inject will result in the inaccurate denial of coverage for insulin injections thus placing the beneficiary at risk.

Response: The discussion surrounding insulin injections was included in the rule to invite public comment and gather industry input on potential sub-regulatory guidance on this issue. We did not propose that the list of codes identified in the CY 2015 HH PPS proposed and final rules would as the sole means of establishing coverage eligibility for insulin injection assistance under the Medicare home health benefit. Rather, we identified these conditions as a means for providers and contractors to identify patients who may not be able to self-inject insulin.

Comment: One commenter stated that they are concerned they will be required to ''screen'' patients and as such, the patient may not be afforded appeal rights.

Response: We will take this opportunity to remind HHAs that they are not to enroll patients that do not meet the eligibility criteria for home health services. A patient that has been determined to be ineligible by a HHA has the right to ask for a review of eligibility by the Quality Improvement Organization.

Comment: A commenter noted a concern that ''Attachment D'' does not permit the HHA to report diagnoses that do not require interventions on the OASIS (and subsequently the home health claim), thus precluding the home health agency from reporting one of these supporting diagnoses.

Response: ''Attachment D'' guidance requires that secondary diagnoses reported be addressed in the home health plan of care. The focus of this discussion surrounds home health visits for the sole purpose of insulin injections. If the patient requires home health services for the sole purpose of insulin injections, it appears logical for these services to be reported in the plan of care and require interventions that may be supported by the reporting of the appropriate diagnosis that prevents the patient from self-injecting. Additionally, ICD–9–CM and ICD–10–CM coding guidelines state ''for reporting purposes the definition for ''other diagnoses'' is interpreted as additional conditions that affect patient care in terms of requiring: Clinical evaluation; or therapeutic treatment; or diagnostic procedures; or extended length of hospital stay; or increased nursing care and/or monitoring.'' Therefore, reporting a diagnosis that supports the reason for daily nursing visits for insulin injections would be in adherence with ICD–9–CM and ICD–10–CM coding guidelines, even if that condition is not the primary reason for the home health encounter. Because that condition is affecting the home health plan of care with the need for daily skilled nursing visits for insulin injections, it would be appropriate to list that diagnosis on the OASIS as well as on the home health claim.

Comment: One commenter noted that CMS should consider a range of clinical reasons that indicate a patient may not be able to self-inject, which may or may not relate to the diagnosis associated with the current home health episode. The commenter provided an example of an amputation or a cognitive defect stemming from a prior stroke.

Response: We have not proposed a policy that limits coverage to a list of conditions that would indicate why a home health beneficiary is unable to self-inject. We recognize that there can be a wide range of reasons and multiple reasons why a beneficiary is unable to self-inject. The list of diagnoses in the CY 2015 HH PPS proposed and final rule was determined, through clinical review, to support reasons why a skilled nurse would have to administer a daily insulin injection(s). In the commenter's scenario, if an amputation or cognitive defect necessitates that a skilled nurse administer insulin injection(s), then those conditions would be related to the reason the patient needs home health care. The presence of such conditions could indicate why there is the need for the skilled nurse to provide the injection(s), even though the insulin injection itself is for the treatment and management of diabetes. If any of the diagnoses listed in the CY 2015 HH PPS proposed and final rules are the reason(s) for the inability for the beneficiary to self-inject, then it is appropriate for the home health agency to report these conditions as they would meet the ICD–9–CM and ICD–10–CM coding guidelines to report those conditions on the OASIS and home health claim. We would also note that the examples provided of an amputation or cognitive defect were included in our list of conditions that may support that a patient is unable to self-inject insulin.

We thank the commenters for providing us with their feedback and will use the information collected to inform any sub-regulatory guidance. We will also continue to monitor home health claims likely for visits to provide insulin injection assistance and we remind providers that historical evidence in the medical record must support the patient's inability to self-inject.

G. Implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM)

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 212 of the PAMA, titled ''Delay in Transition from ICD–9 to ICD–10 Code Sets,'' provides that ''[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and § 162.1002 of title 45, Code of Federal Regulations.'' Since the release of the CY 2015 HH PPS proposed rule (79 FR 38366–38420), HHS has finalized the new compliance date for ICD–10–CM and ICD–10–PCS. The August 4, 2014 final rule titled ''Administrative Simplification: Change to the Compliance Date for the International Classification of Diseases, 10th Revision (ICD–10–CM and ICD–10–PCS Medical Data Code Sets'' (79 FR 45128) announced October 1, 2015 as the compliance date. Under that final rule, the transition to ICD–10–CM is required for entities covered by the Health

Insurance Portability and Accountability Act of 1996 (HIPAA)(Pub. L. 104–91, enacted on August 21, 1996). The rule also requires covered entities to continue using ICD–9 through September 30, 2015. Diagnosis reporting on home health claims must adhere to ICD–9–CM coding conventions and guidelines regarding the selection of principal diagnosis and the reporting of additional diagnoses until that time. The current ICD–9–CM Coding Guidelines refer to the use of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) and are available through the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html* or on the CDC's Web site at *http://www.cdc.gov/nchs/icd/icd9cm.htm.* We plan to disseminate more information about the transition from ICD–9–CM to ICD–10–CM through the HHA Center Web site, the Home Health, Hospice and DME Open Door Forum, and in future rulemaking.

The following is a summary of the comments we received regarding the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM).

Comment: One commenter stated that certain codes were not included in the translation list provided in last year's rule and attributed the omission to the limitations of our GEMS tool.

Response: The CY 2015 HH PPS proposed rule did not contain a discussion of the translation list. Rather, the translation list was discussed in the CY 2014 HH PPS proposed and final rules. We invite further comments on the translation list, which should be submitted via email to *grouperemail@mmm.com.* We will review the comments and provide a response.

Comment: Several commenters suggested that CMS post ICD–10–CM information and the grouper in an expedited manner to afford additional lead time to make the system changes that support ICD–10–CM submission effective October 1, 2015.

Response: We plan to adjust our schedule to provide additional lead time. The CY 2014 HH PPS final rule (77 FR 67450–67531) announced a grouper release date in July 2014, providing three months lead time when the previous implementation date was October 1, 2014. We are adjusting our scheduled to release the ICD–10–CM HH PPS Grouper on April 1, 2015, which provides six months of lead time for HHAs and vendors to prepare for the transition to an ICD–10–CM HH PPS Grouper. In addition, we are planning to conduct additional outreach activities that will be announced in the future.

As background, CMS and our support contractors, Abt Associates and 3M, spent over 2 years implementing a process for the transition from the use of ICD–9–CM diagnosis codes to ICD–10–CM diagnosis codes within the HH PPS Grouper and outlined the process in the CY 2014 HH PPS proposed and final rules. No additional changes have been identified since that time and no additional ICD–10–CM codes have been added that would cause us to revise the grouper that was designed based on the CY 2014 HH PPS final rule.

The final translation list (which includes all of the codes listed in the draft posted to the CMS Web site) will be posted to the Home Health section of the CMS Web site. A draft ICD–10–CM HH PPS Grouper will be released on or before January 1, 2015 to our vendors that have registered as beta-testers. Beta-testers are again being reminded to provide any comments or feedback within 2 weeks of receipt based upon the processed outlined on the CMS Web site. The purpose of an early release to the beta testers is to identify any significant issues early in the process. Providers who are interested in enrolling as a beta site can obtain more information on the HH PPS Grouper Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/CaseMixGrouperSoftware.html.* As we noted above, the final ICD–10–CM HH PPS Grouper will be posted via the CMS Web site by April 1, 2015. As we are providing three months of additional lead-time, providers should take advantage of this time to prepare their systems to submit ICD–10–CM codes for any services that reflect a date of October 1, 2015 and later for item M0090 on the OASIS. Item M0090 is the assessment completion date reported by the HHA on the OASIS and the grouper logic requires that any assessment with a M0090 date on or after October 1, 2015 contain ICD–10–CM codes.

H. Proposed Change to the Therapy Reassessment Timeframes

Effective January 1, 2011, therapy reassessments must be performed on or ''close to'' the 13th and 19th therapy visits and at least once every 30 days (75 FR 70372). A qualified therapist, of the corresponding discipline for the type of therapy being provided, must functionally reassess the patient using a method which would include objective measurement. The measurement results and corresponding effectiveness of the therapy, or lack thereof, must be documented in the clinical record. We anticipated that policy regarding therapy coverage and therapy reassessments would address payment vulnerabilities that have led to high use and sometimes overuse of therapy services. We also discussed our expectation that this policy change would ensure more qualified therapist involvement for beneficiaries receiving high amounts of therapy. In our CY 2013 HH PPS final rule, we provided further clarifications regarding therapy coverage and therapy reassessments (77 FR 67068). Specifically, similar to the existing requirements for therapy reassessments when the patient resides in a rural area, we finalized changes to § 409.44(c)(2)(i)(C)(*2*) and (D)(*2*) specifying that when multiple types of therapy are provided, each therapist must assess the patient after the 10th therapy visit but no later than the 13th therapy visit and after the 16th therapy visit but no later than the 19th therapy visit for the plan of care. In § 409.44(c)(2)(i)(E)(*1*), we specified that when a therapy reassessment is missed, any visits for that discipline prior to the next reassessment are non-covered.

Analysis of data from CYs 2010 through 2013 shows that the frequency of episodes with therapy visits reaching 14 and 20 therapy visits did not change substantially as a result of the therapy reassessment policy implemented in CY 2011 (see Table 35). The percentage of episodes with at least 14 covered therapy visits was 17.2 percent in CY 2010 and decreased to 16.0 percent in CY 2011. In CY 2013 the percentage of episodes with at least 14 covered therapy visits increased to 16.3 percent. Likewise, the percentage of episodes with at least 20 covered therapy visits was 6.0 percent in CY 2010 and decreased to 5.4 percent in CY 2011. In CY 2013, the percentage of episodes with at least 20 covered therapy visits was 5.3 percent. We analyzed data for specific types of providers (for example, non-profit, for profit, freestanding, facility-based), and we found the similar trends in the number of episodes with at least 14 and 20 covered therapy visits. For example, for non-profit HHAs, the percentage of episodes with at least 14 covered therapy visits decreased from 11.8 percent in CY 2010 to 11.1 in CY 2011 and episodes with at least 20 covered therapy visits decreased from 4.2 percent in CY 2010 to 3.9 percent in CY 2011. For proprietary HHAs, the percentage of episodes with at least 14 covered therapy visits decreased from 19.7 percent in CY 2010 to 18.2 percent in CY 2011 and episodes with at least 20 covered therapy visits decreased

from 6.8 percent in CY 2010 to 6.1 percent in CY 2011.

As we stated in section III.A of this final rule, in addition to the implementation of the therapy reassessment requirements in CY 2011, HHAs were also subject to the Affordable Care Act face-to-face encounter requirement, payments were reduced to account for increases nominal case-mix, and the Affordable Care Act mandated that the HH PPS payment rates be reduced by 5 percent to pay up to, but no more than 2.5 percent of total HH PPS payments as outlier payments. The estimated net impact to HHAs for CY 2011 was a decrease in total HH PPS payments of 4.78 percent. The independent effects of any one policy may be difficult to discern in years where multiple policy changes occur in any given year. We note that in our CY 2012 HH PPS final rule (76 FR 68526), we recalibrated and reduced the HH PPS case-mix weights for episodes reaching 14 and 20 therapy visits, thereby diminishing the payment incentive for episodes at those therapy thresholds.

TABLE 35—PERCENTAGE OF EPISODES WITH 14 AND 20 THERAPY VISITS, CY 2010 THROUGH 2013

Calendar year	Episodes with at least 1 covered therapy visit	Episodes with at least 14 covered therapy visits	Episodes with at least 20 covered therapy visits
2010	54.1	17.2	6.0
2011	54.2	16.0	5.4
2012	55.2	15.6	5.2
2013	56.3	16.3	5.3

Source: CY 2010 claims from the Datalink file and CY 2011 through CY 2013 claims from the standard analytic file (SAF).
Note(s): For CY 2010, we included all episodes that began on or after January 1, 2010 and ended on or before December 31, 2010 and we included a 20% sample of episodes that began in CY 2009 but ended in CY 2010. For CY 2011 and CY 2013, we included all episodes that ended on or before December 31 of that CY (including 100% of episodes that began in the previous CY, but ended in the current CY).

Since the therapy reassessment requirements were implemented in CY 2011, providers have expressed frustration regarding the timing of reassessments for multi-discipline therapy episodes. In multiple therapy episodes, therapists must communicate when a planned visit and/or reassessment is missed to accurately track and count visits. Otherwise, therapy reassessments may be in jeopardy of not being performed during the required timeframe increasing the risk of subsequent visits being non-covered. As stated above, our recent analysis of claims data from CY 2010 through CY 2013 does not show significant change in the percentage of cases reaching the 14 therapy visit and 20 therapy visit thresholds between CY 2010 and CY 2011. Moreover, payment increases at the 14 therapy visit and 20 therapy visit thresholds have been somewhat mitigated since the recalibration of the case-mix weights in CY 2012. Therefore, we proposed to simplify § 409.44(c)(2) to require a qualified therapist (instead of an assistant) from each discipline to provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) at least every 14 calendar days.

The proposed requirement to perform a therapy reassessment at least once every 14 calendar days would apply to all episodes regardless of the number of therapy visits provided. All other requirements related to therapy reassessments will remain unchanged, such as a qualified therapist (instead of an assistant) from each therapy discipline provided will still be required to provide the ordered therapy service and functionally reassess the patient using a method which would include objective measurements. The measurement results and corresponding effectiveness of the therapy, or lack thereof, would be documented in the clinical record. In the proposed rule, we stated our belief that revising this requirement would make it easier and less burdensome for HHAs to track and to schedule therapy reassessments every 14 calendar days as opposed to tracking and counting therapy visits, especially for multiple-discipline therapy episodes. We also believed that this proposal would reduce the risk of non-covered visits so that therapists could focus more on providing quality care for their patients, while still promoting therapist involvement and quality treatment for all beneficiaries, regardless of the level of therapy provided.

In the CY 2015 HH PPS proposed rule (79 FR 38366–38420), we invited comment on this proposal and the associated change in the regulation at § 409.44. The following is a summary of comments we received regarding the proposed change to the therapy reassessment timeframes.

Comment: Commenters strongly supported removing the requirement to perform therapy reassessments on or ''close to'' the 13th and 19th therapy visits. Commenters appreciate our effort to simplify the therapy reassessment timeframes in order to allow more time and energy to be focused on the patients and outcomes and less time on counting visits. However, the commenters believe that the proposed reassessment interval of every 14 days would be too frequent. They noted that the 14-day interval is not linked to a clinical objective that benefits the patient. They note that changes in function as a result of improvements in functional strength, balance, and other impairments typically take longer than the 14 days. Commenters state that physiological change requires six to eight weeks to occur depending on the patient's individual goals. They believe this to be true especially in the case of home health patients who typically have complex, multi-system impairments. Most commenters believe that a 30 day reassessment would be more realistic in terms of commonly used functional tests, such as the Berg Balance test, Gait Velocity, Chair Rise test, Timed Up and Go, and Barthel Index, being able to detect a change. Several commenters believe the 14 day requirement would lead to scheduling congestion due to the shortage of qualified therapists and time constraints in rural areas where therapists spend a lot of time traveling to the patient's residence. Commenters state that this would make it exceedingly difficult for HHAs to accommodate both patient and staff scheduling needs, which would negatively impact patient care. Commenters believe that the proposed 14 day reassessment requirement discourages the proper use of assistants and their role in home health care. In addition, commenters state that the 14 day timeframe is burdensome in that it increases documentation requirements and does nothing to promote quality of

care. For example, commenters expect that the 14 day reassessment timeframe will result in patient complaints that therapists are spending too much treatment time on documentation. Additionally, the 14 day reassessment timeframe negatively impacts continuity of care. For example, if a patient is being seen by a certified occupational therapy assistant and a physical therapy assistant, then the patient would be seen by four different therapists in a two week time period. This could be overwhelming for the patient. Continuity of care and personnel are important with this population to ensure trust and follow through which directly impacts the patient's adherence to a home exercise program and to follow the functional and safety recommendations made by the treating therapists.

Several commenters stated that patient care should not be determined by a calendar and that the reassessment should still be based on the frequency of visits. Some commenters recommended that the reassessment be performed every 5th or 6th visit while others recommended that it be performed every 8th or 10th visit. However, the majority of commenters stated that converting this requirement to a calendar day based interval will be far easier to track and manage. Most commenters believe that a calendar day based interval will reduce the likelihood of inadvertently missing an assessment, especially when the patient is receiving multiple types of therapy. Several commenters suggested a reassessment timeframe in the range of every 20 to 28 days. A few commenters suggested every 6 to 8 weeks. One commenter recommended performing the assessment every 60 days. The overwhelming majority of commenters recommended reassessing the patient at least once every 30 days as the most appropriate time frame. Commenters stated that a 30 day reassessment timeframe aligns with many state practice acts, which require that a therapist reassess the patient at least once every 30 days.

Response: As a result of the comments we received, in which most commenters suggested requiring therapy reassessments at least once every 30 days, we are finalizing our proposal to eliminate the therapy reassessments that are required to be performed on or ''close to'' the 13th and 19th therapy visits. We are also finalizing that a qualified therapist (instead of an assistant) from each discipline provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) at least once every 30 calendar days, rather than at least every 14 calendar days, as proposed.

Comment: Some commenters suggested that we provide either a 3 or 5 day window or grace period before and after the 30th day in which to complete the reassessment.

Response: A 3–5 day window before the 30th day is built into the requirement to perform the reassessment at least once every 30 calendar days. However, we will not adopt a policy of allowing for a 3 or 5 day window or grace period after the 30th calendar day as some of the commenters suggested. We believe that requiring therapy reassessments to be performed at least once every 30 calendar days is flexible and enhances patient care.

Comment: Some commenters asked for clarification as to whether the proposed reassessment would be required at least once every 14 calendar days or exactly every 14th calendar day.

Response: We had intended that the proposed requirement would be for the reassessment to be performed at least once every 14 calendar days. We will finalize a requirement that the reassessment be performed at least once every 30 days. The reassessment will not have to be done on exactly the 30th day. For example, the reassessment could be done on the 21st day or the 28th day as clinically appropriate and deemed necessary by the therapist.

Comment: One commenter stated that it is in the best interest of the patient to have regular interaction with the actual therapist, not just the assistant. The commenter believes that assistants generally should not be routinely used in the home setting unless they have demonstrated advanced proficiencies in the setting and that assistant visits should be reimbursed at a lower level since HHAs pay them less.

Response: We believe that therapy assistants play a very important role in supporting therapists and providing care to home health patients, especially in rural areas and areas where there is a shortage of therapists. The home health Conditions of Participation (CoPs), at § 484.32, state that any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs. Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in in-service programs. In addition, guidelines published by the American Physical Therapy Association (APTA) state:

> When supervising the physical therapist assistant in any off-site setting, the following requirements must be observed:
>
> 1. A physical therapist must be accessible by telecommunications to the physical therapist assistant at all times while the physical therapist assistant is treating patients/clients.
>
> 2. There must be regularly scheduled and documented conferences with the physical therapist assistant regarding patients/clients, the frequency of which is determined by the needs of the patient/client and the needs of the physical therapist assistant.
>
> 3. In those situations in which a physical therapist assistant is involved in the care of a patient/client, a supervisory visit by the physical therapist will be made:
>
> a. Upon the physical therapist assistant's request for a reexamination, when a change in the plan of care is needed, prior to any planned discharge, and in response to a change in the patient's/client's medical status.
>
> b. At least once a month, or at a higher frequency when established by the physical therapist, in accordance with the needs of the patient/client.
>
> c. A supervisory visit should include:
>
> i. An on-site reexamination of the patient/client.
>
> ii. On-site review of the plan of care with appropriate revision or termination.
>
> iii. Evaluation of need and recommendation for utilization of outside resources.''[43]

We believe that requiring therapy reassessments at least once every 30 days, the current CoP requirements, and the APTA guidelines together promote regular interaction between the therapist and the patient. We will continue to monitor the frequency of assistant visits. As shown in Table 36 below, CY 2011 through CY 2013 claims data indicates that about 30 percent of the time, physical therapy is provided by assistants and about 15 percent of the time, occupational therapy is provided by assistants.

[43] *http://www.apta.org/uploadedFiles/APTAorg/About_Us/Policies/Practice/DirectionSupervisionPTA.pdf.*

TABLE 36—PERCENTAGE OF VISITS PROVIDED BY A PHYSICAL THERAPY AND OCCUPATIONAL THERAPY ASSISTANTS, CY 2011 THROUGH 2013

Year	Percentage of PT visits provided by a PTA	Percentage of OT visits provided by an OTA
2011	23.8	14.4
2012	28.5	15.4
2013	29.2	15.4

Source: Analysis of CY 2011 through CY 2013 claims data from the Standard Analytic File (SAF).

Note(s): We included all episodes that ended on or before December 31 of that CY (including 100% of episodes that began in the previous CY, but ended in the current CY).

Bureau of Labor Statistics (BLS) data on wage and fringe rates is currently used along with the minutes of care provided during home health episodes, as found on claims, to calculate an episode's resource use (an estimate of the relative cost of the episode). Data on resource use is used to construct case-mix weights that adjust the base payment rate in order to more accurately pay for home health episodes. Since CY 2012, the case mix system takes into account whether visits were performed by a therapist or a therapy assistant when constructing the case mix weights by calculating an episode's resource use accordingly. The Medicare HHA cost report form may be revised in the near future, but currently the form does not allow us to differentiate the cost of a therapist visit from a therapy assistant visit. We will consider whether separate LUPA rates for therapists versus therapy assistants are needed in the future.

Comment: A commenter requested clarification regarding the semantics of our proposal ''. . . to require a qualified therapist (instead of an assistant) from each discipline to provide the needed therapy service and functionally reassess the patient . . .'' as this could be interpreted two different ways. The commenter is concerned that the language could be interpreted to mean that therapy assistants will no longer be eligible to perform visits in the home health setting.

Response: We are not changing our existing policy regarding therapy assistants. Assistants may still perform physical therapy services and occupational therapy services which they are qualified to perform. Therapy assistants may provide therapy visits as medically reasonable and necessary to treat the patient throughout the duration of the episode. As stated in our existing policy, during the visit in which the therapist performs the assessment, the qualified therapist (not a therapy assistant) must also provide the therapy service(s).

Comment: One commenter asked if the new therapy reassessment timeframe will only apply to episodes beginning on or after January 1, 2015 or if it will also apply to episodes spanning January 1, 2015.

Response: The new therapy reassessment requirement will apply to episodes that begin on or after January 1, 2015.

Comment: Several commenters questioned when the reassessment clock would start. They asked for more clarity about whether the count would begin at the start of the episode or from the date the patient is first seen by a therapist.

Response: The clock would start from the date the patient is first seen by the qualified therapist, as per § 409.44(c)(2)(i)(A) the patient's function must be initially assessed by a qualified therapist. As stated in current guidance, the reassessment clock is not measured by episode but by the patient's full course of treatment. That is, the reassessment clock starts with the therapist's first assessment/visit and continues until the patient is discharged from home health. In cases where more than one type of therapy is being provided, each therapy discipline has its own separate clock. The 30-day clock begins with the first therapy service (of that discipline) and the clock resets with each therapist's visit/assessment/measurement/documentation (of that discipline).

In order to determine when the next therapy reassessment visit by a qualified therapist would be required, as it relates to the ''at least every 30 days'' requirement, the counting should begin the day after the service is provided. For example, if a therapist conducted and documented an assessment of a patient during a visit on April 1, the count would begin on April 2. In this case, in order to fulfill the requirement of reassessing the patient at least once every 30 days, the therapist rather than an assistant, would need to return by May 1.

We note that the intent of the policy is to ensure that, at a minimum, a patient is seen by the therapist at least once every 30 days. The intent is not for a therapist to wait until the 30th day to visit a patient. A therapy reassessment visit should include providing the actual therapy service(s), functionally assessing the patient, measuring progress to determine if the goals have been met, and documenting measurement results and corresponding therapy effectiveness in the clinical record.

Comment: A commenter was supportive of a requirement for reassessing the patient every 30 days with the understanding that nothing precludes an agency from doing another assessment earlier than the 30th day if warranted by the patient's condition or ending of therapy.

Response: The commenter is correct. Nothing precludes an agency from doing another assessment earlier than the 30th day if warranted by the patient's condition or ending of therapy. As stated above, the requirement is for the qualified therapist to reassess the patient at least once every 30 days.

Comment: A commenter stated that education regarding any changes to the timing expectations is critical to reduce confusion and prevent misunderstandings and that clearly written instruction with specific examples would be extremely beneficial. The commenter further stated that partnering with the therapy associations in educational efforts will help get the correct word out to the therapists themselves.

Response: We will be updating the policy as published in chapter 7 ''Home Health Services'' of the Medicare Benefit Policy Manual (Pub. 100–20) and publishing a provider education article related to the revised policy. As always, we appreciate any educational efforts that the professional associations are able and willing to provide.

Final Decision: In summary, we are finalizing changes to the regulations at § 409.44, effective for episodes ending on or after January 1, 2015, to require that at least every 30 days a qualified therapist (instead of an assistant) must provide the needed therapy service and functionally reassess the patient. Where more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must provide the needed therapy service and functionally reassess the patient at least every 30 days. Therapy reassessments are to be performed using a method that would include objective measurement, in accordance with accepted professional standards of clinical practice, which enables comparison of successive measurements to determine the effectiveness of therapy goals. Such objective measurements would be made by the qualified therapist using measurements which assess activities of daily living that may include but are not limited to eating, swallowing, bathing, dressing, toileting, walking, climbing stairs, or using assistive devices, and mental and cognitive factors. The measurement results and corresponding effectiveness of the therapy, or lack

thereof, must be documented in the clinical record.

I. HHA Value-Based Purchasing Model

As we discussed previously in the FY 2009 proposed rule for Skilled Nursing Facilities (73 FR 25918, 25932, May 7, 2008), value-based purchasing (VBP) programs, in general, are intended to tie a provider's payment to its performance in such a way as to reduce inappropriate or poorly furnished care and identify and reward those who furnish quality patient care. Section 3006(b)(1) of the Affordable Care Act directed the Secretary to develop a plan to implement a VBP program for home health agencies (HHAs) and to issue an associated Report to Congress (Report). The Secretary issued that Report, which is available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/downloads/stage-2-NPRM.PDF.*

The Report included a roadmap for HHA VBP implementation. The Report outlined the need to develop a HHA VBP program that aligns with other Medicare programs and coordinates incentives to improve quality. The Report indicated that a HHA VBP program should build on and refine existing quality measurement tools and processes. In addition, the Report indicated that one of the ways that such a program could link payment to quality would be to tie payments to overall quality performance.

Section 402(a)(1)(A), of the Social Security Amendments of 1967 (as amended), 42 U.S.C. 1395b–1(a)(1)(A) provided authority for CMS to conduct the Home Health Pay-for-Performance (HHPFP) Demonstration that ran from 2008 to 2010. The results of that Demonstration found limited quality improvement in certain measures after comparing the quality of care furnished by Demonstration participants to the quality of care furnished by the control group. One important lesson learned from the HHPFP Demonstration was the need to link the HHA's quality improvement efforts and the incentives. HHAs in three of the four regions generated enough savings to have incentive payments in the first year of the Demonstration, but the size of payments were unknown until after the conclusion of the Demonstration. This time lag on paying incentive payments did not provide a sufficient incentive to HHAs to make investments necessary to improve quality. The Demonstration suggested that future models could benefit from ensuring that incentives are reliable enough, of sufficient magnitude, and paid in a timely fashion to encourage HHAs to be fully engaged in the quality of care initiative. The evaluation report is available online at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/HHP4P_Demo_Eval_Final_Vol1.pdf.*

We have already successfully implemented the Hospital Value-Based Purchasing (HVBP) program where 1.25 percent of hospital payments in FY 2014 are tied to the quality of care that the hospitals provide. This percentage amount will gradually increase to 2.0 percent in FY 2017 and subsequent years. The President's 2015 Budget proposes that value-based purchasing should be extended to additional providers including skilled nursing facilities, home health agencies, ambulatory surgical centers, and hospital outpatient departments. Therefore, we are now considering testing a HHA VBP model that builds on what we have learned from the HVBP program. The model also presents an opportunity to test whether larger incentives than what have been previously tested will lead to even greater improvement in the quality of care furnished to beneficiaries. The HHA VBP model that is being considered will offer both a greater potential reward for high performing HHAs as well as a greater potential downside risk for low performing HHAs. If implemented, the model will begin at the outset of CY 2016, and include an array of measures that can capture the multiple dimensions of care that HHAs furnish. Building upon the successes of other related programs, we are seeking to implement a model with greater upside benefit and downside risk to motivate HHAs to make the substantive investments necessary to improve the quality of care furnished by HHAs.

As currently envisioned, the HHA VBP model would reduce or increase Medicare payments, in a 5–8 percent range, depending on the degree of quality performance in various measures to be selected. The model would apply to all HHAs in each of the projected five to eight states selected to participate in the model. The distribution of payments would be based on quality performance, as measured by both achievement and improvement across multiple quality measures. Some HHAs would receive higher payments than standard fee-for-service payments and some HHAs would receive lower payments, similar to the HVBP program. We believe the payment adjustment at risk would provide an incentive among all HHAs to provide significantly better quality through improved planning, coordination, and management of care. To be eligible for any incentive payments, HHAs would need to achieve a minimal threshold in quality performance with respect to the care that they furnish. The size of the award would be dependent on the level of quality furnished above the minimal threshold with the highest performance awards going to HHAs with the highest overall level of or improvement in quality.

HHAs that meet or exceed the performance standards based on quality and efficiency metrics would be eligible to earn performance payments. The size of the performance payment would be dependent upon the provider's performance relative to other HHAs within its participating state. HHAs that exceed the performance standards and demonstrate the greatest level of overall quality or quality improvement on the selected measures would have the opportunity to receive performance payment adjustments greater than the amount of the payment reduction, and would therefore see a net payment increase as a result of this model. Those HHAs that fail to meet the performance standard would receive lower payments than what would have been reimbursed under the traditional FFS Medicare payment system, and would therefore see a net payment decrease to Medicare payments as a result of this model. We stated in the proposed rule that we are proposing to use the waiver authority under section 1115A of the Act to waive the applicable Medicare payment provisions for HHAs in the selected states and apply a reduction or increase to current Medicare payments to these HHAs, which will be dependent on their performance.

We are considering a HHA VBP model in which participation by all HHAs in five to eight selected states is mandatory. We believe requiring all HHAs in selected states to participate in the model will ensure that: (1) There is no selection bias, (2) participating HHAs are representative of HHAs nationally, and (3) there is sufficient participation to generate meaningful results. In our experience, providers are generally reluctant to participate voluntarily in models in which their Medicare payments are subject to reduction. In the proposed rule, we invited comments on the HHA VBP model outlined above, including elements of the model, size of the payment incentives and percentage of payments that would need to be placed at risk in order to spur HHAs to make the necessary investments to improve the quality of care for Medicare beneficiaries, the timing of the incentive

payments, and how performance payments should be distributed. We also invited comments on the best approach for selecting states for participation in this model. Approaches could include: (1) Selecting states randomly, (2) selecting states based on quality, utilization, health IT, or efficiency metrics or a combination, or (3) other considerations. We noted that if we decide to move forward with the implementation of this HHA VBP model in CY 2016, we intended to invite additional comments on a more detailed model proposal to be included in future rulemaking.

We received a number of comments on the model design, including the following:

- A number of commenters expressed concern regarding the magnitude of 5–8 percent payment adjustment incentives, particularly when considering HHA margins, and as compared to the Hospital Value-based Purchasing program. A number of commenters also expressed support for a high payment incentive because they believe that this payment incentive will provide adequate remuneration for an investment in quality.
- A number of commenters encouraged a combination of pay-for-performance and pay-for-reporting .
- A number of commenters expressed ideas on the evaluation criteria under the model, for example: Not using the 5-star system, giving higher weight to quality measures relating to conditions requiring home health intervention, excluding HHCAHPS from the criteria due to timeliness reasons, excluding re-hospitalization metrics since they are often determined by physician judgment, and excluding OASIS measures since they might be fraudulently manipulated.
- A number of commenters expressed support for the inclusion of a beneficiary risk adjustment strategy to help prevent cherry picking of easier cases.
- A number of commenters preferred for HHAs to be allowed to select participation as opposed to the mandatory participation being considered by CMS.
- A number of commenters expressed opinions about the methodology for selecting the participating states, including choosing them from various MAC regions, choosing a rural and frontier state, and excluding states with moratoria on new HHAs.
- A number of commenters supported the development of a VBP model.

We thank all commenters for their input and will consider these comments as we make further decisions about implementing a HHA VBP model in CY 2016 which would assess performance from each of the preceding baseline years. As stated in the proposed rule, we intend to invite additional comments on a more detailed model proposal to be included in future rulemaking, including the selection of states and the criteria used for selection, the specific measures to be employed, how these measures are categorized within domains and the criteria used for selection, and the payment adjustment percentage.

J. Advancing Health Information Exchange

HHS believes all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, ''Principles and Strategies for Accelerating Health Information Exchange.'') The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (health IT) across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies, (2) adoption of common standards and certification requirements for interoperable health IT, (3) support for privacy and security of patient information across all HIE-focused initiatives, and (4) governance of health information networks. These initiatives are designed to encourage HIE among all health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive programs, and are designed to improve care delivery and coordination across the entire care continuum. We believe that HIE and the use of certified EHR technology by HHAs (and other providers ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and enable the reporting of electronically specified clinical quality measures (eCQMs).

Comments: Responses from commenters generally supported the use of EHRs to advance standards-based interoperable health information exchange, ensure privacy and security protections, and improve patient-centered quality care. Commenters noted the ability for health IT to enable access to essential information for decision-making by individuals, providers and their family caregivers. One commenter noted the possibility that some vendors may sunset products or increase costs as health IT standards are adopted. Other commenters noted the need for standards that recognize the distinct functional needs of the home care sector and requested notice regarding emerging standards to allow sufficient time for vendor and provider integration. Other commenters expressed concern regarding increased costs associated with implementing HIE and the lack of incentives to support capital expenditures.

Response: We thank commenters for their responses. HHS will continue to promote the adoption and implementation of certified health IT. The use of certified health IT can improve interoperability through the use of national, consensus-based standards as well as facilitate the secure interoperable exchange of health information. To increase flexibility in the Office of the National Coordinator for Health Information Technology's (ONC) regulatory certification structure, ONC expressed in the 2014 Edition Release 2 final rule (79 FR 54472–73) an intent to propose future changes to the ONC HIT Certification Program that would permit the certification of health IT for other health care settings, such as long-term and post-acute care and behavioral health settings. For now, we direct stakeholders to the ONC guidance for EHR technology developers serving providers ineligible for the Medicare and Medicaid EHR Incentive Programs titled ''Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments.'' [44] We encourage stakeholders to also review the Health IT Policy Committee (a Federal Advisory Committee) recommendations for areas in which certification under the ONC HIT Certification Program would help support long-term and post-acute care providers.[45] Further,

[44] *http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf. More information on the current development of standards applicable to HH can be found at: http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG and http://wiki.siframework.org/Longitudinal+Coordination+of+Care.*

[45] *http://www.healthit.gov/facas/sites/faca/files/TransmittalLetter_LTPAC_BH_Certification.pdf;*

stakeholders should consider emerging innovative payment models, quality reporting programs, state Medicaid reimbursement for remote monitoring (available in some states) and grants that could provide funding for health IT implementation for home health or incentivize other providers to assist home health providers' implementation efforts. For an overview of these opportunities, stakeholders are directed to the Health IT in Long-Term Post-Acute Care Issue Brief.[46]

K. Proposed Revisions to the Speech-Language Pathologist Personnel Qualifications

We proposed to revise the personnel qualifications for speech-language pathologists (SLP) to more closely align the regulatory requirements with those set forth in section 1861(ll) of the Act. We proposed to require that a qualified SLP be an individual who has a master's or doctoral degree in speech-language pathology, and who is licensed as a speech-language pathologist by the state in which he or she furnishes such services. To the extent of our knowledge, all states license SLPs; therefore, all SLPs would be covered by this option. We believe that deferring to the states to establish specific SLP requirements would allow all appropriate SLPs to provide services to Medicare beneficiaries. Should a state choose not to offer licensure at some point in the future, we proposed a second, more specific, option for qualification. In that circumstance, we proposed to require that a SLP successfully complete 350 clock hours of supervised clinical practicum (or be in the process of accumulating such supervised clinical experience); perform not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and successfully complete a national examination in speech-language pathology approved by the Secretary. These specific requirements are set forth in the Act, and we believe that they are appropriate for inclusion in the regulations as well.

We invited comments on this technical correction and associated change in the regulations at § 484.4 in section VI. We received five public comments regarding this proposal from individual HHAs, state HHA provider organizations, and a national organization representing SLPs.

Comment: All comments supported the deferral to state licensure standards and validated CMS' understanding that all states currently have licensure standards for SLPs. One commenter supported the inclusion of separate qualifications for those SLPs located in areas without state licensure, noting that these regulations would also apply in US Territories, and that not all Territories have licensure standards for SLPs.

Response: We agree with the commenters that the changes would be appropriate, and are finalizing them as such.

Comment: A commenter suggested that we should replace the specific education, training, and experience requirements set forth in the Social Security Act with a requirement that an SLP must meet the certification standards established by the American Speech-Language-Hearing Association (ASHA).

Response: The Social Security Act (the Act), on which the regulation is based, does not limit SLPs to only those individuals who meet the ASHA certification standards. Since this limitation does not exist in the Act, we do not believe it should exist in the regulations. Therefore, in order to align the regulatory requirements with those requirements set forth in the Act, we are not making the suggested change. States are free to require ASHA certification as part of their SLP licensure standards.

Comment: One comment sought clarification on why this change was being proposed at this time rather than as part of a comprehensive revision of the home health agency Conditions of Participation (CoPs).

Response: While a comprehensive revision of the home health CoPs is underway, we have received information from those in the SLP community that the restrictions currently in place for SLPs are impeding the ability of SLPs to practice. Finalizing a comprehensive revision to the home health agency CoPs will require several years. We believe that it is in the interest of the HHA and SLP communities, as well as the Medicare program, to effect a more timely change to the SLP personnel qualifications. Therefore, we are finalizing the revised requirements, as proposed, in this rule, and the change will be effective on January 1, 2015.

Final decision: We are finalizing the proposal without change.

L. Technical Regulations Text Changes

We proposed to make technical corrections in § 424.22(b)(1) to better align the recertification requirements with the Medicare Conditions of Participation (CoPs) for home health services. Specifically, we proposed that § 424.22(b)(1) will specify that recertification is required at least every 60 days when there is a need for continuous home health care after an initial 60-day episode to coincide with the CoP requirements in § 484.55(d)(1), which require the HHA to update the comprehensive assessment in the last 5 days of every 60-day episode of care. As stated in § 484.55, the comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. We also proposed to specify in § 424.22(b)(1) that recertification is required at least every 60 days unless there is a beneficiary elected transfer or a discharge with goals met and return to the same HHA during the 60-day episode. The word ''unless'' was inadvertently left out of the payment regulations text. Inserting ''unless'' into § 424.22(b)(1) realigns the recertification requirements with the CoPs at § 484.55(d)(1).

As outlined in the ''Medicare Program; Prospective Payment System for Home Health Agencies'' final rule published on July 3, 2000 (65 FR 41188 through 41190), a partial episode payment (PEP) adjustment applies to two intervening events: (1) Where the beneficiary elects a transfer to another HHA during a 60-day episode or the patient; or (2) a discharge and return to the same HHA during the 60-day episode when a beneficiary reached the treatment goals in the plan of care. To discharge with goals met, the plan of care must be terminated with no anticipated need for additional home health services for the balance of the 60-day period. A PEP adjustment proportionally adjusts the national, standardized 60-day episode payment amount to reflect the length of time the beneficiary remained under the agency's care before the intervening event.

We proposed to revised § 424.22(b)(1)(ii) to clarify that if a beneficiary is discharged with goals met and/or no expectation of a return to home health care and returns to the same HHA during the 60-day episode a new start of care would be initiated (rather than an update to the comprehensive assessment) and thus the second episode will be considered a

http://www.healthit.gov/facas/sites/faca/files/HITPC_LTPAC_BH_Certification_Recommendations_FINAL.pdf.

[46] *http://www.healthit.gov/sites/default/files/pdf/HIT_LTPAC_IssueBrief031513.pdf.*

certification, not a recertification,[47] and would be subject to § 424.22(a)(1).

We also proposed to make a technical correction in § 484.250(a)(1) to remove the ''-C'' after ''OASIS'' in § 484.250(a)(1), so that the regulation refers generically to the version of OASIS currently approved by the Secretary, and to align this section with the payment regulations at § 484.210(e). Specifically, an HHA must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) for CMS to administer the payment rate methodologies described in § 484.215, § 484.230, and § 484.235 and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

Most of the comments that we received, where the commenter indicated that they were commenting on these technical corrections and associated changes in the regulations at § 424.22 and § 484.250 in section VI, were, in fact, also commenting on the proposed clarification on when documentation of a face-to-face encounter is required in section III.B.3. While we are finalizing these regulations text changes as proposed, we refer readers to the summary of the comments and responses in section III.B.3. for our rationale.

Final Decision: We are finalizing the proposed regulations text changed at § 424.22 and § 484.250 as proposed.

M. Survey and Enforcement Requirements for Home Health Agencies

1. Statutory Background and Authority

Section 4023 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L 100–203, enacted on December 22, 1987) added subsections 1891(e) and (f) to the Act, which expanded the Secretary's options to enforce federal requirements for home health agencies (HHAs or the agency). Sections 1861(e)(1) and (2) of the Act provide that if CMS determines that an HHA is not in compliance with the Medicare home health Conditions of Participation and the deficiencies involved either do, or do not, immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, then we may terminate the provider agreement, impose an alternative sanction(s), or both. Section 1891(f)(1)(B) of the Act authorizes the Secretary to develop and implement appropriate procedures for appealing determinations relating to the imposition of alternative sanctions.

In the November 8, 2012 **Federal Register** (77 FR 67068), we published the ''Alternative Sanctions for Home Health Agencies With Deficiencies'' final rule (part 488, subpart J), as well as made corresponding revisions to sections § 489.53 and § 498.3. This subpart J added the rules for enforcement actions for HHAs including alternative sanctions. Section 488.810(g) provides that 42 CFR part 498 applies when an HHA requests a hearing on a determination of noncompliance that leads to the imposition of a sanction, including termination. Section 488.845(b) describes the ranges of CMPs that may be imposed for all condition-level findings: upper range ($8,500 to $10,000); middle range ($1,500 to $8,500); lower range ($500 to $4,000), as well as CMPs imposed per instance of noncompliance ($1,000 to $10,000).

Section 488.845(c)(2) addresses the appeals procedures when CMPs are imposed, including the need for any appeal request to meet the requirements of § 498.40 and the option for waiver of a hearing.

2. Reviewability Pursuant to Appeals

We proposed to amend § 488.845 by adding a new paragraph (h) which would explain the reviewability of a CMP that is imposed on a HHA for noncompliance with federal participation requirements. The new language will provide that when administrative law judges (ALJs), state hearing officers (or higher administrative review authorities) find that the basis for imposing a civil money penalty exists, as specified in § 488.485, he or she may not set a penalty of zero or reduce a penalty to zero; review the exercise of discretion by CMS or the state to impose a civil money penalty; or, in reviewing the amount of the penalty, consider any factors other than those specified in §§ 488.485(b)(1)(i) through (b)(1)(iv). That is, when the administrative law judge or state hearing officer (or higher administrative review authority) finds noncompliance supporting the imposition of the CMP, he or she must retain some amount of penalty consistent with the ranges of penalty amounts established in § 488.845(b). The proposed language for HHA reviews is similar to the current § 488.438(e) governing the scope of review for civil money penalties imposed against skilled nursing facilities, and is also consistent with section 1128A(d) of the Act which requires that specific factors be considered in determining the amount of any penalty.

The following is a summary of the comments we received regarding the proposed amendment to § 488.845 to explain the reviewability of a CMP by an ALJ.

Comment: One commenter supported the proposal, as it would align HHA policy more closely with SNF policy regarding ALJ reviewability.

Response: We agree with the commenter who observed that the proposal would align HHA policy with long-standing practice and policy with regard to the manner in which SNF CMPs are reviewed. We believe it is important that CMS be consistent in the application of CMPs among providers, and the proposed language for HHA CMPs is consistent with existing language for SNFs at § 488.438(e).

Comment: Two commenters believed that the HHA CMP process was too new for changes to be addressed in the ALJ review process.

Response: The length of time the HHA CMPs have been in effect is not relevant to the implementation of the requirements of the Act and implementing regulations. Section 1891(f)(1)(B) of the Act requires the Secretary to provide appropriate procedures for appealing the determination relating to the imposition of a sanction. As provided at § 488.845(c)(2)(i) ''Appeals Procedures'', the determination that is the basis for imposition of the CMP may be appealed. The proposed language does not revise the regulation at § 488.845(c)(2)(i), but adds clarification regarding the scope of the review during the appeal process.

Comment: One commenter believed that the ALJs should be allowed to eliminate CMPs as a part of their administrative review.

Response: Section 1891(b) of the Act mandates that it is the duty and responsibility of the Secretary to assure that the conditions of participation as well as the enforcement of such conditions is adequate to protect the health and safety of individuals under the care of an HHA. Section 1891(f) of the Act further specifies that the Secretary establish a range of intermediate sanctions which shall include, among others, civil money penalties. Finally, section 1819(f)(1)(B) of the Act requires the Secretary to provide appropriate procedures for appealing the determination relating to the imposition of the sanction and the implementing regulations at § 488.845(c)(2)(i), ''Appeals Procedures'' provide that the determination that is the basis for imposition of the CMP may be appealed. It is within our discretion as to the choice of remedy to be imposed. While an ALJ may review the underlying findings that support CMS's determination to impose a CMP and

[47] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/downloads/OASISConsiderationsforPPS.pdf*

whether or not the imposed amount falls within the regulatory range, elimination of any CMP is not within the scope of the appeal process.

Comment: One commenter believed the denial of appeal of the implementation of the CMP may not be constitutionally valid. An additional two commenters believed this proposed language added additional restrictions to the ALJ which resulted in the lack of due process.

Response: We do not believe that the proposed language raises constitutional issues or restricts due process. Section 1128A of the Act requires that specific factors be considered in determining the amount of the penalty. Those factors, particularly the deficiencies cited by the survey, are considered by CMS in the establishment of the CMP amount to be imposed. The deficiencies which give rise to a CMP may be appealed. Section 1891(f)(1)(B) of the Act requires the Secretary to provide appropriate procedures for appealing the determination relating to the imposition of the sanction. These procedures are provided at § 488.845(c)(2)(i). The CMP itself would be affected if the deficiencies underlying the determination were not sustained on appeal.

Final Decision: After careful consideration of the comments received, we are finalizing the regulatory language as proposed.

3. Technical Adjustment

We also proposed to amend § 498.3, Scope and Applicability, by revising paragraph (b)(13) to include specific cross reference to proposed § 488.845(h) and to revise the reference to section § 488.740 which was a typographical error and replace it with section § 488.820 which is the actual section that lists the sanctions available to be imposed against an HHA. We also amended § 498.3(b)(14)(i) to include cross reference to proposed § 488.845(h), which establishes the scope of CMP review for HHAs. Finally, we proposed to amend § 498.60 to include specific references to HHAs and proposed § 488.845(h).

IV. 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. 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.

We solicited public comment on the information collection requirement (ICR) related to the proposed changes to the home health face-to-face encounter requirements in section III.B and the proposed change to the therapy reassessment timeframes in section III.H. These proposed changes are associated with ICR approved under OMB control number as 0938–1083.

A. Proposed Changes to the Face-to-Face Encounter Requirements

The following assumptions were used in estimating the burden for the proposed changes to the home health face-to-face requirements:

TABLE 37—HOME HEALTH FACE-TO-FACE ENCOUNTER BURDEN ESTIMATE ASSUMPTIONS

# of Medicare-billing HHAs, from CY 2013 claims with matched OASIS assessments	11,521
Hourly rate of an office employee (Executive Secretaries and Executive Administrative Assistants, 43–6014)	$20.54 ($15.80 ×; 1.30)
Hourly rate of an administrator (General and Operations Managers, 11–1021)	$64.65 ($49.73 ×; 1.30)
Hourly rate of Family and General Practitioners (29–1062)	$112.91 ($86.85 ×; 1.30)

Note: CY = Calendar Year.

All salary information is from the Bureau of Labor Statistics (BLS) Web site at *http://www.bls.gov/oes/current/naics4_621600.htm* and includes a fringe benefits package worth 30 percent of the base salary. The mean hourly wage rates are based on May 2013 BLS data for each discipline, for those providing ''home health care services.''

1. Proposed Changes to the Face-to-Face Encounter Narrative Requirement

Sections 1814(a)(2)(C) and 1835 (a)(2)(A) of the Act, as amended by section 6407 of the Affordable Care Act require that, as a condition for payment, prior to certifying a patient's eligibility for the Medicare home health benefit the physician must document that the physician himself or herself or an allowed nonphysician practitioner (NPP) had a face-to-face encounter with the patient. Section 424.22(a)(1)(v) currently requires that that the face-to-face encounter be related to the primary reason the patient requires home health services and occur no more than 90 days prior to the home health start of care date or within 30 days after the start of the home health care. In addition, as part of the certification of eligibly, the certifying physician must document the date of the encounter and include an explanation (narrative) of why the clinical findings of such encounter support that the patient is homebound, as defined in section 1835(a) of the Act, and in need of either intermittent skilled nursing services or therapy services, as defined in § 409.42(c).

To simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with certification requirements, we propose to eliminate the narrative requirement at § 424.22(a)(1)(v). The certifying physician will still be required to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner as defined in § 424.22(a)(1)(v)(A), and to document the date of the encounter as part of the certification of eligibility.

In eliminating the face-to-face encounter narrative requirement, we assume that there will be a one-time burden for the HHA to modify the certification form, which the HHA provides to the certifying physician. The revised certification form must allow the certifying physician to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care

and was performed by a physician or allowed NPP as defined in § 424.22(a)(1)(v)(A). In addition, the certification form must allow the certifying physician to document the date that the face-to-face encounter occurred.

We estimate that it would take a home health clerical staff person 15 minutes (15/60 = 0.25 hours) to modify the certification form, and the HHA administrator 15 minutes (15/60 = 0.25 hours) to review the revised form. The clerical time plus administrator time equals a one-time burden of 30 minutes or (30/60) = 0.50 hours per HHA. For all 11,521 HHAs, the total time required would be (0.50 ×; 11,521) = 5,761 hours. At $20.54 per hour for an office employee, the cost per HHA would be (0.25 ×; $20.54) = $5.14. At $64.65 per hour for the administrator's time, the cost per HHA would be (0.25 × $64.65) = $16.16. Therefore, the total one-time cost per HHA would be $21.30, and the total one-time cost for all HHAs would be ($21.30 × 11,521) = $245,397.

In the CY 2011 HH PPS final rule (75 FR 70455), we estimated that the certifying physician's burden for composing the face-to-face encounter narrative, which includes how the clinical findings of the encounter support eligibility (writing, typing, or dictating the face-to-face encounter narrative) signing, and dating the patient's face-to-face encounter, was 5 minutes for each certification (5/60 = 0.0833 hours). Because it has been our longstanding manual policy that physicians sign and date certifications and recertifications, there is no additional burden to physicians for signing and dating the face-to-face encounter documentation. We estimate that there would be 3,096,680 initial home health episodes in a year based on 2012 claims data from the home health Datalink file. As such, the estimated burden for the certifying physician to write the face-to-face encounter narrative would have been 0.0833 hours per certification (5/60 = 0.0833 hours) or 257,953 hours total (0.0833 hours × 3,096,680 initial home health episodes). The estimated cost for the certifying physician to write to face-to-face encounter narrative would have been $9.41 per certification (0.0833 × $112.91) or $29,139,759 total ($9.41 × 3,096,680) for CY 2015.

Although we proposed to eliminate the narrative, the certifying physician will still be required to document the date of the face-to-face encounter as part of the certification of eligibility. We estimate that it would take no more than 1 minute for the certifying physician to document the date that the face-to-face encounter occurred (1/60 = 0.0166 hours). The estimated burden for the certifying physician to continue to document the date of the face-to-face encounter would be 0.0166 hours per certification or 51,405 hours total (0.0166 hours × 3,096,680 initial home health episodes). The estimated cost for the certifying physician to continue to document the date of the face-to-face encounter would be $1.87 per certification (0.0166 × $112.91) or $5,790,792 total ($1.87 × 3,096,680) for CY 2015. Therefore, in eliminating the face-to-face encounter narrative requirement, as proposed in section III.B. of the proposed rule, we estimate that burden and costs will be reduced for certifying physicians by 206,548 hours (257,953–51,405) and $23,348,967 ($29,139,759–$5,790,792), respectively for CY 2015.

Comment: A commenter believed that the time estimates were under-reported for the HHA administrator (15 minutes (15/60 = 0.25 hours)) to review the revised certification form. The commenter stated that the administrator would have to review the pertinent statutory and regulatory references to ensure that the certification form is in compliance.

Response: Since all certification requirements are remaining the same, except for the elimination of the narrative, the administrator should already be knowledgeable about the current statutory and regulatory requirements with regard to certifying patient eligibility for the home health benefit. Therefore, we will maintain our original estimate that it will take no more than 15 minutes for the HHA administrator to review the necessary changes to the certification form as a result of the elimination of the face-to-face encounter narrative.

2. Proposed Clarification on When Documentation of a Face-to-Face Encounter Is Required

To determine when documentation of a patient's face-to-face encounter is required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, we proposed to clarify that the face-to-face encounter requirement is applicable for certifications (not recertifications), rather than initial episodes. A certification (versus recertification) is generally considered to be any time that a new SOC OASIS is completed to initiate care. We estimate that of the 6,562,856 episodes in the CY 2012 home health Datalink file, 3,096,680 SOC assessments were performed on initial home health episodes. If this proposal is implemented, an additional 830,287 episodes would require documentation of a face-to-face encounter for subsequent episodes that were initiated with a new SOC OASIS assessment. We estimate that it would take no more than 1 minute for the certifying physician to document the date that the face-to-face encounter occurred (1/60 = 0.0166 hours). The estimated burden for the certifying physician to document the date of the face-to-face encounter for each certification (any time a new SOC OASIS is completed to initiate care) would be 0.0166 hours or 13,783 total hours (0.0166 hours × 830,287 additional home health episodes). The estimated cost for the certifying physician to document the date of the face-to-face encounter for each additional home health episode would be $1.87 per certification (0.0166 × $112.91) or $1,552,637 total ($1.87 × 830,287) for CY 2015.

TABLE 38—ESTIMATED ONE-TIME FORM REVISION BURDEN FOR HHAS

OMB#	Requirement	HHAs	Responses	Hr. burden	Total time (hours)	Total dollars
0938–1083	§ 424.22(a)(1)(v)	11,521	1	0.5	5,761	$245,397

TABLE 39—ESTIMATED BURDEN REDUCTION FOR CERTIFYING PHYSICIANS

[No longer drafting a face-to-face encounter narrative]

OMB#	Requirement	Certifications	Responses	Hr. burden	Total time (hours)	Total dollars
0938–1083	§ 424.22(a)(1)(v)	3,096,680	1	(0.0667)	(206,548)	($23,348,967)

TABLE 40—ESTIMATED BURDEN FOR CERTIFYING PHYSICIANS

[Documenting the date of the face-to-face encounter for additional certifications]

OMB#	Requirement	Certifications	Responses	Hr. burden	Total time (hours)	Total dollars
0938–1083	§ 424.22(a)(1)(v)	830,287	1	0.0166	13,783	$1,552,637

In summary, all of the changes to the face-to-face encounter requirements in section III.B of this final rule, including changes to § 424.22(a)(1)(v), will result in an estimated net reduction in burden for certifying physicians of 192,765 hours or $21,796,330 (see Tables 39 and 40). The changes to the face-to-face encounter requirements at § 424.22(a)(1)(v) will result in a one-time burden for HHAs to revise the certification form of 5,761 hours or $245,397 (Table 38 above).

B. Proposed Change to the Therapy Reassessment Timeframes

Currently, § 409.44(c) requires that patient's function must be initially assessed and periodically reassessed by a qualified therapist, of the corresponding discipline for the type of therapy being provided, using a method which would include objective measurement. If more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must perform the assessment and periodic reassessments. The measurement results and corresponding effectiveness of the therapy, or lack thereof, must be documented in the clinical record. At least every 30 days a qualified therapist (instead of an assistant) must provide the needed therapy service and functionally reassess the patient. If a patient is expected to require 13 and/or 19 therapy visits, a qualified therapist (instead of an assistant) must provide all of the therapy services on the 13th visit and/or 19th therapy visit and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A). When the patient resides in a rural area or if the patient is receiving multiple types of therapy, a therapist from each discipline (not an assistant) must assess the patient after the 10th therapy visit but no later than the 13th therapy visit and after the 16th therapy visit but no later than the 19th therapy visit for the plan of care. In instances where the frequency of a particular discipline, as ordered by a physician, does not make it feasible for the reassessment to occur during the specified timeframes without providing an extra unnecessary visit or delaying a visit, then it is acceptable for the qualified therapist from that discipline to provide all of the therapy and functionally reassess the patient during the visit associated with that discipline that is scheduled to occur closest to the 14th and/or 20th Medicare-covered therapy visit, but no later than the 13th and/or 19th Medicare-covered therapy visit. When a therapy reassessment is missed, any visits for that discipline prior to the next reassessment are non-covered.

To lessen the burden on HHAs of counting visits and to reduce the risk of non-covered visits so that therapists can focus more on providing quality care for their patients, we are simplifying § 409.44(c) to require that therapy reassessments must be performed at least once every 30 calendar days. The requirement to perform a therapy reassessment at least once every 30 calendar days would apply to all episodes regardless of the number of therapy visits provided. All other requirements related to therapy reassessments would remain unchanged. A qualified therapist (instead of an assistant), from each therapy discipline provided, must provide the ordered therapy service and functionally reassess the patient using a method which would include objective measurement. The measurement results and corresponding effectiveness of the therapy, or lack thereof, must be documented in the clinical record.

In the CY 2011 HH PPS final rule we stated that the therapy reassessment requirements in § 409.44(c) are already part of the home health CoPs, as well as from accepted standards of clinical practice, and therefore, we believe that these requirements do not create any additional burden on HHAs (75 FR 70454). As stated in the CY 2011 HH PPS final rule, longstanding CoP policy at § 484.55 requires HHAs to document progress toward goals and the regulations at § 409.44(c)(2)(i) already mandate that for therapy services to be covered in the home health setting, the services must be considered under accepted practice to be a specific, safe, and effective treatment for the beneficiary's condition. The functional assessment does not require a special visit to the patient, but is conducted as part of a regularly scheduled therapy visit. Functional assessments are necessary to demonstrate progress (or the lack thereof) toward therapy goals, and are already part of accepted standards of clinical practice, which include assessing a patient's function on an ongoing basis as part of each visit. The CY 2011 HH PPS final rule goes on to state that both the functional assessment and its accompanying documentation are already part of existing HHA practices and accepted standards of clinical practice. Therefore, we continue to believe that simplifying the required reassessment timeframes from every 30 days and prior to the 14th and 20th visits to every 30 calendar days does not place any new documentation requirements on HHAs.

We are revising the currently approved PRA package (OMB# 0938–1083) to describe these changes to the regulatory text.

C. Submission of PRA-Related Comments

If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this final rule.

PRA-specific comments must be received on/by December 8, 2014.

V. Regulatory Impact Analysis

A. Statement of Need

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare. In addition, section 1895(b)(3)(A) of the Act requires (1) the computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary, and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(5) of the Act gives the Secretary the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Also, section 1886(d)(2)(D) of the Act requires that home health services furnished in a rural area for episodes and visits ending on or after April 1, 2010, and before January 1, 2016, receive an increase of 3 percent the payment amount otherwise made under section 1895 of the Act.

Section 3131(a) of the Affordable Care Act mandates that starting in CY 2014, the Secretary must apply an adjustment to the national, standardized 60-day episode payment rate and other amounts applicable under section 1895(b)(3)(A)(i)(III) of the Act to reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. In addition, section 3131(a) of the Affordable Care Act mandates that rebasing must be phased-in over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment (2010) under section 1895(b)(3)(A)(i)(III) of the Act, and be fully implemented in CY 2017.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as economically significant under section 3(f)(1) of Executive Order 12866, since the aggregate transfer impacts in calendar year 2015 will exceed the $100 million threshold. The net transfer impacts are estimated to be −$60 million. Furthermore, we estimate a net reduction of $21.55 million in calendar year 2015 burden costs related to the certification requirements for home health agencies and associated physicians. Lastly, this final rule is a major rule under the Congressional Review Act and as a result, we have prepared a regulatory impact analysis (RIA) that, to the best of our ability, presents the costs and benefits of the rulemaking. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2015. Accordingly, the following analysis describes the impact in CY 2015 only. We estimate that the net impact of the proposals in this rule is approximately $60 million in decreased payments to HHAs in CY 2015. We applied a wage index budget neutrality factor and a case-mix weights budget neutrality factor to the rates as discussed in section III.D.4. of this final rule; therefore, the estimated impact of the 2015 wage index in section III.D.3. of this final rule and the recalibration of the case-mix weights for 2015 in section III.C. of this final rule is zero. The −$60 million impact reflects the distributional effects of the 2.1 percent home health payment update percentage ($390 million increase) and the effects of the second year of the four-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit payment rates, and the NRS conversion factor for an impact of −2.4 percent ($450 million decrease). The $60 million in decreased payments is reflected in the last column of the first row in Table 41 as a 0.3 percent decrease in expenditures when comparing estimated CY 2014 payments to estimated CY 2015 payments.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. For the purposes of the RFA, we consider all HHAs small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare-paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis for this final rule, which incorporates additional Medicare home health claims data that were not available at the time the CY 2015 HH PPS proposed rule was published, we conclude that the policies final in this rule will result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater

than 5 percent of HHAs. Therefore, the Secretary has determined that this final rule will have a significant economic impact on a substantial number of small entities. Further detailed analysis is presented below and in Table 41, by HHA classification, type, and location.

Executive Order 13563 specifies, to the extent practicable, agencies should assess the costs of cumulative regulations. However, given potential utilization pattern changes, wage index changes, changes to the market basket forecasts, and unknowns regarding future policy changes, we believe it is neither practicable nor appropriate to forecast the cumulative impact of the rebasing adjustments on Medicare payments to HHAs for future years at this time. Changes to the Medicare program may continue to be made as a result of the Affordable Care Act or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact and the complexity of the interactions would make it difficult to predict accurately the full scope of the impact upon HHAs for future years beyond CY 2015. We note that the rebasing adjustments to the national, standardized 60-day episode payment rate and the national per-visit rates are capped at the statutory limit of 3.5 percent of the CY 2010 amounts for each year, 2014 through 2017, and the NRS rebasing adjustment will be −2.82 percent in each year, 2014 through 2017 (as described in section II.C. of this final rule).

In addition, section 1102(b) of the Act requires us to prepare a RIA 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 RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule applies to HHAs. Therefore, the Secretary has determined that this rule will not have a significant economic impact on the operations of small rural hospitals.

C. Detailed Economic Analysis

This final rule sets forth updates for CY 2015 to the HH PPS rates contained in the CY 2014 HH PPS final rule (78 FR 72304 through 72308). The impact analysis of this final rule presents the estimated expenditure effects of policy changes final in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, primarily using Medicare claims data for CY 2013. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact and the complexity of the interactions could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 41 represents how HHA revenues are likely to be affected by the policy changes finalized in this rule. For this analysis, we used an analytic file of CY 2013 home health claims data (as of June 30, 2014) for dates of service that ended on or before December 31, 2013, linked to OASIS assessments. The first column of Table 41 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The third column shows the payment effects of CY 2015 wage index. The fourth column shows the payment effects of the CY 2015 case-mix weights. The fifth column shows the effects of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit payment rates, and NRS conversion factor. The sixth column shows the effects of the CY 2015 home health payment update percentage (the home health market basket update adjusted for multifactor productivity as discussed in section III.D.1. of this final rule). The last column shows the overall payment effects of all the policies discussed in this final rule.

As illustrated in Table 41, the combined effects of all of the changes vary by specific types of providers and by location. A substantial amount of the variation in the estimated impacts of the policies finalized in this rule in different areas of the country can be attributed to variations in the CY 2015 wage index used to adjust payments under the HH PPS and to the effects of the recalibration of the HH PPS case-mix weights. For example, the estimated impact due to the recalibration of the HH PPS case-mix weights for the West South Central census region is a 2.2 percent decrease in payments for CY 2015. The case-mix weights for third or later episodes of care with no or low therapy generally decreased as a result of the recalibration of the HH PPS case-mix weights (see section III.C. of this final rule). In the West South Central region, approximately one-third of episodes are either the first or second episode of care and nearly two-thirds of episodes are the third or later episode of care (analysis of episodes with 0–19 therapy visits). This differs drastically from the rest of the nation where over two-thirds of episodes are either the first or second episode of care and less than one-third of episodes are the third or later episode of care (analysis of episodes with 0–19 therapy visits). Thus, the West South Central census region experiences a larger estimated reduction in payments due to the recalibration of the case-mix weights because it has a much larger share of episodes that are the third or later episode compared to the rest of the nation. Instances where the impact, due to the rebasing adjustments, is less than others can be attributed to differences in the incidence of outlier payments and LUPA episodes, which are paid using the national per-visit payment rates that are subject to payment increases due to the rebasing adjustments. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2015 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2015 relative to CY 2014, and the degree of Medicare utilization.

For CY 2015, the average impact for all HHAs due to the effects of rebasing is an estimated 2.4 percent decrease in payments. The overall impact for all HHAs as a result of this final rule is a decrease of approximately 0.3 percent in estimated total payments from CY 2014 to CY 2015.

TABLE 41—ESTIMATED HOME HEALTH AGENCY IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2015

	Number of agencies	CY 2015 wage index [1] (percentage)	CY 2015 case-mix weights [2] (percentage)	Rebasing [3] (percentage)	CY 2015 HH payment update percentage [4]	Impact of all CY 2015 policies (percentage)
All Agencies	11,781	0.0	0.0	−2.4	2.1	−0.3
Facility Type and Control:						
Free-Standing/Other Vol/NP	1,062	0.3	1.0	−2.3	2.1	1.1
Free-Standing/Other Proprietary	9,194	−0.1	−0.5	−2.4	2.1	−0.9
Free-Standing/Other Government	402	0.4	0.5	−2.3	2.1	0.7
Facility-Based Vol/NP	774	0.2	1.6	−2.3	2.1	1.6
Facility-Based Proprietary	115	−0.2	1.3	−2.3	2.1	0.9
Facility-Based Government	234	0.2	1.4	−2.4	2.1	1.3
Subtotal: Freestanding	10,658	0.0	−0.2	−2.4	2.1	−0.5
Subtotal: Facility-based	1,123	0.2	1.5	−2.3	2.1	1.5
Subtotal: Vol/NP	1,836	0.3	1.2	−2.3	2.1	1.3
Subtotal: Proprietary	9,309	−0.1	−0.5	−2.4	2.1	−0.9
Subtotal: Government	636	0.3	0.9	−2.3	2.1	1.0
Facility Type and Control: Rural:						
Free-Standing/Other Vol/NP	192	0.1	1.3	−2.3	2.1	1.2
Free-Standing/Other Proprietary	140	0.9	0.6	−2.4	2.1	1.2
Free-Standing/Other Government	466	0.2	−0.6	−2.4	2.1	−0.7
Facility-Based Vol/NP	251	0.6	1.5	−2.5	2.1	1.8
Facility-Based Proprietary	27	0.1	0.3	−2.5	2.1	0.0
Facility-Based Government	137	0.6	1.3	−2.3	2.1	1.7
Facility Type and Control: Urban:						
Free-Standing/Other Vol/NP	922	0.3	1.0	−2.3	2.1	1.1
Free-Standing/Other Proprietary	8,870	−0.1	−0.5	−2.4	2.1	−0.9
Free-Standing/Other Government	164	0.3	0.5	−2.4	2.1	0.5
Facility-Based Vol/NP	523	0.2	1.6	−2.3	2.1	1.6
Facility-Based Proprietary	88	−0.2	1.4	−2.3	2.1	1.0
Facility-Based Government	97	0.0	1.4	−2.4	2.1	1.1
Facility Location: Urban or Rural:						
Rural	1,117	0.4	0.4	−2.4	2.1	0.5
Urban	10,664	0.0	0.0	−2.4	2.1	−0.3
Facility Location: Region of the Country:						
Northeast	882	0.4	0.9	−2.2	2.1	1.2
Midwest	3,165	0.2	0.8	−2.5	2.1	0.6
South	5,722	−0.3	−0.9	−2.4	2.1	−1.5
West	1,962	0.5	0.9	−2.4	2.1	1.1
Other	50	1.7	1.8	−2.4	2.1	3.2
Facility Location: Region of the Country (Census Region):						
New England	340	0.8	0.9	−2.2	2.1	1.6
Mid Atlantic	542	0.1	0.9	−2.1	2.1	1.0
East North Central	2,415	0.2	0.6	−2.5	2.1	0.4
West North Central	750	0.1	1.6	−2.4	2.1	1.4
South Atlantic	2,054	−0.1	0.0	−2.4	2.1	−0.4
East South Central	440	−0.6	0.0	−2.5	2.1	−1.0
West South Central	3,228	−0.5	−2.2	−2.4	2.1	−3.0
Mountain	689	0.4	1.5	−2.4	2.1	1.6
Pacific	1,273	0.5	0.6	−2.4	2.1	0.8
Facility Size (Number of 1st Episodes):						
< 100 episodes	2,924	−0.3	−0.3	−2.4	2.1	−0.9
100 to 249	2,767	−0.3	−0.6	−2.4	2.1	−1.2
250 to 499	2,569	−0.2	−0.8	−2.4	2.1	−1.3
500 to 999	1,878	0.0	−0.2	−2.4	2.1	−0.5
1,000 or More	1,643	0.1	0.3	−2.4	2.1	0.1

Source: CY 2013 Medicare claims data for episodes ending on or before December 31, 2013 (as of June 30, 2014) for which we had a linked OASIS assessment.

[1] The impact of the CY 2015 home health wage index reflects the transition to new CBSA designations as outlined in section III.D.3 this final rule offset by the wage index budget neutrality factor described in section III.D.4 this final rule.

[2] The impact of the CY 2015 home health case-mix weights reflects the recalibration of the case-mix weights as outlined in section III.C of this final rule offset by the case-mix weight budget neutrality factor described in section III.D.4 of this final rule.

[3] The impact of rebasing includes the rebasing adjustments to the national, standardized 60-day episode payment rate (−2.73 percent after the CY 2014 payment rate was adjusted for the wage index and case-mix weight budget neutrality factors), the national per-visit rates (+3.26 percent), and the NRS conversion factor (−2.82%). The estimated impact of the NRS conversion factor rebasing adjustment is an overall −0.01 percent decrease in estimated payments to HHAs. The overall impact of all the rebasing adjustments finalized in the CY 2014 HH PPS proposed rule and implemented for CY 2015 are lower than the overall impact in the CY 2014 due to the case-mix budget neutrality factor and an increase in estimated outlier payments. As the national per-visit rates increase and the national, standardized 60-day episode rate decreases more episodes qualify for outlier payments. In addition, we decreased the fixed-dollar loss (FDL) ratio from 0.67 to 0.45 effective CY 2013 in order to qualify more episodes as outliers, and we use CY 2013 utilization in simulating impacts for the CY 2015 HH PPS final rule.

[4] The CY 2015 home health payment update percentage reflects the home health market basket update of 2.6 percent, reduced by a 0.5 percentage point multifactor productivity (MFP) adjustment as required under section 1895(b)(3)(B)(vi)(I) of the Act, as described in section III.D.1 of this final rule.

Region Key:
New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; **Middle Atlantic** = Pennsylvania, New Jersey, New York; **South Atlantic** = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; **East North Central** = Illinois, Indiana, Michigan, Ohio, Wisconsin; **East South Central** = Alabama, Kentucky, Mississippi, Tennessee; **West North Central** = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; **West South Central** = Arkansas, Louisiana, Oklahoma, Texas; **Mountain** = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; **Pacific** = Alaska, California, Hawaii, Oregon, Washington; **Outlying** = Guam, Puerto Rico, Virgin Islands.

D. Anticipated Effects

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This final rule is not anticipated to have an effect on state, local, or tribal governments in the aggregate, or by the private sector, of $141 million or more in CY 2015.

E. Alternatives Considered

In recalibrating the HH PPS case-mix weights for CY 2015, as discussed in section III.C. of this final rule, we considered adjusting the payment rates in section III.D.4 to make the recalibration budget neutral only with regard to our estimate of real case-mix growth between CY 2012 and the CY 2013. Section 1895(b)(3)(B)(iv) of the Act gives CMS the authority to implement payment reductions for nominal case-mix growth—changes in case-mix that are unrelated to actual changes in patient health status. However, instead of implementing a case-mix budget neutrality factor that only reflects our estimate of real increases in patient severity; we finalized the recalibration of the case-mix weights in a fully budget-neutral manner. We will continue to monitor case-mix growth (both real and nominal case-mix growth) as more data become available.

With regard to the adoption of the revised OMB delineations for purposes of calculating the wage index, we will implement the new OMB delineations as we believe they will result in wage index values being more representative of the actual costs of labor in a given area. We considered having no transition period and fully implementing the new OMB delineations beginning in CY 2015. However, this would not provide time for HHAs to adapt to the new OMB delineations. We believe that a transition period would help to mitigate the potential for resulting short-term instability and negative impact on certain HHAs, and to provide time for HHAs to adjust to their new labor market area delineations. In determining an appropriate transition methodology, consistent with the objectives set forth in the FY 2006 SNF PPS final rule (70 FR 45041), we first considered transitioning the wage index to the revised OMB delineations over a number of years in order minimize the impact of the wage index changes in a given year. However, the transition must be balanced against the need to ensure the most accurate payments possible, which called for a faster transition to the revised OMB delineations. As such, utilizing a one-year (rather than a multiple year) transition with a blended wage index in CY 2015 will strike the best balance. Second, we considered what type of blend would be appropriate for purposes of the transition wage index. We are finalizing that HHAs will receive a one-year blended wage index using 50 percent of their CY 2015 wage index based on the new OMB delineations and 50 percent of their CY 2015 wage index based on the FY 2014 OMB delineations. A 50/50 blend best mitigates the negative payment impacts associated with the implementation of the new OMB delineations. While we considered alternatives to the 50/50 blend, this type of split balances the increases and decreases in wage index values as well as provides a readily understandable calculation for HHAs.

Next, we considered whether or not the blended wage index should be used for all HHAs or for only a subset of HHAs, such as those HHAs that would experience a decrease in their respective wage index values due to implementation of the revised OMB delineations. As required in section 1895(b)(3) of the Act, the wage index adjustment must be implemented in a budget-neutral manner. If we were to apply the transition policy only to those HHAs that would experience a decrease in their respective wage index values due to implementation of the revised OMB delineations, the wage index budget neutrality factor, discussed in section III.D.4, would result in reduced base rates for all HHAs as compared to the budget neutrality factor that results from applying the blended wage index to all HHAs.

For the reasons discussed above, we believe that finalizing our proposal to use a one-year transition with a 50/50 blended wage index in CY 2015 as this policy balances the interests of all HHAs and will best achieve our objective of providing relief to negatively impacted HHAs.

Section 3131(a) of the Affordable Care Act mandates that starting in CY 2014, the Secretary must apply an adjustment to the national, standardized 60-day episode payment rate and other amounts applicable under section 1895(b)(3)(A)(i)(III) of the Act to reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. In addition, section 3131(a) of the Affordable Care Act mandates that rebasing must be phased-in over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment (2010) under section 1895(b)(3)(A)(i)(III) of the Act, and be fully implemented in CY 2017. Therefore, in the CY 2014 HH PPS final rule (78 FR 77256), we finalized rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor. As we noted in the CY 2014 HH PPS final rule, because section 3131(a) of the Affordable Care Act requires a four year phase-in of rebasing, in equal increments, to start in CY 2014 and be fully implemented in CY 2017, we do not have the discretion to delay, change, or eliminate the rebasing adjustments once we have determined that rebasing is necessary (78 FR 72283).

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2015 be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. For CY 2015, section 3401(e) of the Affordable Care Act, requires that, in CY 2015 (and in subsequent calendar years), the market basket update under the HHA prospective payment system, as described in section 1895(b)(3)(B) of the Act, be annually adjusted by changes in economy-wide productivity. Beginning in CY 2015, section 1895(b)(3)(B)(vi)(I) of the Act, as amended by section 3401(e) of the Affordable Care Act, requires the application of the productivity

adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the HHA PPS for CY 2015 and each subsequent CY. The −0.5 percentage point productivity adjustment to the CY 2015 home health market basket update (2.6 percent) is discussed in the preamble of this rule and is not discretionary as it is a requirement in section 1895(b)(3)(B)(vi)(I) of the Act (as amended by the Affordable Care Act).

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 42, we have prepared an accounting statement showing the classification of the transfers and costs associated with the provisions of this final rule. Table 42 provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes finalized in this rule. Table 42 also reflects the estimated change in costs and burden for certifying physicians and HHAs as a result of the changes to the face-to-face encounter requirements finalized in section III.B. We estimate a net reduction in burden for certifying physicians of 192,765 hours or $21,796,330 (see section IV of this rule). In addition, Table 42 reflects our estimate of a one-time burden for HHAs to revise the certification form of 5,761 hours or $245,397 as described in section IV. of this rule.

TABLE 42—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM THE CYS 2014 TO 2015 *

Category	Transfers
Annualized monetized transfers	−$60 million.
From Whom to Whom?	Federal Government to HHAs.
Category	**Costs**
Annualized Monetized Net Burden for Physicians Certifying Patient Eligibility for Home Health Services & HHAs for Certification Form Revision.	−$21.55 million.

* The estimates reflect 2014 dollars.

G. Conclusion

In conclusion, we estimate that the net impact of this final rule is a decrease in Medicare payments to HHAs of $60 million for CY 2015. The $60 million decrease in estimated payments for CY 2015 reflects the distributional effects of the 2.1 percent CY 2015 home health payment update percentage ($390 million increase) and the second year of the 4-year phase-in of the rebasing adjustments required by section 3131(a) of the Affordable Care Act ($450 million decrease). Also, starting in CY 2015, certifying physicians are estimated to incur a net reduction in burden costs of $21,796,330 and HHAs are expected to incur a one-time increase in burden costs to revise the certification form of $245,397 as a result of the elimination of the face-to-face encounter narrative requirement finalized in section III.B. This analysis, together with the remainder of this preamble, constitutes the Regulatory Flexibility Analysis.

VI. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of states, local or tribal governments.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 498

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 409.44 [Amended]

■ 2. Section 409.44 is amended by—

■ a. Removing ''intermediary's'' from paragraph (a) and adding ''Medicare Administrative Contractor's'' in its place.

■ b. Adding ''calendar'' between ''30'' and ''days'' in paragraph (c)(2)(i)(B).

■ c. Removing paragraphs (c)(2)(i)(C) and (D).

■ d. Redesignating paragraphs (c)(2)(i)(E) through (H) as paragraphs (c)(2)(i)(C) through (F).

■ e. Removing ''(c)(2)(i)(A), (B), (C), and (D) of this section,'' from newly redesignated paragraph (c)(2)(i)(C) introductory text and adding ''(c)(2)(i)(A) and (B) of this section,'' in its place.

■ f. Removing ''(c)(2)(i)(E)(*2*) and (c)(2)(i)(E)(*3*) of this section are met,'' from newly redesignated paragraph (c)(2)(i)(C)(*1*) and adding ''(c)(2)(i)(C)(*2*) and (c)(2)(i)(C)(*3*) of this section are met,'' in its place.

■ g. Removing ''§ 409.44(c)(2)(i)(H) of this section.'' from newly redesignated paragraph (c)(2)(i)(C)(*3*) and adding ''paragraph (c)(2)(i)(F) of this section.'' in its place.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 3. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 4. Section 424.22 is amended by—

■ a. Revising paragraphs (a) and (b) and adding new paragraph (c).
■ b. Removing ''(d)(i)'' from paragraph (d)(2) and adding ''(d)(1)'' in its place.

The revisions read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(a) *Certification*—(1) *Content of certification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify the patient's eligibility for the home health benefit, as outlined in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as follows in paragraphs (a)(1)(i) through (v) of this section. The patient's medical record, as specified in paragraph (c) of this section, must support the certification of eligibility as outlined in paragraph (a)(1)(i) through (v) of this section.

(i) The individual needs or needed intermittent skilled nursing care, or physical therapy or speech-language pathology services as defined in § 409.42(c) of this chapter. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification form, in addition to the physician's signature on the certification form, the physician must sign immediately following the narrative in the addendum.

(ii) Home health services are or were required because the individual is or was confined to the home, as defined in sections 1835(a) and 1814(a) of the Act, except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and will be or was periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

(iv) The services will be or were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(v) A face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner as defined in paragraph (a)(1)(v)(A) of this section. The certifying physician must also document the date of the encounter as part of the certification.

(A) The face-to-face encounter must be performed by one of the following:

(*1*) The certifying physician himself or herself.

(*2*) A physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health.

(*3*) A nurse practitioner or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in accordance with State law and in collaboration with the certifying physician or in collaboration with an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(*4*) A certified nurse midwife (as defined in section 1861(gg) of the Act) as authorized by State law, under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(*5*) A physician assistant (as defined in section 1861(aa)(5) of the Act) under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(B) The face-to-face patient encounter may occur through telehealth, in compliance with section 1834(m) of the Act and subject to the list of payable Medicare telehealth services established by the applicable physician fee schedule regulation.

(*1*) *Timing and signature.* The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.

(*2*) [Reserved]

(2) [Reserved]

(b) *Recertification*—(1) *Timing and signature of recertification.* Recertification is required at least every 60 days when there is a need for continuous home health care after an initial 60-day episode. Recertification should occur at the time the plan of care is reviewed, and must be signed and dated by the physician who reviews the plan of care. Recertification is required at least every 60 days unless there is a—

(i) Beneficiary elected transfer; or

(ii) Discharge with goals met and/or no expectation of a return to home health care.

(2) *Content and basis of recertification.* The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately following the narrative in the addendum.

(c) *Determining patient eligibility for Medicare home health services.* Documentation in the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) shall be used as the basis for certification of home health eligibility. This documentation shall be provided upon request to the home health agency, review entities, and/or CMS. Criteria for patient eligibility are described in paragraphs (a)(1) and (b) of this section. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 5. The authority citation for part 484 continues to read as follows:

Authority: Secs 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 6. Section 484.4 is amended by revising the definition of ''Speech-language pathologist'' to read as follows:

§ 484.4 Personnel qualifications.

* * * * *

Speech-language pathologist. A person who has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements:

(a) Is licensed as a speech-language pathologist by the State in which the individual furnishes such services; or

(b) In the case of an individual who furnishes services in a State which does not license speech-language pathologists:

(1) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience);

(2) Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and

(3) Successfully completed a national examination in speech-language pathology approved by the Secretary.

■ 7. Section 484.250 is amended by revising paragraph (a)(1) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) The OASIS data described at § 484.55(b)(1) and (d)(1) for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230, and 484.235, and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 8. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a–7j, and 1395hh); Pub. L. 110–149, 121 Stat. 1819.

■ 9. Section 488.845 is amended by adding paragraph (h) to read as follows:

§ 488.845 Civil money penalties.

* * * * *

(h) *Review of the penalty.* When an administrative law judge or state hearing officer (or higher administrative review authority) finds that the basis for imposing a civil monetary penalty exists, as specified in this part, the administrative law judge, State hearing officer (or higher administrative review authority) may not—

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by CMS to impose a civil monetary penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (b) of this section.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTCIPATION OF ICFS/IID AND CERTAIN NFS IN THE MEDICAID PROGRAM

■ 10. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a–7j, and 1395hh).

■ 11. Section 498.3 is amended by revising paragraphs (b)(13) and (14)(i) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(13) Except as provided at paragraph (d)(12) of this section for SNFs, NFs, and HHAs, the finding of noncompliance leading to the imposition of enforcement actions specified in § 488.406 or 488.820 of this chapter, but not the determination as to which sanction was imposed. The scope of review on the imposition if a civil money penalty is specified in §§ 488.438(e) and 488.845(h) of this chapter.

(14) * * *

(i) The range of civil money penalty amounts that CMS could collect (for SNFs or NFs, the scope of review during a hearing on the imposition of a civil money penalty is set forth in § 488.438(e) of this chapter and for HHAs, the scope of review during a hearing on the imposition of a civil money penalty is set forth in § 488.845(h) of this chapter); or

* * * * *

■ 12. Section 498.60 is amended by revising paragraphs (c)(1) and (2) to read as follows:

§ 498.60 Conduct of hearing.

* * * * *

(c) * * *

(1) The scope of review is as specified in §§ 488.438(e) and 488.845(h) of this chapter; and

(2) CMS' determination as to the level of noncompliance of a SNF, NF, or HHA must be upheld unless it is clearly erroneous.

Dated: October 22, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 28, 2014.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2014–26057 Filed 10–30–14; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 411, 413, and 414

Medicare Program; End–Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 411, 413, and 414

[CMS–1614–F]

RIN 0938–AS13

Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015. This rule also finalizes requirements for the ESRD quality incentive program (QIP), including for payment years (PYs) 2017 and 2018. This rule will also make a technical correction to remove outdated terms and definitions. In addition, this final rule sets forth the methodology for adjusting Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule payment amounts using information from the Medicare DMEPOS Competitive Bidding Program (CBP); makes alternative payment rules for certain DME under the Medicare DMEPOS CBP; clarifies the statutory Medicare hearing aid coverage exclusion and specifies devices not subject to the hearing aid exclusion; will not update the definition of minimal self-adjustment; clarifies the Change of Ownership (CHOW) and provides for an exception to the current requirements; revises the appeal provisions for termination of a CBP contract, including the beneficiary notification requirement under the Medicare DMEPOS CBP, and makes a technical change to the regulation related to the conditions for awarding contracts for furnishing infusion drugs under the Medicare DMEPOS CBP.

DATES: Effective on January 1, 2015.

FOR FURTHER INFORMATION CONTACT: Stephanie Frilling, (410) 786–4507, for issues related to the ESRD PPS, the ESRD PPS CY 2015 Base Rate, Wage Indices, Drugs Used for the Treatment of ESRD, and Payment for Frequent Hemodialysis.

Michelle Cruse, (410) 786–7540, for issues related to the ESRD PPS, the Low Volume Payment Adjustment, and the Wage Index.

Wendy Tucker, (410) 786–3004, for issues related to the Low Volume Payment Adjustment and the Wage Index.

Heidi Oumarou, (410) 786–7342, for issues related to the ESRD PPS Market Basket Update.

James Poyer, (410) 786–2261, for issues related to the ESRD QIP.

Christopher Molling (410) 786–6399 and Hafsa Vahora (410) 786–7899 for issues related to the methodology for making national price adjustments based upon information gathered from the DMEPOS CBP.

Sandhya Gilkerson, (410) 786–4085, for issues related to the alternative payment methodologies under the CBP.

Sandhya Gilkerson, (410) 786–4085 and Michelle Peterman, 410–786–2581 for issues related to the clarification of the statutory Medicare hearing aid coverage exclusion.

Michelle Peterman, (410) 786–2591 for issues related to the definition of minimal self-adjustment at 414.402.

Janae James (410) 786–0801 for issues related to CHOW and breach of contract appeals.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/.*

Addenda Are Only Available Through the Internet on the CMS Web site

In the past, a majority of the Addenda referred to throughout the preamble of our proposed and final rules were available in the **Federal Register**. However, the Addenda of the annual proposed and final rules will no longer be available in the **Federal Register**. Instead, these Addenda to the annual proposed and final rules will be available only through the Internet on the CMS Web site. The Addenda to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) rules are available at: *http://www.cms.gov/ESRDPayment/PAY/list.asp.* Readers who experience any problems accessing any of the Addenda to the proposed and final rules of the ESRD PPS that are posted on the CMS Web site identified above should contact Stephanie Frilling at 410–786–4507.

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Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

ACO—Affordable Care Organization
AHRQ—Agency for Healthcare Research and Quality
ANOVA—Analysis of Variance
ARM—Adjusted Ranking Metric
ASP—Average Sales Price
ATRA—The American Taxpayer Relief Act of 2012
AV—Arterial Venous
BEA—Bureau of Economic Analysis
BLS—Bureau of Labor Statistics
BMI—Body Mass Index
CBA—Competitive Bidding Area
CBP—Competitive Bidding Program
CBSA—Core based statistical area
CCN—CMS Certification Number
CDC—Centers for Disease Control and Prevention
CfC—Conditions for Coverage
CHOW—Change of Ownership
CKD—Chronic Kidney Disease
CMSQS—CMS Quality Strategy
CPAP—Continuous positive airway pressure
CY—Calendar Year
DFC—Dialysis Facility Compare
DME—Durable Medical Equipment
DMEPOS—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
ESA—Erythropoiesis stimulating agent
ESRD—End-Stage Renal Disease
ESRDB—End-Stage Renal Disease bundled
ESRD PPS—End-Stage Renal Disease Prospective Payment System
FDA—Food and Drug Administration
GEM—General Equivalence Mappings
HCP—Healthcare Personnel
Health IT—Health Information Technology
HD—Hemodialysis
HAIs—Healthcare-Acquired Infections
HCPCS—Healthcare Common Procedure Coding System
HCFA—Health Care Financing Administration
HLM—Hierarchical Logistic Modeling
HHS—Department of Health and Human Services
ICD—International Classification of Diseases
ICD–9–CM—International Classification of Disease, 9th Revision, Clinical Modification
ICD–10–CM—International Classification of Disease, 10th Revision, Clinical Modification
ICH CAHPS—In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IGI—IHS Global Insight
IIC—Inflation-indexed charge
IOLs—Intraocular Lenses
IPPS—Inpatient Prospective Payment System
ICH CAHPS—In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Services
IUR—Inter-unit reliability
MAC—Medicare Administrative Contractor
MAP—Medicare Allowable Payment
MFP—Multifactor Productivity
MIPPA—Medicare Improvements for Patients and Providers Act of 2008
MLR—Minimum Lifetime Requirement
MSA—Metropolitan statistical areas
NAMES—National Association of Medical Equipment Suppliers
NHSN—National Health Safety Network
NQF—National Quality Forum
NQS—National Quality Strategy
OBRA—Omnibus Budget Reconciliation Act
OMB—Office of Management and Budget
P&O—Prosthetics and orthotics
PAMA—Protecting Access to Medicare Act of 2014
PC—Product category
PD—Peritoneal Dialysis
PEN—Parenteral and enteral nutrition
PFS—Physician Fee Schedule
QIP—Quality Incentive Program
RMA—Reporting Measure Adjuster
RSPA—Regional single payment amounts
RUL—Reasonable useful lifetime
SAF—Standard Analysis File
SHR—Standardized Hospitalization Ratio Admissions
SMR—Standardized Mortality Ratio
SPA—Single payment amount
SRR—Standardized Readmissions Ratio
STrR—Standardized Transfusion Ratio
TENS—Transcutaneous electrical nerve stimulation
TEP—Technical Expert Panel
TPS—Total Performance Score
VBP—Value Based Purchasing

I. Executive Summary

A. Purpose

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted bundled prospective payment system for renal dialysis services furnished by ESRD facilities. This rule updates and makes revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015. Section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), and section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act Public Law 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2011, to reduce the single payment amount to reflect the Secretary's estimate of the change in utilization of ESRD-related drugs and biologicals. We finalized the amount of the drug utilization adjustment pursuant to this section in the CY 2014 ESRD PPS final rule with a 3- to 4-year transition (78 FR 72161 through 72170). Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS before January 1, 2016. And finally, section 632(c) of ATRA requires the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Congress enacted the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93). Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amend sections 1881(b)(14)(F) and (I) of the Act. We interpret the amendments to sections 1881(b)(14)(F) and (I) as replacing the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictate what the market basket update will be for CY 2015 (0.0 percent) and how it will be reduced in CYs 2016 through 2018. Section 217(a)(1) of PAMA amends section 632(b)(1) of ATRA, which now provides that the Secretary may not pay for oral-only

drugs and biologicals used for the treatment of ESRD under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) further amends section 632(b)(1) of ATRA by adding a sentence that provides: ''Notwithstanding section 1881(b)(14)(A)(ii) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(A)(ii)), implementation of the policy described in the previous sentence shall be based on data from the most recent year available.'' Finally, PAMA section 217(c) provides that, as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment. As discussed further below, section 212 of PAMA provides that the Secretary may not adopt ICD–10–CM prior to October 1, 2015. Accordingly, HHS published a final rule on August 4, 2014 that established October 1, 2015 as the new ICD–10 compliance date, and required the use of ICD–9 through September 30, 2015.

2. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

This final rule also sets forth requirements for the ESRD Quality Incentive Program (QIP), including for payment years (PYs) 2017 and 2018. The program is authorized under section 1881(h) of the Social Security Act (the Act). The ESRD QIP is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS.

3. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

This final rule finalizes a methodology for making national price adjustments to payments for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) paid under fee schedules based upon information gathered from the DMEPOS competitive bidding programs (CBPs) and finalizes the phase-in of special payment rules in a limited number of competitive bidding areas (CBAs) under the CBP for certain specified DME at 42 CFR 414.408 and 414.409. This final rule clarifies the statutory Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act and the regulation at § 411.15(d) to further specify the scope of this exclusion. In addition, this final rule will not finalize the definition of minimal self-adjustment at § 414.402 to identify certain individuals with specialized training with regard to off-the-shelf (OTS) orthotics under the CBP. This final rule revises the Change of Ownership (CHOW) policy in the current regulations to allow a product category to be severed from a competitive bidding contract and transferred to a new contract when a contract supplier sells a distinct line of business to a new qualified owner. This rule amends § 414.423 to clarify the effective date for terminations of competitive bidding contracts, and the deadline for contract suppliers notifying its beneficiaries of its contract termination. Finally, this rule includes a technical change related to submitting bids for infusion drugs under the CBP.

B. Summary of the Major Provisions

1. ESRD PPS

• *CY 2015 ESRD PPS base rate:* For CY 2015, the ESRD PPS base rate is $239.43. This amount reflects a 0.0 percent update to the payment rate as required by section 1881(b)(14)(F)(i) of the Act, as amended by section 217(b)(2) of PAMA, and the application of the wage index budget-neutrality adjustment factor of 1.001729 to the CY 2014 ESRD PPS base rate of $239.02.

• *Rebasing and revision of the ESRD bundled (ESRDB) market basket:* For CY 2015, we are rebasing and revising the ESRDB market basket; which entails an update to the base year of the ESRDB market basket from 2008 to 2012. The base year update results in a shift in relative costs from prescription drugs to compensation; mainly driven by the decreased utilization of drugs in furnishing ESRD treatments experienced from 2008 to 2012. Additionally, while we proposed to use PPI—Vitamin, Nutrient, and Hematinic Preparations as the pharmaceutical price proxy (instead of the current PPI—Pharmaceuticals for Human Use, Prescription), we are finalizing, based on comments, a blend of PPI—Biological Products for Human Use (78 percent) and PPI—Vitamin, Nutrient, and Hematinic Preparations (22 percent). The resulting CY 2015 market basket less MFP adjustment would have been 1.6 percent (2.1 percent ESRDB market basket update less 0.5 percent MFP adjustment); however, section 1881(b)(14)(F)(i) of the Act, as amended by section 217(b)(2) of PAMA requires the market basket less MFP adjustment to be 0.0 percent for CY 2015.

• *CY 2015 ESRD PPS labor-related share:* As a result of the ESRDB market basket rebasing and revision, outlined above, the CY 2015 labor-related share is 50.673 percent compared to the current labor-related share of 41.737 percent. This change to the labor-related share will have a significant impact on payments for certain ESRD facilities, specifically those ESRD facilities that have low wage index values. Therefore, for CY 2015 we are implementing the labor-related share of 50.673 with a 2-year transition.

• *CY 2015 wage indices and wage index floor:* We adjust wage indices on an annual basis using the most current hospital wage data to account for differing wage levels in areas in which ESRD facilities are located. In CY 2015, the application of the wage index budget-neutrality adjustment factor will continue to apply to the base rate when computing payments under the ESRD PPS. In addition, we will continue our policy for the gradual phase-out of the wage index floor and reduce the wage index floor values to 0.40 for CY 2015, as finalized in the CY 2014 ESRD PPS final rule (78 FR 72173 through 72174).

• *Update to wage index core-based statistical areas (CBSA):* Beginning January 1, 2015, we will implement the new CBSA delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, for all ESRD facilities, with a 2-year transition. Facilities will receive 50 percent of their CY 2015 wage index based on the CBSA delineations for CY 2014 and 50 percent of their CY 2015 wage index based on the new CBSA delineations. In CY 2016, facilities' wage index values will be based 100 percent on the new CBSA delineations.

• *CY 2015 ESRD PPS outlier payment adjustment:* We have updated the outlier services fixed-dollar loss and Medicare Allowable Payments (MAPs) amounts for adult and pediatric patients for CY 2015 using 2013 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries will increase from $54.01 to $54.35 and the MAP amount will increase from $40.49 to $43.57, as compared to CY 2014 values. For adult beneficiaries, the fixed-dollar loss amount will decrease from $98.67 to $86.19 and the MAP amount will increase from $50.25 to $51.29.

• *Clarification for the low-volume payment adjustment (LVPA):* We clarified two policies regarding Medicare Administration Contractor (MAC) verification for LVPA eligibility requirements and are implementing conforming changes to the LVPA regulation text at 42 CFR 413.232. The first clarification explains that MACs can consider supporting data from hospital-based ESRD facilities to verify the facility's total treatment count. The second clarification explains that MACs can add or prorate treatment counts from non-standard cost reporting

periods (those that are not 12-month periods) where there is a change in ownership that does not result in a new Provider Transaction Access Number.

• *ICD–10–CM codes eligible for the ESRD PPS co-morbidity payment adjustment:* Section 212 of PAMA provides that the Secretary may not adopt ICD–10–CM prior to October 1, 2015. An August 4, 2014 HHS final rule delayed the transition from ICD–9–CM to ICD–10–CM until October 1, 2015 and required the continued use of ICD–9 through September 30, 2015.Therefore, the ESRD PPS will continue to use ICD–9–CM through September 30, 2015, and will require the use of ICD–10–CM beginning October 1, 2015 for purposes of the co-morbidity payment adjustments. For CY 2015, we are correcting several typographical errors and omissions in the ICD–9–CM to ICD–10–CM crosswalk tables that appeared in the CY 2014 ESRD PPS final rule.

• *Delay of payment for oral-only drugs under the ESRD PPS:*

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA, which now provides that the Secretary ''may not implement the policy under section 413.174(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD-related drugs in the ESRD prospective payment system), prior to January 1, 2024.'' Accordingly, we are finalizing our proposal to amend the date in 42 CFR 413.174(f)(6) from January 1, 2016 to January 1, 2024, and to amend the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only ESRD-related drugs made under the ESRD PPS to January 1, 2024.

2. ESRD QIP

This final rule implements requirements for the ESRD QIP, including measure sets for PYs 2017 and 2018.

• *PY 2017 Measure Set:* For PY 2017, we are removing one measure from the ESRD QIP, the Hemoglobin Greater than 12 g/dL clinical measure, on the basis that it is ''topped out''. We are also adopting the Standardized Readmission Ratio (SRR) clinical measure, which assesses care coordination.

• *PY 2018 Measure Set:* For PY 2018, we are adopting two new clinical measures—the Standardized Transfusion Ratio (STrR) and Pediatric Peritoneal Dialysis Adequacy—and three new reporting measures: (1) Pain Assessment and Follow-Up; (2) Clinical Depression Screening and Follow-Up; and (3) National Healthcare Safety Network (NHSN) Healthcare Personnel Influenza Vaccination. We are also converting the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey reporting measure to a clinical measure.

• *Revision to the ICH CAHPS Reporting Measure:* Beginning with the PY 2017 program year, we are revising the ICH CAHPS reporting measure to determine facility eligibility for the measure based on the number of survey-eligible patients treated during the ''eligibility period'', which we define as the Calendar Year (CY) that immediately precedes the performance period. Survey-eligible patients are defined in the ICH CAHPS measure specifications available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html* and *https://ichcahps.org.*

• *Revision to the Mineral Metabolism Reporting Measure:* Beginning with the PY 2018 program year, we are revising the Mineral Metabolism reporting measure to allow facilities to submit both serum phosphorus and plasma phosphorus measurements.

• *Extraordinary Circumstances Exemption:* Beginning with the PY 2017 ESRD QIP, we are exempting dialysis facilities from all requirements of the ESRD QIP clinical and reporting measures during the months in which they are forced to close due to a natural disaster or other extraordinary circumstances.

• *New Scoring Methodology for PY 2018:* Beginning with PY 2018, we are using a new scoring methodology for the ESRD QIP. This scoring methodology creates the Clinical Measure Domain, within which facility scores on clinical measures will be divided into subdomains that align with National Quality Strategy (NQS) domains and weighted according to the number of measures in a subdomain, facility experience with the measure, and the measure's alignment with CMS priorities for quality improvement. These weighted scores will be summed to produce a facility's Clinical Measure Domain score. A facility's Clinical Measure Domain score will be weighted to comprise 90 percent of the facility's TPS, and the facility's scores on the reporting measures will be weighted equally to comprise the remaining 10 percent of the facility's TPS.

3. DMEPOS

• *The methodology for making national price adjustments based upon information gathered from the DMEPOS CBPs:* As required by the MIPPA, this rule finalizes methodologies for using information from the DMEPOS CBP to adjust the fee schedule amounts for DME in areas where CBPs are not implemented. The rule finalizes the same methodologies to adjust the fee schedule amounts for enteral nutrition and off-the shelf (OTS) orthotics in areas where CBPs are not implemented.

• *Phase-in of special payment rules in a limited number of CBAs under the CBP for certain, specified DME:* This rule finalizes a phase-in of special payment rules for certain DME at 42 CFR 414.408 and 414.409 under the DMEPOS CBP in a limited number of CBAs.

• *Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act:* This rule modifies the regulation at § 411.15 to address the scope of the statutory hearing aid exclusion and note the types of devices that are not subject to the hearing aid exclusion.

• *Definition of minimal self-adjustment at § 414.402:* This rule will not finalize changes to the ''minimal self-adjustment'' definition to specify certain ''individuals with specialized training'' with regard to the definition of OTS orthotics under the CBP.

• *Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business:* This rule establishes an exception under the CHOW rules to allow CMS to sever a product category from a contract, incorporate the product category into a new contract, and transfer the new contract to a qualified new owner under certain specific circumstances.

• *Appeals Process for Termination of a Competitive Bidding Contract:* This rule amends § 414.423 to clarify the effective date for terminations of competitive bidding contracts, and the deadline for contract suppliers notifying its beneficiaries of its contract termination.

C. Summary of Costs and Benefits

In section XIV of this final rule, we set forth a detailed analysis of the impacts of the finalized changes for affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section XIV.B.1 of this final rule displays the estimated change in payments to ESRD facilities in CY 2015 compared to estimated payments in CY 2014. The overall impact of the CY 2015 changes is projected to be a 0.3 percent increase in payments. Hospital-based ESRD facilities have an estimated 0.5 percent increase in payments compared with freestanding facilities with an estimated 0.3 percent increase.

We estimate that the aggregate ESRD PPS expenditures will increase by approximately $30 million from CY 2014 to CY 2015. This reflects a $0 change from the payment rate update and a $30 million increase due to the updates to the outlier threshold amounts. As a result of the projected 0.3 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 0.3 percent in CY 2015, which translates to approximately $10 million.

2. Impacts for ESRD QIP

The overall economic impact of the ESRD QIP is an estimated $12 million in PY 2017 and $11.8 million in PY 2018. In PY 2017, we expect the total payment reductions to be approximately $11.9 million, and the costs associated with the collection of information requirements for the validation of NHSN data feasibility study to be approximately $27 thousand for all ESRD facilities. In PY 2018, we expect the total payment reductions to be approximately $11.6 million, and the costs associated with the collection of information requirements for the NHSN Healthcare Personnel Influenza Vaccination reporting measure to be approximately $248 thousand for all ESRD facilities.

The ESRD QIP will continue to incentivize facilities to provide high-quality care to beneficiaries.

3. Impacts for DMEPOS

a. Final Methodology for Making National Price Adjustments to DMEPOS Fee Schedule Amounts Based Upon Information Gathered From the CBPs

The final regulation adjusts Medicare fee schedule amounts for items subject to DMEPOS CBPs beginning January 1, 2016, using information from the DMEPOS CBPs to be applied to items in non-competitive bidding areas. It is estimated that these adjustments would save over $4.4 billion in gross payments for the 5-year period beginning January 1, 2016, and ending December 30, 2020. The estimated gross savings are primarily derived from price reductions for items. It is expected that most of the economic impact would result from reduced payment amounts. The ability of suppliers to furnish items is not expected to be impacted.

b. Phase-In of Special Payment Rules Under the CBP for Certain DME and Enteral Nutrition in Certain CBAs

We believe that the special payment rules we are finalizing for certain DME under the DMEPOS CBPs would not have a significant impact on beneficiaries and suppliers. Contract suppliers are responsible for furnishing items and services needed by the beneficiary, and the cost to suppliers for furnishing these items and services does not change based on whether or not the equipment and related items and services are paid for separately under a capped rental payment method. Because the supplier's bids would reflect the cost of furnishing items in accordance with the new payment rules, we expect the overall savings to generally be the same as they are under the current payment rules.

Furthermore, the final special payment rules would be phased in under a limited number of areas first to evaluate their impact on the program, beneficiaries, and suppliers, including costs, quality, and access. Expanded use of the special payment rules in other areas or for other items would be addressed in future rulemaking.

c. Clarification of the Statutory Medicare Hearing Aid Coverage Exclusion Under Section 1862(a)(7) of the Act

This final rule clarifies the scope of the Medicare coverage exclusion for hearing aids. This rule will not have a fiscal impact on the Medicare program because there will be no change in the devices that are currently covered for Medicare payment purposes. This rule provides further guidance about coverage of DME with regard to the statutory hearing aid exclusion.

d. Definition of Minimal Self-Adjustment at 42 CFR 414.402

This final rule will not finalize the definition of minimal self-adjustment at this time.

e. Change of Ownership Rules To Allow Contract Suppliers To Sell Specific Lines of Business

This rule finalizes changes to the CHOW rules in order to limit disruption to the normal course of business for DME suppliers. This final rule establishes an exception under the current CHOW rules to allow CMS to sever a product category from a contract, incorporate the product category into a new contract, and transfer the new contract to a qualified new owner under certain specific circumstances. This change would impact businesses in a positive way by allowing them to conduct everyday transactions with less disruption from our rules and regulations.

II. Calendar Year (CY) 2015 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background on the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On August 12, 2010, we published in the **Federal Register** a final rule (75 FR 49030 through 49214) in which we implemented a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis services beginning January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA. On November 10, 2011, we published in the **Federal Register** a final rule (76 FR 70228 through 70316) in which we made a number of routine updates for CY 2012, implemented the second year of the transition to the ESRD PPS, made several policy changes and clarifications, and made technical changes. On November 9, 2012, we published in the **Federal Register** a final rule (77 FR 67450 through 67531) in which we made a number of routine updates for CY 2013, implemented the third year of the transition to the ESRD PPS, and made several policy changes and reiterations.

On December 2, 2013, we published in the **Federal Register** a final rule (78 FR 72156 through 72253) in which we made a number of routine updates for CY 2014, implemented the fourth and final year of the transition to the ESRD PPS, implemented sections 632(a) and (b)(1) of ATRA, and made several policy changes and clarifications. Specifically, we updated the ESRD PPS base rate to $239.02 per treatment to reflect the CY 2014 ESRD bundled (ESRDB) market basket update of 3.2 percent minus a multifactor productivity adjustment of 0.4 percent, that is, a 2.8 percent increase. This amount also reflected the application of the wage index budget-neutrality adjustment of 1.000454, the home dialysis training add-on budget-neutrality adjustment factor of 0.999912, and the portion of the drug utilization adjustment for CY 2014, or $8.16, and delayed the payment for oral-only ESRD-related drugs and biologicals until January 1, 2016. In addition, this rule also extends the gradual reduction of the wage index floor, delays application of ICD–10–CM diagnosis codes to the comorbidity payment adjustment and updates the fixed-dollar loss and MAP amounts for the outlier policy.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2015 ESRD PPS Proposed Rule

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' (79 FR 40208 through 40315), (hereinafter referred to as the CY 2015 ESRD PPS proposed rule), was published in the **Federal Register** on July 11, 2014, with a comment period that ended on September 2, 2014. In that proposed rule, for the ESRD PPS, we proposed routine updates to the payment system; proposed to implement the statutory provisions set forth in PAMA, and clarified policies for billing and payment of short frequent hemodialysis services and facility eligibility requirements for the low-volume payment adjustment (LVPA) available under the ESRD PPS. We received approximately 400 public comments on our proposals, including comments from: ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses. In addition, we received a several thousand signature petition requesting that CMS include ''full coverage ''of the cost of home hemodialysis patient training under Medicare. We note that we made no proposals in our CY 2015 ESRD PPS proposed rule regarding these issues, and therefore we are not finalizing a modification to them in this final rule. We will, however, consider the comments set forth in the petition and in other public comments in the future.

In addition, we received other comments regarding policies for the ESRD PPS for which we made no proposals. For example, a few comments from industry stakeholders and medical associations encouraged CMS to consider race and ethnicity when assessing the cost of care. One commenter contended that African American dialysis patients require significantly more ESA utilization per treatment. Another commenter encouraged CMS to monitor race and ethnicity for the purpose of establishing a race adjustment factor in the future. We will consider these comments as we refine the payment system in CY 2016. Other comments requested that CMS clarify inconsistent manual language in Internet Only Manual Pub. 100–02 Medicare Benefit Policy, chapter 11 End-Stage Renal Disease. We appreciate these suggestions and will clarify our manual language through sub-regulatory guidance.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2015 ESRD PPS. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

C. Routine Updates and Policy Changes to the CY 2015 ESRD PPS

1. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we discussed the development of the ESRD PPS per treatment base rate that is codified in the Medicare regulations at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment Medicare Allowable Payment (MAP) for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and regulations at § 413.230, the ESRD PPS base rate is adjusted for the patient-specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, as well as applicable outlier payments or training payments.

a. Changes to the Drug Utilization Adjustment

i. The Drug Utilization Adjustment Finalized in the CY 2014 ESRD PPS Final Rule

Section 1881(b)(14)(I) of the Act, as added by section 632(a) of the American Taxpayer Relief Act of 2012 (ATRA), required that, for services furnished on or after January 1, 2014, the Secretary shall make reductions to the single payment for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs) by comparing per patient utilization data from 2007 with such data from 2012. Section 1881(b)(14)(I) further required that in making the reductions, the Secretary take into account the most recently available data on Average Sales Prices (ASP) and changes in prices for drugs and biologicals reflected in the ESRD market basket percentage increase factor under section 1881(b)(14)(F). Consistent with these requirements, in CY 2014, we finalized a payment adjustment to the CY 2014 ESRD PPS base rate that reflected the change in utilization of ESRD-related drugs and biologicals from CY 2007 to CY 2012.

Specifically, we finalized the drug utilization adjustment amount of $29.93 per treatment, and finalized a policy to implement this amount over a 3- to 4-year transition period. For CYs 2014 and 2015, we stated that we would implement the transition by offsetting the payment update by a portion of the reduction amount necessary to create an overall impact of zero percent for facilities from the previous year's payments. For example, in CY 2014 we finalized a per treatment drug utilization adjustment amount for the first transition year of $8.16 or 3.3 percent, which represented the CY 2014 ESRDB market basket update minus productivity and other impacts to create an overall impact of zero percent. For a complete discussion of the methodology for computing the drug utilization adjustment, please see the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170).

ii. PAMA Changes to the Drug Utilization Adjustment

On April 1, 2014, Congress enacted PAMA. Section 217(b), titled ''Mitigation of the Application of Adjustment to ESRD Bundled Payment Rate to Account for Changes in the Utilization of Certain Drugs and Biologicals,'' amends section 1881(b)(14)(I) of the Act by inserting ''and before January 1, 2015'' after January 1, 2014. This amendment effectively eliminates the remaining years of the drug utilization adjustment transition. In its place, the PAMA amendments to section 1881(b)(14)(F)(i) dictate what the market basket increase factor will be for 2015 and how it will be reduced in 2016 through 2018. In particular, PAMA section 217(b)(2)(C) amended section 1881(b)(14)(F)(i) by adding subclause (III), which provides that ''[n]otwithstanding subclauses (I) and (II), in order to accomplish the purposes of subparagraph (I) with respect to 2015, the increase factor described in subclause (I) for 2015 shall be 0.0 percent.'' We interpret subclause

(III) to mean that the market basket increase factor less the productivity adjustment for 2015 is 0.0 percent.

The PAMA amendments also provide for a payment reduction in lieu of the drug utilization adjustment in 2016 through 2018. In particular, PAMA section 217(b)(2)(ii) further amends section 1881(b)(14)(i)(I) by adding at the end the following new sentence, ''In order to accomplish the purpose of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the increase factor described in the preceding sentence for each of 2016, 2017, and 2018, the Secretary shall reduce such increase factor by 1.25 percentage points for each of 2016 and 2017 and by 1 percentage point for 2018.'' We interpret this provision as requiring us to reduce the market basket increase factor for 2016 through 2018 by the percentages prescribed in the statute.

Comment: All commenters were supportive of CMS's interpretation of section 217 of PAMA and agreed that PAMA required a 0.0 percent market basket update in CY 2015. A few commenters expressed concern that the cumulative economic effect of ATRA's drug reduction, sequestration, and now PAMA's 0.0 percent update may be jeopardizing care and access for Medicare beneficiaries. Some commenters noted an unstainable Medicare payment trajectory and cited an independent analysis that estimates a mean gross margin of negative 7.4 percent for CY 2018.

Response: We thank the commenters for their support of our interpretation of section 217 of PAMA as requiring a 0.0 percent market basket update for CY 2015. We acknowledge the commenters' concern for the collective effects of reduced Medicare margins on care quality and patient access. However, PAMA, ATRA, and sequestration were congressionally mandated payment reductions and CMS must implement them. CMS has finalized policies that would mitigate the negative impacts of statutorily mandated reductions on facility margins. For example, we proposed and finalized a transition not to exceed four years for the ATRA drug utilization adjustment, thus reducing the CY 2014 payment reduction from $29.93 to $8.16. We adopted this transition policy to mitigate the negative economic impact for facilities (78 FR 72161 through 72170), and to ensure our beneficiaries' access to quality care.

Comment: A few commenters requested greater transparency in the data used to establish the annual update and other Medicare payment updates included in the ESRD PPS. One commenter noted that transparency in rate setting data gives the industry confidence in a predictable and fair payment methodology, and that facilities can only then make operational and investment decisions for the future. Other commenters provided a specific list of data files they need in order to replicate CMS's update calculations, and provided additional analysis to CMS: annual claims level rate setting files for the ESRD PPS; Medicare Part D Standard Analytic File (SAF); 100 percent SAF for physician services; and Medicare Part C SAF.

Response: We agree with commenters that transparency in rate setting is desirable. We posted the provider-level impact file with the proposed rule because we believe that furnishing an impact file, sorted by facility, is the most transparent method and enables facilities to assess the economic impact of policy changes at the facility level. In addition, beginning in CY 2015, we have made a Limited Data Set (LDS) of ESRD PPS facility claims used for CY 2015 rate settings available for purchase. A link to the LDS file was included in our proposed rule in section XIX titled Files Available to the Public via the Internet (79 FR 40311). Likewise, we included an updated LDS file with this final rule that is discussed in section XIX of this rule. The LDS files are available for purchase at *http://www.cms.gov/research-statistics-data-and=systems/files-for-order/limiteddatasets/endstagerenaldiseasesystemfile.html.* We note that interested parties may request Part D data from CMS at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/GuidePartD,* and we will consider furnishing encounter data under Medicare Part C, and other Medicare claims files in the future.

b. Payment Rate Update for CY 2015

As discussed in section II.A of this final rule, section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the rate of increase in the ESRD market basket, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. In accordance with section 1881(b)(14)(F)(i)(III) of the Act, as added by PAMA section 217(b)(2)(C), we are finalizing a 0.0 percent update to the CY 2014 ESRD PPS base rate of $239.02 for CY 2015.

Comment: Generally, commenters were supportive of the CY 2015 proposed base rate. Some commenters cautioned that CMS ''maintain financial integrity'' of the ESRD PPS by addressing crucial components of the payment system that inappropriately reduce the base rate. A few commenters identified the ESRD PPS payment components of case-mix and the outlier policy as examples of payment adjustments that they believe are structurally broken. The commenters contend that these adjustments result in lowering overall payments to facilities, making it difficult for facilities to furnish high quality care to patients.

Response: We thank the commenters for their support of the proposed CY 2015 ESRD PPS base rate. While we do not agree with the commenters who contend that the case-mix and outlier adjustments are structurally broken, we believe that these adjustments have been underutilized in the payment system. We note that section 632 of ATRA requires CMS to review the case-mix payment adjustments and make appropriate modifications by CY 2016. We will consider these comments as part of that larger ESRD PPS refinement that will take place for CY 2016.

Comment: Other commenters cautioned CMS to correct what they term ''flaws in standardization,'' calling upon CMS to use the most current data available in re-calculating the standardization factor in this final rule in order to mitigate losses facilities may have in CY 2015. As an alternative, commenters suggest that CMS make an interim reduction to the adjustor values that would take into account the decrease in drug utilization. With these values, CMS could reduce the dollars in the standardization factor for CY 2015. They estimated that the standardization factor discrepancy accounts for a loss of one to two percent in the base rate.

They also suggested that for 2015, CMS: (1) Eliminate the co-morbidity case-mix adjustments because the facilities are unable to obtain the necessary documentation to substantiate a co-morbid diagnosis and thus, are unable to claim the adjustment; and (2) reduce the outlier percentage so that it reflects the percentage of cases paid as outlier cases (0.5 percent) and so that it is paid out annually in its entirety, or else provide for a zero percent outlier policy.

Response: We thank the commenters for their suggestions for protecting the integrity of the base rate and questioning the necessity for some payment adjustments available under the ESRD PPS. However, as we stated in the CY 2011 ESRD PPS final rule (75 FR

49081), to account for the overall effects of the proposed ESRD PPS patient- and facility-level adjustment factors and wage indexes, we had to standardize payments in order to ensure that total projected PPS payments were equal to what would otherwise have been paid had the ESRD PPS not been implemented, prior to application of the 98 percent budget-neutrality adjustment. The standardization factor was calculated by dividing total estimated payments in 2011 under the basic case-mix adjusted composite rate payment system by estimated payments under the final ESRD PPS in 2011.

We wish to remind commenters that we used the best data available for the development of the standardization factor and made a good faith effort to simulate payments under the ESRD PPS beginning in CY 2011. In addition, CMS plans to conduct a regression analysis for the CY 2016 ESRD PPS rulemaking cycle to reassess the appropriateness of the patient- and facility-level payment adjustments applied under the ESRD PPS. This analysis will include a thoughtful assessment of utilization and economic impact of the various payment adjustments under the PPS to determine whether they should continue to apply, or if the magnitude of the adjustments is over or understated in the ESRD PPS.

We plan to consider all of the improvements suggested as part of the ESRD PPS refinement for CY 2016. We do not think it would be appropriate to eliminate any co-morbidity adjustments in isolation from a broader refinement that assesses all current and potentially significant adjustments.

c. CY 2015 ESRD PPS Wage Index Budget-Neutrality Adjustment

As discussed in section II.C of this final rule, for CY 2015 we apply the wage index budget-neutrality adjustment factor of 1.001729 to the CY 2014 ESRD PPS base rate (that is, $239.02), yielding a CY 2015 ESRD PPS wage index budget-neutrality adjusted base rate of $239.43 ($239.02 × 1.001729 = $239.43).

Comment: Commenters were supportive of the CY 2015 proposed wage index budget-neutrality adjustment. A few commenters noted the small payment increase for CY 2015, and thanked CMS for continuing to apply an updated wage index budget-neutrality adjustment in a year where a 0.0 percent market basket update was congressionally mandated.

Response: We thank the commenters for their support of our finalized wage index budget-neutrality factor, and note that the wage index budget-neutrality update is computed separately from the annual market basket update. Therefore, the wage index budget-neutrality update continues to apply even in years when a 0.0 market basket update is statutorily required.

d. Labor-Related Share

As discussed in section II.C.2 of this final rule, as part of the ESRDB market basket rebase and revision, we are updating the labor-related share from 41.737 percent to 50.673 percent. We noted that some ESRD facilities are adversely affected by this update. For example, rural facilities and facilities located in core-based statistical areas (CBSA) with wage indexes below 1.0 will experience reduced payments due to an increase in the labor-related share, while other facilities located in CBSAs where wage indices are above 1.0 will experience increased payments. While we are finalizing the new labor-related share of 50.673 percent, we shall implement this value using a 2-year transition.

Therefore, for CY 2015 we will apply 50 percent of the value of the current labor-related share under the ESRD PPS (41.737 percent) and 50 percent of the value of the new labor-related share (50.673 percent), add the percentages together and divide by two, for a CY 2015 labor-related share of 46.205 percent ((41.737 + 50.673)/2 = 46.205). Beginning in CY 2016, we will apply 100 percent of the total labor-related share of 50.673 percent. We shall continue to apply a labor-related share of 50.673 percent in computing a wage index-adjusted base rate for ESRD facilities until such time in the future the ESRDB market basket is again rebased or revised. This approach is similar to the transition finalized for the CY 2015 wage indexes and discussed in section II.3 of this final rule, and is intended to allow ESRD facilities time to adjust to the new labor-related share.

Comment: While the majority of commenters supported the updated labor-related share, some commenters expressed concern regarding the negative impact for rural facilities and any facility with a wage index value of less than 1.0, and noted that they will experience reduced ESRD PPS payments in CY 2015 as a result of the updated labor-related share. A few commenters contended that this update would be better received during a larger payment system refinement and encouraged CMS to delay the ESRDB market basket update, with the new labor-related share, until CY 2016 where negative impacts could be offset with other payment system refinements. Another commenter noted that if the ESRDB market basket update was delayed until CY 2016, 2012 audited cost reports would be available to ensure better accuracy. The commenter noted that the PAMA legislation mandated the audits and provided $18 million to fund the effort.

Response: We thank the commenters for their support of our updated labor-related share. We share stakeholders' concern for negatively impacted facilities. Moreover, we agree with commenters that delaying the ESRDB market basket update until CY 2016 may have the advantage of offsetting some of the negative impact indicated in section XIV of this final rule. However, we believe the labor-related share has been undervalued in the payment system, especially after the ATRA drug utilization reduction finalized in the ESRD PPS CY 2014 final rule (78 FR 72161 through 72170). Therefore, we are finalizing a labor-related share of 46.205 percent for CY 2015 and a labor-related share of 50.673 percent for CY 2016 and until such time in the future the labor-related share is updated.

Lastly, we wish to clarify for commenters that the audits of Medicare cost reports beginning during 2012 will not be available for CY 2016 rulemaking. Any cost report findings resulting from the statutorily-mandated audits of Medicare cost reports beginning during 2012 will be available for future ESRDB market basket updates.

Comment: Many commenters supported the update to the labor-related share and the 2-year transition to dampen the immediate impact of the change. A few commenters thanked CMS for appropriately recognizing shifting costs in furnishing dialysis services from drugs to labor.

Response: We thank the commenters for their support and note that we considered implementing the full amount of the revised labor-related share percentage of 50.673 for CY 2015, but that would have increased the CY 2015 proposed wage index budget-neutrality factor. Such an increase would have resulted in a further decrease in CY 2015 Medicare payments to rural facilities, and an additional increase to urban facilities. When we apply the transition labor-related share of 46.205 percent the disparity in impacts for rural and urban facilities is reduced, resulting in a more stable economic environment for all facilities in general. We believe that offsetting the negative economic impact for rural facilities with the 2-year transition for the labor-share will enhance access to quality care for Medicare beneficiaries living in rural communities. (For more information of the CY 2015 Impact of

Changes in Payments to ESRD Facilities for CY 2015 ESRD final rule, see section XIV of this final rule). Therefore, we believe a 2-year transition strikes an appropriate balance between ensuring that ESRD PPS payments are as accurate and stable as possible, while giving rural and urban facilities in low wage index areas time to adjust to the new labor-related share.

Comment: A few commenters requested that CMS consider a longer transition to further mitigate the financial pressures on rural providers. One commenter encouraged CMS to provide a longer transition period, ''such as 3 or 4 years.'' Another commenter encouraged CMS to extend the transition to 3 years to give rural facilities more time to adjust to the lower reimbursement and ''get them closer to the end of the PAMA cuts.''

Response: We thank the commenters for their concern for the economic impacts on rural and urban facilities located in areas with low wage indices. In addition, we acknowledge the commenter's suggestion to extend the transition period to 3 or 4 years to allow disadvantaged facilities time to adjust to the new labor-related share percentage. However, we continue to believe a 2-year transition strikes an appropriate balance between allowing ESRD facilities time to adjust to the new labor-related share while appropriately accounting for facility costs associated with labor in furnishing renal dialysis services.

In summary, we are finalizing a CY 2015 ESRD PPS base rate of $239.43. This reflects, updated claims data used for rate setting, a 0.0 percent payment update consistent with section 1881(b)(14)(F)(i)(III) of the Act, as added by section 217(b)(2) of PAMA, a 2-year transition for the labor related share(46.205 percent for CY 2015 and 50.673 for CY 2016), and the CY 2015 wage index budget-neutrality adjustment factor of 1.001729.

2. ESRD Bundled Market Basket and Labor-Related Share

a. Rebasing and Revision of the ESRD Bundled Market Basket

In July, we proposed to rebase and revise the ESRD Bundled (ESRDB) market basket for CY 2015. In accordance with section 1881(b)(14)(F)(i) of the Act, beginning in 2012, the ESRD payment amounts are required to be annually increased by an ESRD market basket increase factor that is reduced by the productivity adjustment in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

In the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162), we established an ESRDB market basket using CY 2008 as the base year. This market basket was used to annually update the ESRD base rate payments for CY 2012, CY 2013, and CY 2014.

In the CY 2015 ESRD proposed rule, we proposed to rebase and revise the ESRDB market basket for CY 2015, in accordance with, section 1881(b)(14)(F)(i) of the Act, which provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services. The multi-factor productivity adjustment is applied to the ESRDB market basket update under the requirements of sections 1881(b)(14)(F)(i)(II) and 1886(b)(3)(B)(xi)(II) of the Act.

The CY 2012-based ESRDB market basket represents the costs of operating and capital-related costs. The percentage change in the ESRDB market basket reflects the average change in the price of a fixed set of goods (both operating and capital) and services purchased by ESRD facilities necessary for providing renal dialysis services. For further background information, see the CY 2011 final rule with comment period (75 FR 49151 through 49162).

The ESRDB market basket is a fixed-weight (Laspeyres-type) price index. A Laspeyres-type index compares the cost of purchasing a specified mix of goods and services in a selected base period to the cost of purchasing that same group of goods and services at current prices. The effects on total expenditures resulting from changes in the quantity or mix of goods and services purchased subsequent or prior to the base period are, by design, not considered.

The market basket is constructed in three main steps: the first step is to select a base period and estimate total base period expenditure shares for mutually exclusive and exhaustive spending categories. We use total costs for operating and capital expenses. These shares are called ''cost'' or ''expenditure'' weights. The second step is to match each expenditure category to a price/wage variable, called a price proxy. We draw these price proxy variables from publicly available statistical series published on a consistent schedule, preferably at least quarterly. The final step involves multiplying the price proxy index level for each spending category by the cost weight for that category. The sum of these products (that is, cost weights multiplied by proxy index levels) for all cost categories yields the composite index level of the market basket for a given quarter or year. Repeating the third step for other quarters and years produces a time series of market basket index levels, from which we can calculate rates of growth.

We proposed to use CY 2012 as the base year for the rebased and revised ESRDB market basket cost weights. The cost weights are based on the cost report data for independent ESRD facilities. We refer to the market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2012 = 100. Source data included CY 2012 Medicare cost reports (Form CMS–265–11), supplemented with 2012 data from the U.S. Census Bureau's Services Annual Survey (SAS) for Kidney Dialysis Centers (NAICS 621492). Medicare cost reports from hospital-based ESRD providers were not used to construct the proposed ESRDB market basket because data from independent ESRD facilities tend to better reflect the actual cost structure faced by the ESRD facility itself, and are not influenced by the allocation of overhead over the entire institution, as can be the case with hospital-based providers. This approach is consistent with our standard methodology used in the development of other market baskets.

b. Rebasing and Revision of the ESRD Bundled Market Basket

The terms ''rebasing'' and ''revising'', while often used interchangeably, actually denote different activities. Rebasing means shifting the base year for the structure of costs of the input price index (for example, we proposed to shift the base year cost structure from CY 2008 to CY 2012). Revising means changing data sources, cost categories, price proxies, and/or methodology used in developing the input price index. We proposed both to rebase and revise the ESRDB market basket.

We selected CY 2012 as the new base year because 2012 is the most recent year for which relatively complete Medicare cost report (MCR) data are available. In developing the market basket, we reviewed ESRD expenditure data from ESRD MCRs (CMS Form 265–11) for CY 2012 for each freestanding ESRD facility that reported expenses and payments. The CY 2012 cost reports

are those with cost reporting periods beginning on or after January 1, 2012 and before December 31, 2012.

We developed cost category weights for the proposed CY 2012-based ESRDB market basket in two stages. First, we derived base weights for nine major categories (Wages and Salaries, Employee Benefits, Medical Supplies, Lab Services, Housekeeping & Operations, Pharmaceuticals, Administrative and General, Capital-Related Building & Fixed Equipment, and Capital-Related Machinery) from the ESRD MCRs. Second, we proposed to divide the Administrative & General cost category into further detail using 2012 U.S. Census Bureau Services Annual Survey (SAS) Data for the industry Kidney Dialysis Centers (NAICS 621492). We applied the 2012 distributions from the SAS data to the 2012 ''Administrative & General'' cost weight to yield the more detailed 2012 cost weights. This is similar to the methodology we used to break the 2008-based Administrative & General Costs into more detail for the ESRDB market basket as detailed in the CY 2011 ESRD final rule (75 FR 49154 through 49159). For more information on the SAS data, see *http://www.census.gov/services/sas/about_the_surveys.html*.

We proposed to include a total of 20 detailed cost categories in the CY 2012-based ESRDB market basket, which is four more cost categories than the CY 2008-based ESRDB market basket. In addition, we proposed to further decompose both the Wages and Salaries and Employee Benefits cost categories into four more detailed cost categories reflecting the occupational mix of full time equivalents (FTEs) at ESRD facilities. The four detailed occupational categories are: (1) Health-related workers; (2) Management workers; (3) Administrative workers; and (4) Service workers. Having more detailed cost categories for these compensation costs enables them to be proxied more precisely. We also proposed to collapse the Professional Fees and All Other Services cost categories into single categories rather than splitting those categories into Labor-Related and Non-Labor-Related Services. In addition, we proposed to revise our labels for All Other Materials to Medical Materials and Supplies, Laboratories to Lab Services, and All Other Labor-Related/Non Labor-Related to All Other Goods and Services.

i. Cost Category Weights

Using Worksheets A and B from the CY 2012 Medicare cost reports, we computed cost shares for nine major expenditure categories: Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Lab Services, Administrative and General (A&G), Housekeeping and Operations, Capital-Related Building & Equipment, and Capital-Related Machinery. Edits were applied to include only cost reports that had total costs greater than zero. In order to reduce potential distortions from outliers in the calculation of the cost weights for the major expenditure categories, cost values for each category less than the 5th percentile or greater than the 95th percentile were excluded from the computations. The resulting data set included information from approximately 4,700 independent ESRD facilities' cost reports from an available pool of 5,333 cost reports. Expenditures for the nine cost categories as a proportion of total expenditures can be found in the CY 2015 Proposed Rule (79 FR 40217).

Some costs are reported on the Medicare cost report but are not included in the ESRD bundled payment. For example, we removed the expenses related to vaccine costs from total expenditures since these are excluded from the ESRD bundled payment, but reported on the Medicare cost report.

We also proposed to expand the expenditure categories developed from the Medicare cost reports to allow for more detailed expenditure decomposition. To expand these cost categories, SAS data were used because the Medicare Cost Reports do not collect detailed information on the items of interest. Those categories include: Benefits for all employees, professional fees, telephone, utilities, and all other goods and services. We chose to separately break out these categories to more accurately reflect ESRD facility costs. For a detailed description of how the costs were further refined to yield the proposed 2012-based ESRDB cost weights please see (79 FR 40217 through 40221).

Table 1 lists all of the cost categories and cost weights in the CY 2012-based ESRDB market basket compared to the cost categories and cost weights in the CY 2008-based ESRDB market basket.

TABLE 1—COMPARISON OF THE CY 2012–BASED ESRDB MARKET BASKET COST CATEGORIES & WEIGHTS AND THE CY 2008-BASED ESRDB MARKET BASKET COST CATAGORIES & WEIGHTS

2008 Cost category	2008 Cost weight (percent)	2012 Cost weight (percent)	2012 Cost category
Total	100.000	100.000	Total.
Compensation	33.509	42.497	Compensation.
Wages and Salaries	26.755	33.650	Wages and Salaries.
Employee Benefits	6.754	8.847	Employee Benefits.
Utilities	1.264	1.839	Utilities.
Electricity	0.621	0.973	Electricity.
Natural Gas	0.127	0.101	Natural Gas.
Water and Sewerage	0.516	0.765	Water and Sewerage.
All Other Materials	39.765	28.139	Medical Materials and Supplies.
Pharmaceuticals	25.052	16.510	Pharmaceuticals.
Supplies	9.216	10.097	Supplies.
Lab Services	5.497	1.532	Lab Services.
All Other Services	15.929	15.277	All Other Goods and Services.
Telephone	0.597	0.468	Telephone Service.
Housekeeping and Operations	2.029	3.785	Housekeeping and Operations.
Labor-Related Services	2.768		
Prof. Fees: Labor-related	1.549	0.617	Professional Fees (Labor-related and NonLabor-related services).
All Other Labor-related	1.219		
NonLabor-Related Services	10.535	10.407	All Other Goods and Services
Prof. Fees: Nonlabor-related	0.224		
All Other Nonlabor-related	10.311		

TABLE 1—COMPARISON OF THE CY 2012–BASED ESRDB MARKET BASKET COST CATEGORIES & WEIGHTS AND THE CY 2008-BASED ESRDB MARKET BASKET COST CATAGORIES & WEIGHTS—Continued

2008 Cost category	2008 Cost weight (percent)	2012 Cost weight (percent)	2012 Cost category
Capital Costs	9.533	12.248	Capital Costs.
Capital Related-Building and Equipment	7.459	8.378	Capital Related-Building and Equipment.
Capital Related-Machinery	2.074	3.870	Capital Related-Machinery.

Note: Totals may not sum to 100.000 percent due to rounding

ii. Price Proxies for the CY 2012 ESRDB Market Basket

For each cost category in the CY 2012-based ESRDB market basket, we selected the most appropriate wage and price proxies that measure the rate of price change for each expenditure category. An explanation of our rationale for the proposed price proxies used for each cost category can be found in the proposed rule (79 FR 40221 through 40224). With the exception of the pharmaceuticals cost category, all of the price proxies we proposed to use for each cost category weight are the same in this final rule. We based the price proxies on Bureau of Labor Statistics (BLS) data and grouped them into one of the following BLS categories:

• *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour.

• *Producer Price Indexes.* Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.

• *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs were available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

• *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population.

• *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket.

• *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this ensures that the market basket updates are as transparent to the public as possible.

• *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

Pharmaceuticals

In the CY 2015 proposed rule, we proposed to change the price proxy used for the pharmaceuticals cost category from the one used for the 2008-based ESRDB market basket—the PPI: Pharmaceuticals for Human Use, Prescription (79 FR 40223). We referenced a recent Health and Human Services Office of the Inspector General (OIG) report titled ''Update: Medicare Payment for End Stage Renal Disease Drugs'' which recommended that CMS consider updating the ESRD payment bundle using a factor that takes into account drug acquisition costs. CMS had responded to this recommendation by stating that we would consider these findings in the continual evaluation of the ESRD market basket, particularly during the next rebasing and revising of the market basket index.[1]

Drug acquisition cost data is not publicly available, nor are the methods used to determine it transparent, and, therefore, wouldn't meet our price proxy criteria of relevance, reliability, transparency, and public availability. However, after considering several viable options that do meet the criteria we proposed to use the PPI: Vitamin, Nutrient, and Hematinic Preparations (BLS series code #WPU063807).

Based on public comments and, for the reasons articulated below in comments and responses, we have decided to finalize a price proxy blend as the price proxy for the pharmaceutical cost category. The blend we are using is 22 percent PPI: Vitamin, Nutrient, and Hematinic Preparations (BLS series code #WPU063807) and 78 percent PPI: Biological Products, Human Use (BLS series code #WPU063719). Table 2 lists all price proxies for the revised and rebased ESRDB market basket.

TABLE 2—PRICE PROXIES FOR THE CY 2012-BASED ESRDB MARKET BASKET

Cost category	Price proxy	Cost weight (percent)
Compensation		42.497
Wages and Salaries		33.650
Health-related Wages	ECI—Wages & Salaries—Hospital (Civilian)	26.920
Management Wages	ECI—Wages & Salaries—Management, Business, and Financial (Private)	2.356
Administrative Wages	ECI—Wages & Salaries—Office and Administrative Support (Private)	2.356
Service Wages	ECI—Wages & Salaries—Service Occupations (Private)	2.019
Employee Benefits		8.847
Health-related Benefits	ECI—Benefits—Hospital (Civilian)	7.078

[1] *http://oig.hhs.gov/oei/reports/oei-03-12-00550.asp*

TABLE 2—PRICE PROXIES FOR THE CY 2012-BASED ESRDB MARKET BASKET—Continued

Cost category	Price proxy	Cost weight (percent)
Management Benefits	ECI—Benefits—Management, Business, and Financial (Private)	0.619
Administrative Benefits	ECI—Benefits—Office and Administrative Support (Private)	0.619
Service Benefits	ECI—Benefits—Service Occupations (Private)	0.531
Utilities		1.839
Electricity	PPI—Commercial Electric Power	0.973
Natural Gas	PPI—Commercial Natural Gas	0.101
Water and Sewerage	CPI—Water and Sewerage Maintenance	0.765
Medical Materials and Supplies		28.139
Pharmaceuticals	Blend of PPI Biological Products for Human Use and PPI—Vitamin, Nutrient, and Hematinic Preparations	16.510
Supplies	PPI—Surgical and Medical Instruments	10.097
Lab Services	PPI—Medical Laboratories	1.532
All Other Goods and Services		15.277
Telephone Service	CPI—Telephone Services	0.468
Housekeeping and Operations	PPI—Cleaning and Building Maintenance Services	3.785
Professional Fees	ECI—Compensation—Professional and Related Occupations (Private)	0.617
All Other Goods and Services	PPI—Finished Goods less Foods and Energy	10.407
Capital Costs		12.248
Capital Related Building and Equipment	PPI—Lessors of Nonresidential Buildings	8.378
Capital Related Machinery	PPI—Electrical Machinery and Equipment	3.870
Total		100.000

Note: Totals may not sum to 100.000 percent due to rounding.

iii. 2012-Based ESRDB Market Basket Updates Compared to 2008-Based ESRDB Market Basket Updates

Beginning with the CY 2015 ESRD PPS update, we proposed to adopt the CY 2012-based ESRDB market basket as the appropriate market basket of goods and services for the ESRD PPS.

Based on the IHS Global Insight, Inc. (IGI) first quarter 2014 forecast with history through the fourth quarter of 2013, the proposed CY 2012-based ESRDB market basket for CY 2015 was 2.0 percent while the proposed CY 2008-based ESRDB market basket for CY 2015 was 2.7 percent.

Table 3 compares the proposed CY 2012-based ESRDB market basket and the CY 2008-based ESRDB market basket percent changes. For the historical period between CY 2011 and CY 2013, the average difference between the two market baskets was −1.8 percentage points. This is primarily the result of the proposed lower pharmaceutical cost share weight combined with the proposed revised price proxy for the pharmaceutical cost category. For the CY 2014 and CY 2015 forecasts, the differences in the market basket forecasts are mainly driven by the same factors as in the historical period.

TABLE 3—PROPOSED CY 2012-BASED ESRDB MARKET BASKET AND CY 2008 BASED ESRDB MARKET BASKET, PERCENT CHANGES: 2011–2015

Calendar year (CY)	Proposed CY 2012-based ESRDB market basket	CY 2008-based ESRDB market basket
Historical data:		
CY 2011	1.2	2.8
CY 2012	1.4	3.4
CY 2013	1.1	3.0
Average CY 2011–2013	1.3	3.1
Forecast:		
CY 2014	1.8	2.3
CY 2015	2.0	2.7

Source: IHS Global Insight, Inc. 1st quarter 2014 forecast with historical data through 4th quarter 2013.

b. Proposed ESRDB Market Basket Update, Adjusted for Multifactor Productivity for CY 2015

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by the productivity adjustment. For CY 2015, section 1881(b)(14)(F)(i)(III) of the Act, as added by section 217(b)(2) of PAMA, requires the Secretary to implement a 0.0 percent ESRDB market basket increase to the ESRD PPS base rate. In addition, we interpret the reference to ''[n]otwithstanding subclause (III)'' that was added to amended section 1881(b)(14)(F)(i)(III) of the Act as precluding the application of the multi-factor productivity (MFP) adjustment in 2015. As a result of these provisions, the proposed CY 2015 ESRD market basket increase was 0.0 percent. We note that the proposed 2012-based ESRDB market basket update less the productivity adjustment for CY 2015 would have been 1.6 percent, or 2.0 percent less 0.4 percentage point, based

on IGI's 1st quarter 2014 forecast of the ESRDB market basket and MFP.

c. Labor-Related Share

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share is typically the sum of Wages and Salaries, Benefits, Professional Fees, Labor-related Services, and a portion of the Capital share from a given market basket.

We proposed to use the 2012-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities of 50.673 percent, as shown in Table 4 below. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping and Operations, 87 percent of the weight for Professional Fees (details discussed below), and 46 percent of the weight for Capital-related Building and Equipment expenses (details discussed below). We note that this is a similar methodology used to compute the labor-related share used from CY 2011 through CY 2014.

TABLE 4—CY 2015 LABOR-RELATED SHARE AND CY 2014 ESRDB LABOR-RELATED SHARE

Cost category	Proposed CY 2015 ESRDB labor-related share (percent)	CY 2014 ESRDB labor-related share (percent)
Wages	33.650	26.755
Benefits	8.847	6.754
Housekeeping and operations	3.785	2.029
Professional fees (labor-related)	0.537	2.768
Capital labor-related	3.854	3.431
Total	50.673	41.737

The labor-related share for Professional Fees (87 percent) reflects the proportion of ESRD facilities' professional fees expenses that we believe vary with local labor market. We conducted a survey of ESRD facilities in 2008 to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD facility's local labor market. Thus, we proposed to include 87 percent of the cost weight for Professional Fees in the labor-related share, the same percentage as used in prior years.

The labor-related share for capital-related expenses (46 percent of ESRD facilities' adjusted Capital-related Building and Equipment expenses) reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages. Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

d. Responses to Comments on Proposed Market Basket Rebasing & Revision

Comment: Many commenters support rebasing the ESRDB market basket using the most current and accurate data that are available. Most commenters stated that an updated base year allows the market basket to better reflect the relative costs of running an ESRD facility under the PPS and accurately captures the decline in dialysis drug use that has occurred since 2008 (the base year of the current market basket).

Response: We thank the commenters who supported the rebasing of the ESRDB market basket to reflect cost data for 2012. The 2012 MCR data is the first year of data available under the bundled PPS system and reflects the changes to the relative costs associated with furnishing ESRD treatments. We agree that the decline in dialysis drug use since 2008 and its subsequent impact on the relative costs of other goods and services is an important update to consider when estimating price pressures faced by providers.

Comment: Several commenters requested that CMS delay the market basket rebasing until CY2016 so that the rebasing weights could be based on 2012 audited cost report data instead of the proposed unaudited reports. One commenter claimed that audits have historically shown that facilities' cost reports have included unallowable costs that either overstate or understate provider costs. They believe these errors could change the results of the cost share weights derived from the market basket data.

Response: We disagree with the commenters that the market basket rebasing should be delayed until CY 2016 in order to use audited cost report data rather than the unaudited reports. First, the audits will begin in fiscal year 2015 and the processing and analysis of the audited data could take several years to complete and therefore would not be available to use for the CY 2016 updates. Additionally, although the audits might lead to different cost levels reported by some providers, we don't believe that different levels would result in substantial variation in the relative cost share weights derived from the unaudited data since the cost weights are based on shares of the total rather than on levels. Additionally the weights are derived from all providers and therefore for a change to appear in the market basket cost shares the misreporting would have to be prevalent across a significant percentage of providers. Therefore, we do not agree the upcoming audits are a reason to delay the update to the market basket weights for CY 2015. We believe the use of the 2012 Medicare Cost Report data to be a technical improvement to the use of the 2008 ESRD relative cost shares.

Comment: One commenter believes that rebasing the market basket goes against the intent of PAMA since the rebasing will result in decreased payments to some providers and increased payments to others. They believe that PAMA was passed to mitigate the adjustment to ESRD bundled payments for all dialysis facilities by dictating a market basket update for CY 2015 through 2018.

Response: The CY 2015 ESRD PPS update will be 0.0 percent as mandated by PAMA. For CY 2016 through CY 2018, PAMA mandates a reduction to the market basket increase to the ESRD PPS payment updates. PAMA did not specify what the annual updates would be for those years. It is critical that CMS estimate an appropriate market basket increase that reflects the inputs used to furnish ESRD treatments in order for the legislatively required reductions to be applied in CYs 2016 through 2018.

Comment: One commenter believes that the difference in the market basket rate using the 2008 data versus the 2012 data is significant. They compared rules where market basket rebasings have been proposed and finalized for other providers such as hospital and home health and found that the rebasings did not result in significant changes in current or historical market basket updates.

Response: We agree with the commenter that the rebasing of other market baskets has not, historically, resulted in significant changes to the market basket update rate. However, between 2008 and 2012 the dialysis market experienced considerable changes. Most notable was the change in the relative cost of pharmaceuticals; specifically, the cost category weight dropped from 25.052 percent to 16.510 percent, due largely to decreases in drug utilization. In addition, we updated the price proxy associated with the pharmaceutical cost category based in part on the recommendation of a Health and Human Services Office of the Inspector General (OIG) report titled ''Update: Medicare Payment for End Stage Renal Disease Drugs.'' The combined changes to the pharmaceutical cost weight and the update of the pharmaceutical price proxy are the primary drivers of the changes to the market basket updates. For CY 2015, we note that the changes to the cost share weights from 2008 to 2012 account for about 50 percent of the difference while the change to the price proxy, as finalized, accounts for the other 50 percent of the difference.

Comment: One commenter requested clarification on several of the cost category calculations based on MCR data. First, the commenter requested we review the ''Administrative and General'' (A&G) and ''Wages & Salaries'' cost categories. The commenter specifically requested that CMS clarify the source of the percentage of non-direct wages associated with A&G that are obtained from Sheet A of the MCR as well as verify the method used on worksheet B to estimate total costs for each cost center. Second, the commenter requested that CMS clarify whether estimated salary costs for capital-related machinery were reallocated to salaries or if they were not.

Response: Below we clarify the calculation of the Wages & Salaries cost share methodology as well as the method for inclusion of the Capital-Related Machinery cost center into the moveable capital cost share weight.

To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from worksheet A of the MCR. The estimated ratios were calculated as the ratio of salary costs (worksheet A, columns 1 & 2) to total costs (worksheet A, column 4). The ratios were calculated for seven distinct cost centers: 'Operations & Maintenance' combined with 'Machinery & Rental & Maintenance' (line 3 & 6), Housekeeping (line 4), EH&W Benefits for Direct Pt. Care (line 8), Supplies (line 9), Laboratory (line 10), Administrative & General (line 11), and Drugs (line 12). Each of the ratios for the seven cost centers was applied to the corresponding reimbursable costs center totals as reported on worksheet B. The worksheet B totals were based on the sum of reimbursable costs reported on lines 8–17. We did not use line 18, the subtotal line, as the commenter presumes. For example, the salary percentage for supplies (as measured by line 9 on worksheet A) was applied to the total expenses for the supply cost center (the sum of costs reported on worksheet B, column 7, lines 8–17).

Regarding the calculation of costs associated with 'Machinery & Rental & Maintenance', the estimated salary ratio for this category was calculated jointly with the ratio for 'Operations & Maintenance' expenses. Therefore the same ratio was applied to 'Operations & Maintenance' and 'Machinery & Rental & Maintenance'. This ratio was applied to the total of worksheet B, column 4, lines 8–17. The salaries associated with the 'Machinery & Rental & Maintenance' costs were added to 'Total Salaries'. The remaining costs reported in worksheet B column 4, line 8–17 were considered moveable capital-related expenses (excluding salaries). We believe, the commenter's confusion was the result of the estimated salary share for the capital 'Machinery & Rental & Maintenance' costs being combined with the operation and maintenance costs before being added to salaries rather than being added separately. We hope this clarifies that the salary portion of 'Machinery & Rental & Maintenance' costs follows the same method as all other cost centers.

Comment: One commenter requested CMS revisit the allocation of laboratory costs from A&G once some of the providers have re-filed their cost reports. The commenter recommends that CMS not allocate A&G to the laboratory cost center and apply the lab price proxy only to directly reported lab costs. They note that allocating A&G to laboratory costs would overstate the proportion of lab costs based upon their understanding as to how some providers will allocate these costs once they re-file the cost reports.

Response: The lab costs included in the lab category in the rebased and revised ESRDB market basket do not include any allocation of administrative and general (A&G) costs. The costs are calculated based on lab expenses reported on Medicare Cost Report, worksheet B, lines 8–17, and column 8. We did not allocate any A&G costs to the lab category for the 2012 cost shares.

Comment: One commenter noted that what goes into each of the provided categories is not standardized. They believe that CMS should use consistent information from all providers to ensure the accuracy of the data. They note that smaller dialysis facilities, especially those in rural areas, will likely struggle to collect the information required to be reported on the MCR.

Response: We are sensitive to all reasonable cost report data being included in the calculation of the market basket cost share weights. We perform various trimming techniques to estimate the variability in the cost share weight results. Trimming the data removes providers that may have misreported costs or are extreme outliers. We analyze the results of the cost share weights for various samples of providers to ensure reasonability of the overall cost share weights. We also compare the results to other publicly available data sources for reasonableness of results. Our trimming methods rely on relative share outliers rather than dollar level outliers. Therefore, smaller dialysis facilities are subject to similar criteria as larger facilities to be included or excluded based on trimming methods. For example, we would exclude a provider in a 5 percent trim if the cost weight for

the wages and salaries was plus or minus 2 standard deviations from the mean cost weight of all providers for wages and salaries. If costs are significantly misreported we are unable to use the data, as submitted. It is the facility's responsibility to work with the MACs to ensure proper reporting.

Comment: One commenter is concerned with CMS re-apportioning certain costs and increasing the labor-related share of the ESRD PPS base rate. The commenter notes that they have one of the lowest CBSA wage indexes in the continental United States and are therefore impacted adversely when the labor-related share increases. Their concern is based on CMS's reliance upon assumptions to re-apportion certain costs. The commenter believes these cost assumptions may not accurately reflect the percentage of the ESRD PPS base rate impacted by the wage rate. The commenter recommends that CMS determine how it may best collect specific data on the labor-related cost categories where CMS currently relies on assumptions.

Response: We believe the assumptions that we have made in determining the labor-related share are reasonable and follow a similar methodology and assumptions used in other CMS PPS payment systems. The commenter's recommendation to review how we may gather detailed information on the ESRD PPS's labor-related cost categories is helpful in identifying future research opportunities. As part of CMS's ongoing efforts to update and refine the Medicare Cost Reports we can explore the opportunities for collecting more specific information. Beyond the Medicare Cost Reports, we can explore conducting new surveys that would help determine the costs that are influenced or vary with the local labor market, although these are subject to resource availability and approval through OMB's standard survey and auditing process (see ''Standards and Guidelines for Statistical Surveys'' *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/statpolicy/standards_stat_surveys.pdf* and ''Guidance on Agency Survey and Statistical Information Collections'' *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/pmc_survey_guidance_2006.pdf*).

Comment: Many commenters disagreed with the proposed price proxy for the drug cost category in the ESRDB market basket. They requested we reconsider the proposed proxy and use either a more appropriate index: The PPI Biological Products, Human Use (PPI–BPHU), or a composite proxy that would better reflect the costs of drugs and biologicals that are included in the ESRD bundle. Some commenters noted that ESAs account for over 80 percent of drug expenses and noted they are supplied by a sole source manufacturer that routinely imposes product price increases on facilities. Some commenters further point out that since ESAs are fully represented in, the PPI–BPHU, it is more relevant than the PPI Vitamin, Nutrient, & Hematinic Preparations (PPI–VNHP). Some commenters agreed that the PPI–Pharmaceutical for Human Use, Prescription (PPI–RX) is likely not the most appropriate proxy since it does not track well with the acquisition costs for ESRD drugs, as documented by the OIG study. Another commenter notes that the drugs in the PPI–VHNP include non-prescription (over-the-counter) medicines.

Response: Given concerns raised by commenters and further analysis into the appropriateness of the proposed price proxy, we agree with the commenters that the proposed PPI–VNHP suffers some shortcomings that can be mitigated if we were to use the PPI –BPHU. Most importantly, the PPI–BPHU measures the price change of drugs that are prescriptions, and ESAs would be captured within this index if they are included in the PPI sample (although, because the PPI relies on confidentiality with respect to the companies and drugs/biologicals included in the sample, we do not know if these drugs are indeed reflected in this price index). However, we believe the PPI–BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI–BPHU. We did this by comparing the historical price changes in the PPI–BPHU and the ASP for ESAs and found the cumulative growth to be consistent over several years. We will continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI–BPHU is still an appropriate price proxy.

On the other hand, since the non-ESA drugs used in the treatment of ESRD are mainly vitamins and nutrients, we believe that the PPI–VNHP is the best available proxy for these types of drugs. While this index does include over-the-counter drugs as well as prescription drugs, a comparison of trends in the prices for non-ESA drugs shows growth to the proposed PPI–VNHP.

Therefore we think it is appropriate to use both the PPI–VNHP and the PPI–BPHU, and we will proxy the price change for drugs included in the ESRD bundle by a blended drug price proxy with 78 percent of the index measured by the PPI–BPHU and 22 percent of the index measured by the PPI–VNHP. The shares within the blend are based on the 2012 ESRD Part B spending for ESA and non-ESA drugs included in the bundle. ESA drugs are those considered as a form of epoeitin alpha while the non-ESA drugs are the remaining drugs specified in the ESRD bundle.

Comment: One commenter claims that the OIG criticism of the current index as the drug price proxy—the PPI Pharmaceuticals for Human Use, Prescription—was based on a retrospective analysis of drugs price trends during a narrow 3-year window at a significant time of transition in the ESRD marketplace. They claim that if the OIG looked at a broader window of time (for example, 2003–2012), it would likely show that the PPI for prescription drugs has more closely tracked to cost changes for most drugs within the ESRD PPS. They note the OIG raised concerns with the use of the PPI–RX prior to the implementation of the ESRD PPS and CMS did not concur with the recommendation at that time and they noted that the OIGs figures were not suitable for inferring future price trends. The commenter recommends that CMS continue to use the PPI–RX as the proxy.

Response: At the time of the implementation of the ESRD market basket, we proposed and finalized the use of the PPI–RX since it is the proxy used in other CMS market baskets to proxy drug price growth and it would be representative of the average prescription drug price increase for the overall prescription drug market. However, analysis of the pricing trends of the drugs used in furnishing ESRD care (either the acquisition costs collected by OIG or by ASP data as collected by CMS) show relatively flat price growth over the 2008–2014 period (when taken on average) while the PPI RX has grown at a much faster rate. Additionally, there are a limited number of drugs included in the ESRD bundle and those drugs are mainly defined as biological products which are not captured in the PPI–RX. Therefore, as explained in the proposed rule, we do not believe that the PPI–RX should continue to be used in the ESRDB market basket.

Comment: One commenter recommended that the pharmaceutical price proxy changes be suspended and CMS follow the OIG recommendation to determine how drug acquisition costs may be taken into consideration when updating the ESRD PPS base rate.

Response: The direct use of drug acquisition costs in the ESRD market basket is not possible, as noted in our response to the OIG recommendation: ''We will consider these findings in our continual evaluation of the ESRD market basket, particularly during the next rebasing and revising of the index. As we have done for all of the market baskets developed by CMS, we will base the decision on which price proxy is used on four criteria: reliability, timeliness, availability, and relevance. We will be evaluating alternative data sources and methods to determine if we can improve the relevance of the ESRD drug price proxy while not sacrificing on the other three requirements. For instance, the data used in the OIG analysis is based on acquisition cost data, which is not data that is readily available in a public or timely manner. Additionally, the ESRD annual market basket updates are based on a projection and any price proxy ultimately will need to be forecasted. The more restrictive or specific a price series, the more difficult it can be to accurately forecast future price movements. Finally, the price proxy should also reflect price trends associated with an efficient market; therefore, to the extent market inefficiencies exist, there would be concerns with using direct cost or price data.'' [2]

Comment: Several commenters relayed the concern that CMS is making changes to the market basket that exacerbate the payment problems particularly for rural and low volume facilities while not contemporaneously addressing other changes to the ESRD payment. Other commenters support the proposed revised labor-related share as it reflects the proportionate decline over the past three years in EPO utilization. They recognize the impact on nonprofit and small providers with wage adjustors less than 1.0, and therefore support a 2-year transition for labor changes and updated CBSAs.

Response: We believe that the proposed 2012-based ESRDB market basket is a technical improvement to the 2008-based ESRDB market basket and therefore should be implemented in CY 2015. A transition policy, for the revised labor-related share, was proposed and finalized that will help to mitigate the impact to providers for any given year.

e. Final ESRDB Market Basket and Labor-Related Share

In summary, we are finalizing the rebasing and revision of the ESRDB market basket effective for CY 2015. The cost share weights will be based on the 2012 cost shares detailed in the proposed rule (79 FR 40217 through 40221) and presented in this final rule. We are also finalizing a labor-related share of 50.673 percent as detailed in the proposed rule (79 FR 40225 through 40226) and presented in this final rule.

We are finalizing all price proxies, as proposed, with the exception of the price proxy for the pharmaceutical cost category. As detailed in our response to comments, we believe that the PPI–VNHP suffers some shortcomings that can be mitigated with the use of the PPI–BPHU, particularly for the ESA drugs. We will, however, continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI–BPHU is still an appropriate price proxy given the unique market conditions related to the manufacturing and production of these types of drugs. On the other hand we will use the PPI–VNHP for the remaining drugs included in the ESRDB market basket. While this index does include over-the-counter drugs as well as prescription drugs, a comparison of trends in the prices for non-ESA drugs shows growth similar to the PPI–VNHP. Therefore, we are finalizing a blend of the PPI Biological Products, Human Use (PPI–BPHU) and the PPI Vitamin, Nutrient, & Hematinic Preparations (PPI–VNHP). The weights within the blend are based on 2012 estimated ESRD Part B spending for the drugs used in the bundle, which results in a split of 78 percent for ESAs (proxied by the PPI–BPHU) and 22 percent for non-ESAs (proxied by the PPI–VNHP).

Section 1881(b)(14)(F)(i)(III) of the Act, as added by section 217(b)(2) of PAMA requires a 0.0 percent market basket less productivity update for CY 2015. We are therefore finalizing 0.0 percent as the ESRDB market basket update less productivity adjustment for CY 2015. In the absence of PAMA, the CY2015 ESRDB market basket update less productivity would be 1.6 percent (2.1 percent market basket update less 0.5 percent MFP adjustment), based on the IHS Global Insight, Inc. (IGI) third quarter 2014 forecast with historical data through the second quarter of 2014. Table 5 compares the update of the proposed market basket to the final market basket; the only difference between the two arises from the change to the pharmaceutical price proxy.

TABLE 5—FINAL CY 2012-BASED ESRDB AND PROPOSED CY 2012-BASED ESRDB MARKET BASKET, PERCENT CHANGES: 2011–2015

Calendar Year (CY)	Final CY 2012-based ESRDB market basket	Final CY 2012-based ESRDB market basket
Historical data:		
2011	1.2	1.7
2012	1.4	1.5
2013	1.1	1.4
Average CY 2011–2013	*1.2*	*1.5*
Forecast:		
2014	1.4	1.6
2015	2.0	2.1

Source: IHS Global Insight, Inc. 3rd quarter 2014 forecast with historical data through 2nd quarter 2014.

3. The CY 2015 ESRD PPS Wage Indices

a. Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized for the ESRD PPS the use of the Office of Management and Budget's (OMB) Core-Based Statistical Areas (CBSAs)-based geographic area designations described in OMB bulletin 03–04, issued June 6,

[2] *https://oig.hhs.gov/oei/reports/oei-03-12-00550.pdf*, Appendix D.

2003 as the basis for revising the urban and rural areas and their corresponding wage index values. This bulletin, as well as subsequent bulletins, is available online at *http://www.whitehouse.gov/omb/bulletins_index2003-2005.*

We also finalized that we would use the urban and rural definitions used for the Medicare IPPS but without regard to geographic reclassification authorized under sections 1886(d)(8) and (d)(10) of the Act. In the CY 2012 ESRD PPS final rule (76 FR 70239), we finalized that, under the ESRD PPS, we will continue to utilize the ESRD PPS wage index methodology, first established under the basic case-mix adjusted composite rate payment system, for updating the wage index values using the OMB's CBSA-based geographic area designations to define urban and rural areas.

b. Implementation of New Labor Market Delineations

OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. In accordance with our established methodology, we have historically adopted via rulemaking CBSA changes that are published in the latest OMB bulletin. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-;01.pdf.* According to OMB, ''[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and Census Bureau data.'' In this CY 2015 ESRD PPS final rule, when referencing the new OMB geographic boundaries of statistical areas, we are using the term ''delineations'' rather than the term ''definitions'' that we have used in the past, consistent with OMB's use of the terms (75 FR 37249). Because the bulletin was not issued until February 28, 2013, with supporting data not available until later, and because the changes made by the bulletin and their ramifications needed to be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of the FY 2014 IPPS/LTCH PPS proposed rule and, thus, did not implement changes to the hospital wage index for FY 2014 based on these new CBSA delineations. Likewise, for the same reasons, the CY 2014 ESRD PPS wage index (based upon the pre-floor, pre-reclassified hospital wage data, which is unadjusted for occupational mix) also did not reflect the new CBSA delineations. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we finalized the implementation of the new CBSA delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, beginning with the FY 2015 IPPS wage index. Similarly, in this CY 2015 ESRD PPS final rule, we are finalizing the new CBSA delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, beginning with the CY 2015 ESRD PPS wage index. We believe that the most current CBSA delineations accurately reflect the local economies and wage levels of the areas where facilities are located, and we believe that it is important for the ESRD PPS to use the latest CBSA delineations available in order to maintain an up-to-date payment system that accurately reflects the reality of populations shifts and labor market conditions. We have reviewed our findings and impacts relating to the new CBSA delineations using the most recent data available at the time of this final rule, and have concluded that there is no compelling reason to further delay the implementation of the CBSA delineations as set forth in OMB Bulletin 13–01.

In order to implement these changes for the ESRD PPS, it is necessary to identify the new labor market area delineation for each county and facility in the country. For example, there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart. Because the wage index of urban areas is typically higher than that of rural areas, ESRD facilities currently located in rural counties that will become urban, beginning January 1, 2015, will generally experience an increase in their wage index values. We identified approximately 100 counties and 110 facilities that will move from rural to urban status when we adopt the new CBSA delineations beginning in CY 2015. Table 6: (CY 2015 Rural to Urban CBSA Crosswalk) shows the CBSA delineations for CY 2014 and the rural wage index values for CY 2015 based on those delineations, compared to the final CBSA delineations for CY 2015 and the urban wage index values for CY 2015 based on the new delineations, and the percentage change in these values for those counties that will change from rural to urban when we adopt the new CBSA delineations. Approximately 100 facilities will experience an increase in their wage index values.

TABLE 6—CY 2015 RURAL TO URBAN CBSA CROSSWALK

County name	State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
BALDWIN	AL	01	RURAL	0.6963	19300	URBAN	0.7248	4.09%
PICKENS	AL	01	RURAL	0.6963	46220	URBAN	0.8337	19.73
COCHISE	AZ	03	RURAL	0.9125	43420	URBAN	0.8937	−2.06
LITTLE RIVER	AR	04	RURAL	0.7311	45500	URBAN	0.7362	0.70
WINDHAM	CT	07	RURAL	1.1251	49340	URBAN	1.1493	2.15
SUSSEX	DE	08	RURAL	1.0261	41540	URBAN	0.9289	−9.47
CITRUS	FL	10	RURAL	0.8006	26140	URBAN	0.7625	−4.76
GULF	FL	10	RURAL	0.8006	37460	URBAN	0.7906	−1.25
HIGHLANDS	FL	10	RURAL	0.8006	42700	URBAN	0.7982	−0.30
SUMTER	FL	10	RURAL	0.8006	45540	URBAN	0.8095	1.11
WALTON	FL	10	RURAL	0.8006	18880	URBAN	0.8156	1.87
LINCOLN	GA	11	RURAL	0.7425	12260	URBAN	0.9225	24.24

TABLE 6—CY 2015 RURAL TO URBAN CBSA CROSSWALK—Continued

County name	State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
MORGAN	GA	11	RURAL	0.7425	12060	URBAN	0.9369	26.18
PEACH	GA	11	RURAL	0.7425	47580	URBAN	0.7542	1.58
PULASKI	GA	11	RURAL	0.7425	47580	URBAN	0.7542	1.58
KALAWAO	HI	12	RURAL	1.0741	27980	URBAN	1.0561	−1.68
MAUI	HI	12	RURAL	1.0741	27980	URBAN	1.0561	−1.68
BUTTE	ID	13	RURAL	0.7398	26820	URBAN	0.8933	20.75
DE WITT	IL	14	RURAL	0.8362	14010	URBAN	0.9165	9.60
JACKSON	IL	14	RURAL	0.8362	16060	URBAN	0.8324	−0.45
WILLIAMSON	IL	14	RURAL	0.8362	16060	URBAN	0.8324	−0.45
SCOTT	IN	15	RURAL	0.8416	31140	URBAN	0.8605	2.25
UNION	IN	15	RURAL	0.8416	17140	URBAN	0.9473	12.56
PLYMOUTH	IA	16	RURAL	0.8451	43580	URBAN	0.8915	5.49
KINGMAN	KS	17	RURAL	0.7806	48620	URBAN	0.8472	8.53
ALLEN	KY	18	RURAL	0.7744	14540	URBAN	0.8410	8.60
BUTLER	KY	18	RURAL	0.7744	14540	URBAN	0.8410	8.60
ACADIA	LA	19	RURAL	0.7580	29180	URBAN	0.7869	3.81
IBERIA	LA	19	RURAL	0.7580	29180	URBAN	0.7869	3.81
ST. JAMES	LA	19	RURAL	0.7580	35380	URBAN	0.8821	16.37
TANGIPAHOA	LA	19	RURAL	0.7580	25220	URBAN	0.9452	24.70
VERMILION	LA	19	RURAL	0.7580	29180	URBAN	0.7869	3.81
WEBSTER	LA	19	RURAL	0.7580	43340	URBAN	0.8325	9.83
ST. MARYS	MD	21	RURAL	0.8554	15680	URBAN	0.8593	0.46
WORCESTER	MD	21	RURAL	0.8554	41540	URBAN	0.9289	8.59
MIDLAND	MI	23	RURAL	0.8207	33220	URBAN	0.7935	−3.31
MONTCALM	MI	23	RURAL	0.8207	24340	URBAN	0.8799	7.21
FILLMORE	MN	24	RURAL	0.9124	40340	URBAN	1.1398	24.92
LE SUEUR	MN	24	RURAL	0.9124	33460	URBAN	1.1196	22.71
MILLE LACS	MN	24	RURAL	0.9124	33460	URBAN	1.1196	22.71
SIBLEY	MN	24	RURAL	0.9124	33460	URBAN	1.1196	22.71
BENTON	MS	25	RURAL	0.7589	32820	URBAN	0.8991	18.47
YAZOO	MS	25	RURAL	0.7589	27140	URBAN	0.7891	3.98
GOLDEN VALLEY	MT	27	RURAL	0.9024	13740	URBAN	0.8686	−3.75
HALL	NE	28	RURAL	0.8924	24260	URBAN	0.9219	3.31
HAMILTON	NE	28	RURAL	0.8924	24260	URBAN	0.9219	3.31
HOWARD	NE	28	RURAL	0.8924	24260	URBAN	0.9219	3.31
MERRICK	NE	28	RURAL	0.8924	24260	URBAN	0.9219	3.31
JEFFERSON	NY	33	RURAL	0.8208	48060	URBAN	0.8386	2.17
YATES	NY	33	RURAL	0.8208	40380	URBAN	0.8750	6.60
CRAVEN	NC	34	RURAL	0.7995	35100	URBAN	0.8994	12.50
DAVIDSON	NC	34	RURAL	0.7995	49180	URBAN	0.8679	8.56
GATES	NC	34	RURAL	0.7995	47260	URBAN	0.9223	15.36
IREDELL	NC	34	RURAL	0.7995	16740	URBAN	0.9073	13.48
JONES	NC	34	RURAL	0.7995	35100	URBAN	0.8994	12.50
LINCOLN	NC	34	RURAL	0.7995	16740	URBAN	0.9073	13.48
PAMLICO	NC	34	RURAL	0.7995	35100	URBAN	0.8994	12.50
ROWAN	NC	34	RURAL	0.7995	16740	URBAN	0.9073	13.48
OLIVER	ND	35	RURAL	0.7099	13900	URBAN	0.7216	1.65
SIOUX	ND	35	RURAL	0.7099	13900	URBAN	0.7216	1.65
HOCKING	OH	36	RURAL	0.8329	18140	URBAN	0.9539	14.53
PERRY	OH	36	RURAL	0.8329	18140	URBAN	0.9539	14.53
COTTON	OK	37	RURAL	0.7799	30020	URBAN	0.7918	1.53
JOSEPHINE	OR	38	RURAL	1.0083	24420	URBAN	1.0086	0.03
LINN	OR	38	RURAL	1.0083	10540	URBAN	1.0879	7.89
ADAMS	PA	39	RURAL	0.8719	23900	URBAN	1.0104	15.88
COLUMBIA	PA	39	RURAL	0.8719	14100	URBAN	0.9347	7.20
FRANKLIN	PA	39	RURAL	0.8719	16540	URBAN	1.0957	25.67
MONROE	PA	39	RURAL	0.8719	20700	URBAN	0.9372	7.49
MONTOUR	PA	39	RURAL	0.8719	14100	URBAN	0.9347	7.20
UTUADO	PR	40	RURAL	0.4000	10380	URBAN	0.4000	0.00
BEAUFORT	SC	42	RURAL	0.8374	25940	URBAN	0.8708	3.99
CHESTER	SC	42	RURAL	0.8374	16740	URBAN	0.9073	8.35
JASPER	SC	42	RURAL	0.8374	25940	URBAN	0.8708	3.99
LANCASTER	SC	42	RURAL	0.8374	16740	URBAN	0.9073	8.35
UNION	SC	42	RURAL	0.8374	43900	URBAN	0.8277	−1.16
CUSTER	SD	43	RURAL	0.8312	39660	URBAN	0.8989	8.14
CAMPBELL	TN	44	RURAL	0.7365	28940	URBAN	0.7015	−4.75
CROCKETT	TN	44	RURAL	0.7365	27180	URBAN	0.7747	5.19
MAURY	TN	44	RURAL	0.7365	34980	URBAN	0.8969	21.78

TABLE 6—CY 2015 RURAL TO URBAN CBSA CROSSWALK—Continued

County name	State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
MORGAN	TN	44	RURAL	0.7365	28940	URBAN	0.7015	−4.75
ROANE	TN	44	RURAL	0.7365	28940	URBAN	0.7015	−4.75
FALLS	TX	45	RURAL	0.7855	47380	URBAN	0.8137	3.59
HOOD	TX	45	RURAL	0.7855	23104	URBAN	0.9386	19.49
HUDSPETH	TX	45	RURAL	0.7855	21340	URBAN	0.8139	3.62
LYNN	TX	45	RURAL	0.7855	31180	URBAN	0.8830	12.41
MARTIN	TX	45	RURAL	0.7855	33260	URBAN	0.8940	13.81
NEWTON	TX	45	RURAL	0.7855	13140	URBAN	0.8508	8.31
OLDHAM	TX	45	RURAL	0.7855	11100	URBAN	0.8277	5.37
SOMERVELL	TX	45	RURAL	0.7855	23104	URBAN	0.9386	19.49
BOX ELDER	UT	46	RURAL	0.8891	36260	URBAN	0.9225	3.76
AUGUSTA	VA	49	RURAL	0.7674	44420	URBAN	0.8326	8.50
BUCKINGHAM	VA	49	RURAL	0.7674	16820	URBAN	0.9053	17.97
CULPEPER	VA	49	RURAL	0.7674	47894	URBAN	1.0403	35.56
FLOYD	VA	49	RURAL	0.7674	13980	URBAN	0.8473	10.41
RAPPAHANNOCK	VA	49	RURAL	0.7674	47894	URBAN	1.0403	35.56
STAUNTON CITY	VA	49	RURAL	0.7674	44420	URBAN	0.8326	8.50
WAYNESBORO CITY	VA	49	RURAL	0.7674	44420	URBAN	0.8326	8.50
COLUMBIA	WA	50	RURAL	1.0892	47460	URBAN	1.0934	0.39
PEND OREILLE	WA	50	RURAL	1.0892	44060	URBAN	1.1425	4.89
STEVENS	WA	50	RURAL	1.0892	44060	URBAN	1.1425	4.89
WALLA WALLA	WA	50	RURAL	1.0892	47460	URBAN	1.0934	0.39
FAYETTE	WV	51	RURAL	0.7410	13220	URBAN	0.8024	8.29
RALEIGH	WV	51	RURAL	0.7410	13220	URBAN	0.8024	8.29
GREEN	WI	52	RURAL	0.9041	31540	URBAN	1.1130	23.11

The wage index values of rural areas are typically lower than that of urban areas. Therefore, ESRD facilities located in a county that is currently designated as urban under the ESRD PPS wage index that will become rural when we adopt the new CBSA delineations may experience a decrease in their wage index values. We identified approximately 35 counties and 30 ESRD facilities that will move from urban to rural status when we adopt the new CBSA delineations beginning in CY 2015. Table 7: (CY 2015 Urban to Rural CBSA Crosswalk) shows the CBSA delineations for CY 2014 and the urban wage index values for CY 2015 based on those delineations, compared with the CBSA delineations and wage index values for CY 2015 based on those delineations, and the percentage change in these values for those counties that would change from urban to rural, beginning in CY 2015, when we adopt the new CBSA delineations. We expect that when we adopt the new CBSA delineations illustrated in Table 7 below, approximately 30 facilities will experience a decrease in their wage index values.

TABLE 7—CY 2015 URBAN TO RURAL CBSA CROSSWALK

County name	State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
FRANKLIN	AR	22900	URBAN	0.7593	04	RURAL	0.7311	−3.71
POWER	ID	38540	URBAN	0.9672	13	RURAL	0.7398	−23.51
FRANKLIN	IN	17140	URBAN	0.9473	15	RURAL	0.8416	−11.16
GIBSON	IN	21780	URBAN	0.8537	15	RURAL	0.8416	−1.42
GREENE	IN	14020	URBAN	0.9062	15	RURAL	0.8416	−7.13
TIPTON	IN	29020	URBAN	0.8990	15	RURAL	0.8416	−6.38
FRANKLIN	KS	28140	URBAN	0.9419	17	RURAL	0.7779	−17.41
GEARY	KS	31740	URBAN	0.8406	17	RURAL	0.7779	−7.46
NELSON	KY	31140	URBAN	0.8593	18	RURAL	0.7748	−9.83
WEBSTER	KY	21780	URBAN	0.8537	18	RURAL	0.7748	−9.24
FRANKLIN	MA	44140	URBAN	1.0271	22	RURAL	1.1553	12.48
IONIA	MI	24340	URBAN	0.8965	23	RURAL	0.8288	−7.55
NEWAYGO	MI	24340	URBAN	0.8965	23	RURAL	0.8288	−7.55
GEORGE	MS	37700	URBAN	0.7396	25	RURAL	0.7570	2.35
STONE	MS	25060	URBAN	0.8179	25	RURAL	0.7570	−7.45
CRAWFORD	MO	41180	URBAN	0.9366	26	RURAL	0.7725	−17.52
HOWARD	MO	17860	URBAN	0.8319	26	RURAL	0.7725	−7.14
WASHINGTON	MO	41180	URBAN	0.9366	26	RURAL	0.7725	−17.52
ANSON	NC	16740	URBAN	0.9230	34	RURAL	0.7899	−14.42

TABLE 7—CY 2015 URBAN TO RURAL CBSA CROSSWALK—Continued

County name	State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
GREENE	NC	24780	URBAN	0.9371	34	RURAL	0.7899	−15.71
ERIE	OH	41780	URBAN	0.7784	36	RURAL	0.8348	7.25
OTTAWA	OH	45780	URBAN	0.9129	36	RURAL	0.8348	−8.56
PREBLE	OH	19380	URBAN	0.8938	36	RURAL	0.8348	−6.60
WASHINGTON	OH	37620	URBAN	0.8186	36	RURAL	0.8348	1.98
STEWART	TN	17300	URBAN	0.7526	44	RURAL	0.7277	−3.31
CALHOUN	TX	47020	URBAN	0.8473	45	RURAL	0.7847	−7.39
DELTA	TX	19124	URBAN	0.9703	45	RURAL	0.7847	−19.13
SAN JACINTO	TX	26420	URBAN	0.9734	45	RURAL	0.7847	−19.39
SUMMIT	UT	41620	URBAN	0.9512	46	RURAL	0.9005	−5.33
CUMBERLAND	VA	40060	URBAN	0.9625	49	RURAL	0.7554	−21.52
DANVILLE CITY	VA	19260	URBAN	0.7963	49	RURAL	0.7554	−5.14
KING AND QUEEN	VA	40060	URBAN	0.9625	49	RURAL	0.7554	−21.52
LOUISA	VA	40060	URBAN	0.9625	49	RURAL	0.7554	−21.52
PITTSYLVANIA	VA	19260	URBAN	0.7963	49	RURAL	0.7554	−5.14
SURRY	VA	47260	URBAN	0.9223	49	RURAL	0.7554	−18.10
MORGAN	WV	25180	URBAN	0.9080	51	RURAL	0.7274	−19.89
PLEASANTS	WV	37620	URBAN	0.8186	51	RURAL	0.7274	−11.14

We note that facilities in some urban CBSAs will experience a change in their wage index values even though they remain urban because an urban CBSA's boundaries and/or the counties included in that CBSA could change. Table 8 (CY 2015 Urban to a Different Urban CBSA Crosswalk) shows those counties that experienced a change in their wage index value when the CBSA delineations for CY 2014 and urban wage index values for CY 2015 based on those delineations, compared with the CBSA delineations and urban wage index values for CY 2015 based on those delineations, and the percentage change in these values for counties that will remain urban even though the CBSA boundaries and/or counties included in that CBSA will change.

TABLE 8—CY 2015 URBAN TO A DIFFERENT URBAN CBSA CROSSWALK

County name	State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
FLAGLER	FL	37380	URBAN	0.8462	19660	URBAN	0.8376	−1.02
DE KALB	IL	16974	URBAN	1.0412	20994	URBAN	1.0299	−1.09
KANE	IL	16974	URBAN	1.0412	20994	URBAN	1.0299	−1.09
MADISON	IN	11300	URBAN	1.0078	26900	URBAN	1.0133	0.55
MEADE	KY	31140	URBAN	0.8593	21060	URBAN	0.7701	−10.38
ESSEX	MA	37764	URBAN	1.0769	15764	URBAN	1.1159	3.62
OTTAWA	MI	26100	URBAN	0.8136	24340	URBAN	0.8799	8.15
JACKSON	MS	37700	URBAN	0.7396	25060	URBAN	0.7896	6.76
BERGEN	NJ	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
HUDSON	NJ	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
MIDDLESEX	NJ	20764	URBAN	1.0989	35614	URBAN	1.2837	16.82
MONMOUTH	NJ	20764	URBAN	1.0989	35614	URBAN	1.2837	16.82
OCEAN	NJ	20764	URBAN	1.0989	35614	URBAN	1.2837	16.82
PASSAIC	NJ	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
SOMERSET	NJ	20764	URBAN	1.0989	35084	URBAN	1.1233	2.22
BRONX	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
DUTCHESS	NY	39100	URBAN	1.1533	20524	URBAN	1.1345	−1.63
KINGS	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
NEW YORK	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
ORANGE	NY	39100	URBAN	1.1533	35614	URBAN	1.2837	11.31
PUTNAM	NY	35644	URBAN	1.3110	20524	URBAN	1.1345	−13.46
QUEENS	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
RICHMOND	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
ROCKLAND	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
WESTCHESTER	NY	35644	URBAN	1.3110	35614	URBAN	1.2837	−2.08
BRUNSWICK	NC	48900	URBAN	0.8867	34820	URBAN	0.8620	−2.79
BUCKS	PA	37964	URBAN	1.0837	33874	URBAN	1.0157	−6.27
CHESTER	PA	37964	URBAN	1.0837	33874	URBAN	1.0157	−6.27
MONTGOMERY	PA	37964	URBAN	1.0837	33874	URBAN	1.0157	−6.27

TABLE 8—CY 2015 URBAN TO A DIFFERENT URBAN CBSA CROSSWALK—Continued

County name	State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
		CBSA	Urban/Rural	Wage Index Value	CBSA	Urban/Rural	Wage Index Value	
ARECIBO	PR	41980	URBAN	0.4449	11640	URBAN	0.4213	−5.30
CAMUY	PR	41980	URBAN	0.4449	11640	URBAN	0.4213	−5.30
CEIBA	PR	21940	URBAN	0.4000	41980	URBAN	0.4438	10.95
FAJARDO	PR	21940	URBAN	0.4000	41980	URBAN	0.4438	10.95
GUANICA	PR	49500	URBAN	0.4000	38660	URBAN	0.4154	3.85
GUAYANILLA	PR	49500	URBAN	0.4000	38660	URBAN	0.4154	3.85
HATILLO	PR	41980	URBAN	0.4449	11640	URBAN	0.4213	−5.30
LUQUILLO	PR	21940	URBAN	0.4000	41980	URBAN	0.4438	10.95
PENUELAS	PR	49500	URBAN	0.4000	38660	URBAN	0.4154	3.85
QUEBRADILLAS	PR	41980	URBAN	0.4449	11640	URBAN	0.4213	−5.30
YAUCO	PR	49500	URBAN	0.4000	38660	URBAN	0.4154	3.85
ANDERSON	SC	11340	URBAN	0.8744	24860	URBAN	0.9161	4.77
GRAINGER	TN	34100	URBAN	0.6983	28940	URBAN	0.7015	0.46
LINCOLN	WV	16620	URBAN	0.7988	26580	URBAN	0.8846	10.74
PUTNAM	WV	16620	URBAN	0.7988	26580	URBAN	0.8846	10.74

Likewise, ESRD facilities currently located in a rural area may remain rural under the new CBSA delineations but experience a change in their rural wage index value due to implementation of the new CBSA delineations. Table 9 (CY 2015 Changes to the Statewide Rural Wage Index Crosswalk) shows the CBSA delineations for CY 2014 and the rural statewide wage index values for CY 2015, compared with the rural statewide wage index values for CY 2015, and the percentage change in these values.

TABLE 9—CY 2015 CHANGES TO THE STATEWIDE RURAL WAGE INDEX CROSSWALK

State	ESRD PPS CY 2014 CBSA delineations			Final ESRD PPS CY 2015 CBSA delineations			Change in value (percent)
	CBSA	Urban/Rural	Wage index value	CBSA	Urban/Rural	Wage index value	
AL	39	RURAL	0.8719	39	RURAL	0.8083	−7.3
AZ	19	RURAL	0.7580	19	RURAL	0.7108	−6.2
CT	51	RURAL	0.7410	51	RURAL	0.7274	−1.8
FL	49	RURAL	0.7674	10	RURAL	0.8371	9.1
GA	38	RURAL	1.0083	38	RURAL	0.9949	−1.3
HI	34	RURAL	0.7995	34	RURAL	0.7899	−1.2
IL	44	RURAL	0.7365	44	RURAL	0.7277	−1.2
KS	01	RURAL	0.6963	01	RURAL	0.6914	−0.7
KY	28	RURAL	0.8924	28	RURAL	0.8877	−0.5
LA	17	RURAL	0.7806	17	RURAL	0.7779	−0.3
MD	25	RURAL	0.7589	25	RURAL	0.7570	−0.3
MI	33	RURAL	0.8208	33	RURAL	0.8192	−0.2
MS	50	RURAL	1.0892	50	RURAL	1.0877	−0.1
NC	45	RURAL	0.7855	45	RURAL	0.7847	−0.1
NE	18	RURAL	0.7744	18	RURAL	0.7748	0.1
NY	14	RURAL	0.8362	14	RURAL	0.8369	0.1
OH	11	RURAL	0.7425	11	RURAL	0.7439	0.2
OR	36	RURAL	0.8329	36	RURAL	0.8348	0.2
PA	07	RURAL	1.1251	07	RURAL	1.1295	0.4
TN	52	RURAL	0.9041	52	RURAL	0.9087	0.5
TX	23	RURAL	0.8207	23	RURAL	0.8288	1.0
UT	03	RURAL	0.9125	03	RURAL	0.9219	1.0
VA	12	RURAL	1.0741	12	RURAL	1.0872	1.2
WA	46	RURAL	0.8891	46	RURAL	0.9005	1.3
WI	21	RURAL	0.8554	21	RURAL	0.8746	2.2
WV	10	RURAL	0.8006	10	RURAL	0.8371	4.6

While we believe that the new CBSA delineations will result in wage index values that are more representative of the actual costs of labor in a given area, we also recognize that use of the new CBSA delineations will result in reduced payments to some facilities. In particular, approximately 30 facilities would experience reduced payments when we adopt the new CBSA delineations. At the same time, use of the new CBSA delineations will result in increased payments for approximately 100 facilities, while the majority of facilities would experience

no change in payments due to the implementation of the new CBSA delineations. We are finalizing the implementation the new CBSA delineations, as proposed, using a 2-year transition with a 50/50 blended wage index value for all facilities in CY 2015 and 100 percent of the wage index based on the new CBSA delineations in CY 2016.

Comment: Commenters largely agreed with the implementation of the new CBSAs and thanked CMS for offsetting any negative impacts with a 2-year transition. A few commenters expressed concerns for low wage areas and for areas where hospital wage data is not available, and where proxies are used to establish an areas wage index. Another commenter requested reclassification to address the Wheeling WV–OH wage index, as well as, other areas with very low wage indices. The commenter also suggested that we apply the rural floor policy that applies in the IPPS under which an urban area with a wage index below the statewide rural average would be paid the statewide rural average wage index value.

Response: We thank the commenters for their support and are finalizing the CY 2015 ESRD PPS wage indexes as proposed. We agree that some areas of the country will continue to have low wage values, despite the annual updated hospital wage data and the finalized new CBSA delineations. However, the purpose of updating the ESRD PPS wage indexes as part of our annual update is based upon the premise that our wage index value should reflect the costs of furnishing renal dialysis services in the area where those services are provided

In addition, the ESRD PPS uses ''pre-floor'' and ''pre re-classified'' hospital wage data in computing the wage indexes used in the ESRD PPS. That is, the ESRD PPS uses IPPS wage data that has not been adjusted based on hospital reclassifications or application of the IPPS rural floor policy. Because we do not collect ESRD facility wage data, we rely upon IPPS hospital wage data as the best wage proxy for ESRD facilities. We believe the IPPS hospital wage data most closely reflects the costs of furnishing renal dialysis services in an area and it is the most accurate and up-to-date wage data. We understand that many rural areas generally have lower wage values than urban areas, and that in some cases rural facilities may have to compete with urban areas for staffing. In addition, a few areas do not have a hospital upon which to base a wage index and we apply a proxy wage index value as described in the CY 2014 ESRD PPS final rule (78 FR 72172). For these reasons, we plan to evaluate the effect of the IPPS rural floor policy, the wage index floor, and other wage index-related policies under the ESRD PPS.

c. Transition Period

We considered having no transition period and fully implementing the new CBSA delineations beginning in CY 2015, which would mean that all facilities would have payments based on the new delineations starting on January 1, 2015. However, because more facilities would have increased rather than decreased payments beginning in CY 2015, and because the overall amount of ESRD payments would increase slightly due to the new CBSA delineations, the wage index budget-neutrality factor would be higher. This higher factor would reduce the ESRD PPS per treatment base rate for all facilities paid under the ESRD PPS, despite the fact that the majority of ESRD facilities are unaffected by the new CBSA delineations. We believe that it would be appropriate to provide for a transition period to mitigate any resulting short-term instability of a lower ESRD PPS base rate as well as any negative impacts to facilities that experience reduced payments.

Comment: Generally, commenters were supportive of our proposed transition to implement the new CBSA delineations and our CY 2015 wage indices. Many commenters agreed that the transition approach allowed all facilities the ability to adjust to their new status, without lowering the overall base rate for all providers. A few commenters noted that a longer transition period would be helpful for rural providers.

Response: We thank the commenters for their support and agree that the transition period allows all facilities to adjust to their new CBSA status. We continue to believe that the transition period is sufficient to mitigate the economic impact for ESRD facilities as the impact analysis demonstrates an impact of less than 1 percent.

Therefore, we are finalizing a 2-year transition blended wage index for all facilities. Facilities would receive 50 percent of their CY 2015 wage index value based on the CBSA delineations for CY 2014 and 50 percent of their CY 2015 wage index value based on the new CBSA delineations. This results in an average of the two values. A facility's CY 2016 wage index values will be based 100 percent on the new CBSA delineations. We believe a 2-year transition strikes an appropriate balance between ensuring that ESRD PPS payments are as accurate and stable as possible while giving facilities time to adjust to the new CBSA delineations.

In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized a policy to use the labor-related share of 41.737 percent for the ESRD PPS. For the CY 2015 ESRD PPS, we are finalizing a labor-related share of 50.673 percent, which we are implementing with a 2-year transition of 46.205 percent for CY 2015 and 50.673 percent for CY 2016. For a complete discussion of the changes in the CY 2015 ESRD PPS market basket and labor-related share, as well as the transition of the labor-related share. See section II.C of this final rule.

Comment: One commenter encouraged CMS to explore alternative payment mechanisms for small rural providers. Whereas a standard payment rate that is adjusted based on the national labor-related share may work for providers with moderate to high patient volumes, the same does not hold true for small rural providers. Small providers have a different cost structure than larger counterparts. Specifically, small rural providers incur a higher share of non-labor costs than the national average. For example, a small facility with 20 patients may only need part-time employees. The small rural town may not have potential employees with the appropriate skill set who are willing to work part time. As a result, the ESRD facility will pay significant amounts for mileage and lodging for employees to travel from other sites, or the facility may hire contracted labor. The commenter encouraged CMS to evaluate the labor versus non-labor costs for small rural facilities compared to the national average and propose payment adjustments to address inequalities.

Response: We thank the commenters for their concern for rural facilities and appreciate the suggestions for alternative payment mechanisms for small rural ESRD facilities. We plan to consider these comments as part of the ESRD PPS refinement in CY 2016.

4. CY 2015 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Our regulations at 42 CFR 413.237(a)(1) provide that ESRD outlier services are the following items and services that are included in the ESRD PPS bundle: (i) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) ESRD-related laboratory tests that were or would have been, prior to

January 1, 2011, separately billable under Medicare Part B; (iii) medical/surgical supplies, including syringes, used to administer ESRD-related drugs, that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (iv) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding ESRD-related oral-only drugs.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that we would recognize as outlier services were specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. With respect to the outlier policy, Transmittal 2094 identified additional drugs and laboratory tests that may be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which was issued to correct the subject on the Transmittal page and made no other changes.

In the CY 2012 ESRD PPS final rule (76 FR 70246), we eliminated the issuance of a specific list of eligible outlier service drugs which were or would have been separately billable under Medicare Part B prior to January 1, 2011. However, we use separate guidance to continue to identify renal dialysis service drugs which were or would have been covered under Part D for outlier eligibility purposes in order to provide unit prices for calculating imputed outlier services. We also can identify, through our monitoring efforts, items and services that are incorrectly being identified as eligible outlier services in the claims data. Information about these items and services and any updates to the list of renal dialysis items and services that qualify as outlier services are made through administrative issuances, if necessary.

Our regulations at § 413.237 specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed Medicare Allowable Payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed-dollar loss amount. In accordance with § 413.237(c) of the regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule, using 2007 data, we established the outlier percentage at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the fixed-dollar loss amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and fixed-dollar loss amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140).

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments. For CY 2014, the outlier services MAP amounts and fixed-dollar loss amounts were based on 2012 data (78 FR 72180). Therefore, the outlier thresholds for CY 2014 were based on utilization of renal dialysis items and services furnished under the ESRD PPS. Because of the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, we lowered the MAP amounts and fixed-dollar loss amounts for CYs 2013 and 2014 to allow for an increase in payments for ESRD beneficiaries requiring higher resources.

a. CY 2015 Update to the Outlier Services MAP Amounts and Fixed-Dollar Loss Amounts

For CY 2015, we did not propose any changes to the methodology used to compute the MAP or fixed-dollar loss amounts. Rather, the proposed rule updated the outlier services MAP amounts and fixed-dollar loss amounts to reflect the utilization of outlier services reported on 2013 claims using the December 2013 claims file. For this final rule, the outlier services MAP amounts and fixed dollar loss amounts were updated using the 2013 claims from the June 2014 claims file. The impact of this update is shown in Table 10, which compares the outlier services MAP amounts and fixed-dollar loss amounts used for the outlier policy in CY 2014 with the updated estimates finalized in this rule. The estimates for the final CY 2015 outlier policy, which are included in Column II of Table 10, were inflation adjusted to reflect projected 2015 prices for outlier services.

TABLE 10—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I		*Column II*	
	Final outlier policy for CY 2014 (based on 2012 data price inflated to 2014) *		Proposed outlier policy for CY 2015 (based on 2013 data price inflated to 2015) *	
	Age < 18	Age > = 18	Age < 18	Age > = 18
Average outlier services MAP amount per treatment [1]	$37.29	$51.97	$39.89	$52.98
Adjustments:				
Standardization for outlier services [2]	1.1079	0.9866	1.1145	0.9878
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount [3]	$40.49	$50.25	$43.57	$51.29
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold [4]	$54.01	$98.67	$54.35	$86.19

TABLE 10—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY—Continued

	Column I		Column II	
	Final outlier policy for CY 2014 (based on 2012 data price inflated to 2014) *		Proposed outlier policy for CY 2015 (based on 2013 data price inflated to 2015) *	
	Age < 18	Age > = 18	Age < 18	Age > = 18
Patient months qualifying for outlier payment	6.7%	5.3%	6.3%	6.3%

* The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect updated prices for outlier services (that is, 2014 prices in Column I and projected 2015 prices in Column II).

[1] Excludes patients for whom not all data were available to calculate projected payments. The outlier services MAP amounts are based on 2013 data. The medically unbelievable edits of 400,000 units for EPO and 1,200 mcg for Aranesp that are in placeunder the ESA claims monitoring policy were applied.

[2] Applied to the average outlier MAP per treatment. Standardization for outlier services is based on existing case mix adjusters for adult and pediatric patient groups.

[3] This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP for each patient.

[4] The fixed dollar loss amounts were calculated using 2013 data to yield total outlier payments that represent 1 percent of total projected payments for the ESRD PPS.

As demonstrated in Table 10, the estimated fixed-dollar loss amount that determines the CY 2015 outlier threshold amount for adults (Column II) is lower than that used for the CY 2014 outlier policy (Column I). The threshold is lower in spite of the fact that the average outlier services MAP per treatment has increased. Between 2012 and 2013, the variation in outlier services across patients declined among adults. The net result is an increase in the percentage of patient-months qualifying for outlier payment (6.3 percent based on 2013 data versus 5.3 percent based on 2012 data) but a decrease in the average outlier payment per case. The estimated fixed-dollar loss amount that determines the CY 2015 outlier threshold amount for pediatric patients (Column II) is slightly higher than that used for the CY 2014 outlier policy (Column I).

For pediatric patients, there was an increase in the overall average outlier service MAP amount between 2012 ($37.29 per treatment as shown in Column I) and 2013 ($40.05 per treatment, as shown in Column II). In addition, there was a continuing tendency in 2013 for a relatively small percentage of pediatric patients to account for a disproportionate share of the total outlier service MAP amounts. The 1 percent target for outlier payments is therefore expected to be achieved based on a smaller percentage of pediatric outlier cases using 2013 data compared to 2012 data (6.3 percent of pediatric patient months are expected to qualify for outlier payments rather than 6.7 percent). These patterns led to the estimated fixed-dollar loss amount for pediatric patients being slightly higher for the outlier policy for CY 2015 compared to the outlier policy for CY 2014.

The updated fixed-dollar loss amounts are added to the predicted MAP amounts per treatment, yielding the outlier thresholds for CY 2015 from $98.67 to $86.19 for adult patients and from $54.01 to $54.35 for pediatric patients compared with CY 2014 amounts. We estimate that the percentage of patient months qualifying for outlier payments under the current policy will be 6.3 percent for both adult and pediatric patients, based on the 2013 data. The pediatric outlier MAP and fixed-dollar loss amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

b. Outlier Policy Percentage

42 CFR 413.220(b)(4) stipulates that the per treatment base rate is reduced by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments. Based on the 2013 claims, outlier payments represented approximately 0.5 percent of total payments, again falling short of the 1 percent target due to further declines in the use of outlier services. Recalibration of the thresholds, which use 2013 data, reflects the reduced variation in outlier services among adults, is expected to result in aggregate outlier payments close to the 1 percent target in CY 2015. We believe the update to the outlier MAP and fixed-dollar loss amounts for CY 2015 will increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy.

We note that recalibration of the fixed-dollar loss amounts in this final rule for CY 2015 outlier payments results in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but increases payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations would also increase for renal dialysis services eligible for outlier payments.

Comment: All commenters expressed disappointment that the outlier target percentage has not been achieved under the ESRD PPS. Some commenters encouraged CMS to revise the target so that the adjustment would be more attainable for facilities. Other commenters requested that CMS eliminate the adjustment from the payment system altogether and return the 1 percent back to the base rate for CY 2015. One commenter suggested that CMS could annually update the amount withheld in the outlier pool based on actual use in the two prior years. Still other commenters encouraged CMS to return the outlier ''pool'' to facilities, as the adjustment erroneously lowered the base rate in prior years.

Response: We thank the commenters for their suggestions in improving the ESRD PPS outlier policy. With regard to the comment that we eliminate the outlier adjustment altogether, we note that, under section 1881(b)(14)(D)(ii) of the Act, the ESRD PPS must ''include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management.'' Therefore, we would be unable to do so and comply with section 1881(b)(14)(D)(ii) of the Act. In addition, it is important to note that the ESRD PPS base rate captures the cost for the

average patient. To the extent data analysis continues to show that certain patients, including certain racial and ethnic groups, receive more ESAs than average, we believe an outlier policy, even a small one, is an important payment adjustment to provide under the ESRD PPS. Concerning comments that we modify the outlier payment adjustment, we did not propose to do so, therefore, we will not finalize such an adjustment. However, we will consider the commenters' suggestions as part of the refinement process that we will undertake in the CY 2016 ESRD PPS proposed and final rules.

We share the industry's frustration that payments under the outlier policy have not reached 1 percent of total ESRD PPS payments. However, the outlier policy is a target percentage rather than a ''pool.'' As we explained in the CY 2014 ESRD PPS final rule (78 FR 72165), each year we simulate payments under the ESRD PPS in order to set the outlier fixed-dollar loss and MAP amounts for adult and pediatric patients to try to achieve the 1 percent outlier policy. We do not increase the base rate to account for years where outlier payments were less than 1 percent of total ESRD PPS payments, nor would we reduce the base rate if the outlier payments exceed 1 percent of total ESRD PPS payments. Rather, we would simulate payments in the following year and adjust the fixed-dollar loss and MAP amounts to try to achieve outlier payments that meet the 1 percent outlier percentage. This approach to updating the outlier policy is consistent with how we update outlier policies in other Medicare prospective payment systems, for example, the prospective payment system for inpatient psychiatric facilities.

We believe the 1 percent outlier percentage has not been reached under the payment system due to the significant drop, over 20 percent, in the utilization of high cost drugs such as Epogen. In fact, we believe the drop in utilization of ESAs and the QIP measures, have made it less likely that a patient's treatment costs would meet the outlier threshold, despite the fact we have lowered the MAP amounts as part of our annual update to the payment system since 2011. We believe that the 2013 data used to update the CY 2015 outlier policy are representative of stable drug utilization, and we believe that in the future the outlier policy will be an important payment adjustment compensating facilities for high cost services as the adjustment was intended.

D. Restatement of Policy Regarding Reporting and Payment for More Than Three Dialysis Treatments per Week

1. Reporting More Than Three Dialysis Treatments per Week on Claims

Since the composite payment system was implemented in the 1980s, CMS has reimbursed ESRD facilities based upon three hemodialysis treatments per week and allowed for the payment of additional weekly dialysis treatments with medical justification. When a dialysis modality regimen requires more than three weekly dialysis treatments, such as with short, frequent hemodialysis (HD) and peritoneal dialysis (PD) modalities, we apply payment edits to ensure that Medicare payment on the monthly claim is consistent with the three times-weekly dialysis treatment payment limit, which translates to payment for 13 treatments for a 30-day month and 14 treatments for a 31-day month.

Under section 1881(b)(14)(C) of the Act, the ESRD PPS may provide for payment on the basis of renal dialysis services furnished during a week, or month, or such other appropriate unit of payment as the Secretary specifies. In the CY 2011 ESRD PPS final rule (75 FR 49064), CMS finalized the per treatment basis of payment in which ESRD facilities are paid for up to three treatments per week, unless there is medical justification for more than three treatments per week. We codified the per-treatment unit of payment under the ESRD PPS at 42 CFR 413.215(a). Also in the CY 2011 ESRD PPS final rule (75 FR 49078), we explained how we converted patient weeks to HD-equivalent sessions for PD patients. Specifically, we noted that one week of PD was considered equivalent to three HD treatments. For example, a patient on PD for 21 days would have $(21/7) \times 3$ or 9 HD-equivalent sessions. Our policy is that ESRD facilities treating patients on PD or home HD will be paid for up to three HD-equivalent sessions for each week of dialysis, unless there is medical justification for furnishing additional treatments.

Increasingly, some ESRD facilities have begun to offer dialysis modalities where the standard treatment regimen is more than three treatments per week. Also, we have observed a payment variation among Medicare Administrative Contractors (MACs) in processing claims for dialysis treatments for modalities that require more frequent dialysis, resulting in payment of more than 14 treatments per month without medical justification. Lastly, CMS has received several requests for clarification regarding Medicare payment and billing policies for dialysis treatments for modalities requiring more than three treatments per week that are furnished in-facility or in the patient's home. Specifically, ESRD facilities, renal physician groups, and MACs have requested billing guidance regarding whether all of the dialysis treatments furnished to the patient during the billing month should be reported on the claim form, even though the Medicare benefit only provides for payment of three dialysis treatments per week.

For these reasons, we are reiterating our policy with respect to payment for more than three dialysis treatments per week. We note that we are not changing our policy for reporting extra dialysis sessions. ESRD facility claims should continue to include all dialysis treatments furnished during the month on claims, but payment is limited to three dialysis treatments per week through the payment edits of 13 treatments for a 30-day month or 14 treatments for a 31-day month. For example, an ESRD facility that furnishes dialysis services to patients who dialyze using modalities requiring shorter, more frequent dialysis (for example, a dialysis regimen of 4, 5, 6 or 7 days a week in-facility or at home), should report all of the patient's dialysis treatments on the monthly claim. However, payment for these services will reflect existing claims processing system edits, and the monthly Medicare payment would mirror the Medicare ESRD benefit of three dialysis treatments per week.

2. Medical Necessity for More Than Three Treatments per Week

Under the ESRD benefit, we have always recognized that some patient conditions benefit from more than three dialysis sessions per week and as such, the Medicare policy for medically necessary additional dialysis treatments was developed. Under this policy, the MACs determine whether additional treatments furnished during a month are medically necessary. While Medicare does not define specific patient conditions that meet the requirements of medical necessity, we do furnish instructions to MACs to consider appropriate patient conditions that would result in a patient's medical need for additional dialysis treatments (for example, excess fluid of five or more pounds). When such patient conditions are indicated with the claim requesting payment, we instruct MACs to consider medical justification and the appropriateness of payment for the additional sessions.

In section 50.A of the Medicare Benefit Policy Manual (Pub. 100–02), we explained our policy regarding

payment for hemodialysis-equivalent PD and payment for more than three dialysis treatments per week under the ESRD PPS. We restated that ESRD facilities are paid for a maximum of 13 treatments during a 30-day month and 14 treatments during a 31-day month unless there is medical justification for additional treatments. The only time facilities should seek payment for additional dialysis sessions, is when the patient has a medical need for additional dialysis and the facility has furnished supporting medical justification of the patient's condition for the extra treatments. Modality choice does not constitute medical justification.

Comment: Commenters were generally supportive of our policy clarification for reporting short frequent hemodialysis treatments. Many commenters noted the importance of allowing Medicare payment for additional medically necessary weekly treatments. One commenter requested that CMS clarify that medical justification is subject to approval by the MAC's medical officer, as opposed to the MAC's local policy decisions.

Response: We thank the commenters for their support of our policy clarification and agree with commenters that when medically necessary additional dialysis treatments are warranted based upon the patients' medical conditions, Medicare should pay for those treatments. In addition, CMS has no national policy for medical justification for additional dialysis treatments, and we rely upon either a MAC's local coverage determination (LCD) policy or medical review by a physician working under the direction of the MAC's medical director.

Comment: One commenter expressed concern that the language in the proposed rule gives more authority to the MACs to determine medical necessity. The commenter cited to the proposed rule that states, ''the MACs determine whether additional treatments furnished during a month are medically necessary,'' and encouraged CMS to communicate to the MACs that physicians are ultimately responsible for determining the medical justification of ESRD services after considering the patient's health status and relevant evidence-based medicine. The MAC's responsibility is to review the documentation provided by the physician to ensure the medical justification meets the guidelines set forth by CMS.

Another commenter indicated that longer or more frequent schedules are purposefully prescribed by the physician to meet individual patient medical and lifestyle needs and because the patient would medically benefit based upon the ever-expanding base of clinical literature finding clinical benefit to these schedules compared to conventional dialysis schedules. The commenter believes that if such a regimen is prescribed based upon sound medical justification, it should be eligible for payment of the additional treatments under CMS's long-standing policy. The commenter believes this approach has worked effectively for many years during the modest growth of home hemodialysis (HHD) and there is no evidence of overutilization. The commenter believes this is the policy described in the proposed rule.

Other commenters pointed out that, while a growing body of research shows that more frequent dialysis improves patient outcomes overall, the payment policy for dialysis is limited based on three times per week HD treatments. The flexibility in permitting extra payments for HD treatments, when medical justification is provided, is a reasonable approach to ensuring those patients who need the extra treatments the most are able to get them.

Response: We agree with the commenter that, while we refer to MACs' approval for the payment of medically necessary additional weekly treatments, we do not mean that the MACs make these decisions unilaterally. Rather, necessity for these extra treatments is reviewed, and ultimately paid or unpaid, based upon the policy and payment guidance furnished by Medicare, the local policies and guidance of the MAC, and the information submitted by the patient's physician. It was not our intent to imply a change in our requirements for medical justification for additional treatments, nor were we dismissing the importance of the assessment of the patient's physician. We will continue to follow research assessing the clinical benefits of more frequent dialysis schedules and monitoring the number of treatments furnished and paid per month.

In circumstances where a nephrologist has ''prescribed'' shorter, more frequent hemodialysis for their patient there should be no expectation of payment beyond three treatments per week. For prescribed dialysis regimes beyond three sessions per week, furnished in the home or in center, such as four, five, six or even seven times per week, payment for the additional weekly treatments is based on patient conditions, supported by medical documentation, that require additional dialysis.

Comment: One commenter believes that it is inconsistent for CMS to require that all dialysis treatments be reported, while limiting payment to three times per week.

Response: We thank the commenter for their comment; however, dialysis services furnished by a facility are reported to Medicare, for purposes of payment, on a monthly claim form. During a given month, weekly dialysis services may differ in terms of number of treatments, drug dosing, acute case-mix or other payment adjustments, laboratory services. Therefore, we require that all dialysis services be reported on the Medicare 72x type of bill so that all of the services furnished to the beneficiary will be identifiable on the claim form. More importantly, reporting all treatments furnished allows CMS to keep up with changes in dialysis schedules over time.

Comment: One commenter believes a reference we made in the proposed rule to ''dialysis modalities that require more frequent dialysis'' could be misconstrued or misunderstood. The commenter believes the reference implies a comparison of more frequent home HD to PD, where daily exchanges are required in order to deliver a minimally adequate dose. The commenter pointed out that home HD, and the equipment that delivers this home therapy, may be prescribed with adequate dose delivery under a variety of treatment schedules, from the conventional thrice-weekly to longer or more frequent schedules. The commenter suggests that correlating short more frequent HD with PD should be avoided.

Response: We thank the commenter for this clarification and we will avoid such references in the future.

Comment: One commenter disagreed with CMS's policy and stated that it should not preclude modality choice as a medical justification for more frequent HD treatments, as precluding modality choice would likely have a significant adverse impact on the physical and emotional well-being of patients undergoing home hemodialysis currently, and would significantly limit Medicare beneficiaries' access to home HD. The commenter contends that this policy is counter to CMS and Congress's stated goal of promoting the use of home dialysis in lieu of continued growth of patients undergoing in-center hemodialysis. A few commenters encouraged CMS to continue to be flexible in providing beneficiaries with more than three treatments per week when medically necessary. Other commenters noted that they support our objectives in removing barriers for home

dialysis modalities, including home hemodialysis, but only if our policies do not shift resources from in-center patients.

Response: Payments provided by MACs for additional hemodialysis weekly dialysis treatments that are furnished in-facility or in the home, have been audited by CMS. We recognize that some MACs were not requiring documented patient conditions for medical justification for additional weekly treatments and were inappropriately authorizing Medicare payment for additional dialysis services where no medical justification was included in the claim. Thus, our intent in clarifying our policy was to remind facilities and MACs of the Medicare ESRD benefit, which only allows for the payment of three weekly dialysis treatments, and that additional weekly dialysis treatments may be paid for if there's documented medical justification. We believe that our policy clarification will result in a consistent Medicare benefit for all beneficiaries and eliminate the regional payment differences for HD.

Lastly, we thank the commenters who suggest that Medicare should remove the barriers to home modalities while not jeopardizing the Medicare base rate for in-facility services. We agree with these commenters and believe our ESRD PPS payment policies have contributed to the increase in utilization of home dialysis modalities as indicated in Table 11 below.

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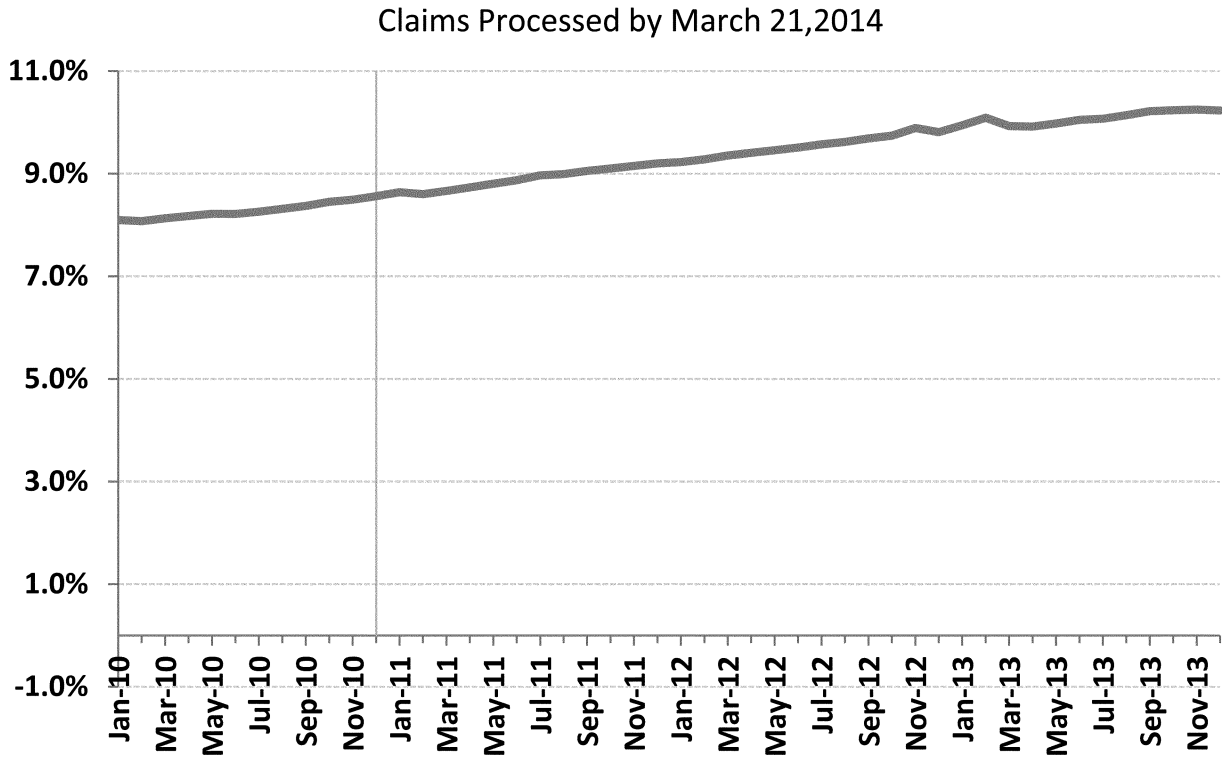
Table 11: Medicare Beneficieries on Home Modailties



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E. Delay of Payment for Oral-Only Drugs Under the ESRD PPS

As we discussed in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), section 1881(b)(14)(A)(i) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for ''renal dialysis services'' in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and subclause (iii) of that section states that these services include ''other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (before the application of this paragraph) made separately under this title, and any oral equivalent form of such drug or biological[.]''

We interpreted this provision as including not only injectable drugs and biologicals used for the treatment of ESRD (other than ESAs, which are included under clause (ii) of section 1881(b)(14)(B)), but also all non-injectable oral drugs used for the treatment of ESRD furnished under title XVIII of the Act. We also concluded that, to the extent ESRD-related oral-only drugs do not fall within clause (iii) of the statutory definition of renal dialysis services, such drugs would fall under clause (iv), and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B). As such, CMS finalized and promulgated the payment policies for oral-only drugs used for the treatment of ESRD in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053), and we defined ''renal dialysis services'' at 42 CFR 413.171(3) as including, among other things ''other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form).''

Although ESRD-related oral-only drugs are included in the definition of

renal dialysis services, in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the PPS until January 1, 2014. We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs, including allowing ESRD facilities additional time to make operational changes and logistical arrangements in order to furnish oral-only ESRD-related drugs and biologicals to their patients. Accordingly, 42 CFR 413.174(f)(6) provides that payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form is incorporated into the PPS payment rates effective January 1, 2014.

On January 3, 2013, the Congress enacted ATRA. Section 632(b) of ATRA states that the Secretary ''may not implement the policy under section 413.176(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD-related drugs in the ESRD prospective payment system), prior to January 1, 2016.'' Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for ESRD-related oral-only drugs under the ESRD PPS until January 1, 2016, instead of on January 1, 2014, which is the original date we finalized for payment of ESRD-related oral-only drugs under the ESRD PPS. We implemented this delay by revising the effective date for providing payment for oral-only ESRD-related drugs under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2014 to January 1, 2016. In addition, we also changed the date when oral-only drugs would be eligible for outlier services under the outlier policy described in 42 CFR 413.237(a)(1)(iv) from January 1, 2014 to January 1, 2016.

On April 1, 2014, PAMA was enacted. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA, which now provides that the Secretary ''may not implement the policy under section 413.174(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD drugs in the ESRD prospective payment system), prior to January 1, 2024.'' Accordingly, payment for ESRD-related oral-only drugs will not be made under the ESRD PPS prior to January 1, 2024 instead of on January 1, 2016, which is the date we finalized for payment of ESRD-related oral-only drugs under the ESRD PPS in the CY 2014 ESRD PPS final rule (78 FR 72186).

We shall implement this delay by modifying the effective date for providing payment for renal dialysis oral-only drugs and biologicals under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2016 to January 1, 2024. We also shall change the date in 42 CFR 413.237(a)(1)(iv) regarding outlier payments for oral-only ESRD-related drugs made under the ESRD PPS from January 1, 2016 to January 1, 2024. We continue to believe that oral-only drugs used for the treatment of ESRD are an essential part of the ESRD PPS payment bundle and should be paid for under the ESRD PPS as soon as possible, or beginning January 1, 2024. We received no public comments on these proposals and therefore will finalize our regulatory changes to 42 CFR Part 413 as proposed.

In addition to the delay of payment for renal dialysis oral-only drugs, section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by adding a new sentence that provides, ''[n]otwithstanding section 1881(b)(14)(A)(ii) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(A)(ii)), implementation of the policy described in the previous sentence shall be based on data from the most recent year available.'' We interpret this provision to mean that we are not to use per patient utilization data from 2007, 2008, or 2009 (whichever has the lowest per patient utilization) as we were required to do for the original ESRD PPS in implementing payment for renal dialysis oral-only drugs under the ESRD PPS. We will make proposals consistent with section 632(b)(1) of ATRA, as amended by section 217(a)(2) of PAMA, in future rulemaking.

Section 217(c) of PAMA requires the Secretary, as part of the CY 2016 ESRD PPS rulemaking, to establish a process for ''(1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the bundled payment under such system.'' Consistent with this statutory requirement, we plan to propose a drug designation process in our CY 2016 rulemaking cycle.

Comment: We received many comments from industry stakeholders questioning CMS's authority to incorporate additional renal dialysis services into the payment bundle. A few commenters were encouraged by CMS's request for comments and outlined a comprehensive 7 principle drug designation process. Other commenters urged CMS to be cautious when adding renal dialysis services to the bundle and noted that separate payment for new services would be important until utilization and practice patterns have been established. Another commenter urged that the process should be transparent, predictable, and result in increases to the payment rate to reflect the cost of these therapies and to promote adoption of innovations with a demonstrated impact on patient outcomes.

One commenter recommends a collaborative process to determine when a product is no longer an oral-only drug, noting that MIPPA is unclear on this point for non-ESA medications. The commenter suggests that reasonable criteria for inclusion of previously oral-only agents in the bundle may be when a parenteral formulation has been adequately shown to be clinically superior in terms of efficacy and safety with acceptable cost and cost-effectiveness compared to already available oral medications. The commenter also believes it would be appropriate to include new products in the bundle if they are intended to be used in practice as substitutes for already bundled products or if their primary use reflects management of conditions specifically related to ESRD and its complications as evidenced by current use of bundled medications or oral but not bundled medications.

Response: We thank the commenters for the thoughtful comments regarding a drug designation process. We will take these comments into consideration when we propose the drug designation process in the CY 2016 ESRD PPS proposed rule. In response to commenters who questioned CMS's authority, we believe CMS does have the authority to add services to the bundle. Our definition of renal dialysis services, which was adopted in our CY 2011 ESRD PPS final rule (75 FR 49036), is consistent with section 1881(b)(14)(B)(iii) of the Act that includes as renal dialysis services, ''Other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before application of this [new ESRD PPS]) made separately under this title, and any oral equivalent form of such drug or biological.'' We continue to believe that we have the authority to add drugs and biologicals that are furnished to individuals for the treatment of ESRD to the payment bundle. We have done this in the case when new ESAs have been made available.

Lastly, we thank the commenters for the very thoughtful 7 principle drug designation process outlined in comments. Specifically, we are encouraged by recommendations regarding processes for coverage and payment, data collection, and protections for providers and beneficiaries so that facilities ''are not forced to absorb the drug's new costs themselves.''

F. ESRD Drug Categories Included in the ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49050), we finalized Table 4, (Renal Dialysis Service ESRD Drug Categories Included in the Final ESRD PPS Base Rate), and have included Table 12 below for the purpose of this discussion. In that rule, we noted that the categories of drugs and biologicals used for access management, anemia management, anti-infectives, bone and mineral metabolism, and cellular management would always be considered renal dialysis drugs when furnished to an ESRD patient, and that payment for such drugs would be included in the ESRD PPS payment bundle. As such, beginning January 1, 2011, Medicare no longer makes a separate payment when a drug or biological (except for renal dialysis oral-only drugs for which we are delaying payment under the ESRD PPS until January 1, 2024) identified in the categories listed in the following table is furnished to a Medicare ESRD beneficiary.

TABLE 12—RENAL DIALYSIS SERVICE ESRD DRUG CATEGORIES INCLUDED IN THE FINAL ESRD PPS BASE RATE

Drug category	Rationale for inclusion
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Anti-infectives	Vancomycin and daptomycin used to treat access site infections.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.

In the CY 2011 ESRD PPS final rule (75 FR 49050), we noted that we included the anti-infective drugs of vancomycin and daptomycin because these drugs were routinely furnished for the renal dialysis conditions, such as, access site infections and peritonitis. However, in the CY 2012 ESRD PPS final rule (76 FR 70242 through 70243), we responded to public comments that noted that vancomycin is a common anti-infective drug appropriate for treating infections that are both ESRD- and non-ESRD-related by modifying our policy to eliminate the payment restriction for vancomycin when it is furnished for reasons other than for the treatment of ESRD. In addition, we finalized the use of CMS payment modifier AY (Item or service furnished to an End-Stage Renal Disease (ESRD) patient that is not for the treatment of ESRD) and instructed facilities to append the modifier to the claim line reporting vancomycin to indicate that the drug was furnished for reasons other than for the treatment of ESRD. The presence of the AY modifier on the claim line allows the MAC to make a separate payment for the drug when it is furnished by the facility to a Medicare beneficiary for reasons other than for the treatment of ESRD.

In the CY 2013 ESRD PPS final rule (77 FR 67461), we further amended this policy to allow ESRD facilities to bill separately for daptomycin when it is furnished to ESRD beneficiaries for reasons other than for the treatment of ESRD. Once again, we instructed facilities to append claim lines reporting daptomycin furnished for reasons other than for the treatment of ESRD with the AY modifier so that MACs would be able to make a separate payment.

Because we have removed the payment limitation for both vancomycin and daptomycin, and because we believe that anti-infectives are a drug category that may be furnished for both ESRD- and non-ESRD-related reasons, we updated the list of drug categories that are always considered renal dialysis drugs under the ESRD PPS by removing the drug category for anti-infectives. We included Table 13 (Renal Dialysis Service ESRD Drug Categories Included in the ESRD PPS Base Rate and Not Separately Payable) below to appropriately recognize the drug categories that are always considered to be renal dialysis services and we confirm that the revised table reflects policy changes made in the CY 2012 and CY 2013 ESRD PPS rulemaking cycles and does not constitute new policy.

Over the past few years, we have received payment and billing inquiries requesting clarification for the payment for drugs represented by one of the drug categories included in the ESRD PPS, but not furnished for the treatment of ESRD. Therefore, we clarify that any drug included in the drug categories of access management, anemia management, bone and mineral metabolism, and cellular management is not separately paid by Medicare regardless of why the drug is being furnished. In addition, the facility may not furnish a prescription for such drugs with the expectation that a Medicare Part D payment would be made, as the payment for the drug is included in the ESRD PPS payment bundle. Beginning in CY 2011 when the ESRD PPS was implemented, Part D plan sponsors were encouraged to implement prior authorization requirements for drugs in the categories below in Table 13. In addition, the drug categories presented below are covered by the ESRD PPS payment regardless of whether the drug is expected to be taken at home or on non-dialysis days.

TABLE 13—RENAL DIALYSIS SERVICE ESRD DRUG CATEGORIES INCLUDED IN THE ESRD PPS BASE RATE AND NOT SEPARATELY PAYABLE

Drug category	Rationale for inclusion
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.

TABLE 13—RENAL DIALYSIS SERVICE ESRD DRUG CATEGORIES INCLUDED IN THE ESRD PPS BASE RATE AND NOT SEPARATELY PAYABLE—Continued

Drug category	Rationale for inclusion
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.

The drug categories that may be separately paid by Medicare when furnished for reasons other than for the treatment of ESRD were included in Table 5 (ESRD Drug Categories Included in the ESRD PPS Base Rate But May be Used for Dialysis and non-Dialysis Purposes) (75 FR 49051). Table 14 is included below for the purpose of this discussion. When any drug identified in the drug categories listed in Table 14 (antiemetics, anti-infectives, antipruritic, anxiolytic, excess fluid management, fluid and electrolyte management, or pain management), is furnished for the treatment of ESRD, payment for the drug is included in the ESRD PPS payment and may not be paid separately. When these drugs are used for the treatment of ESRD, the facility may not furnish a prescription for such drugs with the expectation that a Medicare Part D payment would be made, as the payments for the injectable drugs, which are generally more expensive than oral substitutes, in those categories were included in computing the ESRD PPS base rate. Therefore, drugs in these categories furnished for the treatment of ESRD are covered by the ESRD PPS payment regardless of whether the drug is expected to be taken at home or on non-dialysis days.

If a drug represented by a drug category in Table 14 is furnished by ESRD facilities for reasons other than for the treatment of ESRD, a separate Medicare payment is permitted when the AY modifier is indicated on the claim line reporting the drug for payment. Prescriptions for oral versions of drugs used for non-ESRD conditions are appropriately billed to Part D.

TABLE 14—ESRD DRUG CATEGORIES INCLUDED IN THE ESRD BASE RATE BUT MAY BE USED FOR DIALYSIS AND NON-DIALYSIS PURPOSES

Antiemetic	Used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications and are included for their action to treat itching secondary to dialysis.
Anxiolytic	Drugs in this classification have multiple actions but are included for the treatment of restless leg syndrome secondary to dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders.	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat graft site pain and to treat pain medication overdose.

Comment: A few commenters, including national industry organizations, expressed appreciation for our efforts to clarify what drugs and biologicals are included in the ESRD PPS payment bundle. However, they expressed concern that current guidance has resulted in Part D plan sponsors' inappropriately refusing to cover oral drugs that are not renal dialysis services nor essential to the delivery of such services. Specifically, they noted that beneficiaries have had difficulties obtaining necessary medications such as oral antibiotics prescribed for pneumonia and pain medications prescribed for back pain.

A commenter believes that, prior to January 1, 2014, there appeared to be a clear understanding as to what drugs and biologicals should be reimbursed through the ESRD PPS and those that should appropriately be covered under Part D. The commenter noted that guidance issued by CMS in 2011 to all Part D plans correctly recognized that drugs used as substitutes for any of the drugs listed in Table C of the CY 2011 ESRD PPS final rule, or used to accomplish the same effect, would also be covered under the ESRD bundled payment and were, therefore, ineligible for separate payment.

However, implementation of the CY 2014 Part D Call Letter provision for prior authorization for drug categories that may be renal dialysis services but may also prescribed for other conditions has resulted in confusion for Part D plan sponsors and delays in beneficiaries obtaining essential medications at the pharmacy. Another commenter pointed out that patients should not be put in the middle of benefit determinations, and that they should receive their medications when they arrive at the pharmacy and payment disputes should be settled after the fact.

Response: There has been no change in CMS policy with respect to the drugs considered to be renal dialysis services and covered under the ESRD PPS since CY 2013 when we removed daptomycin from the list of drug categories that are always considered to be renal dialysis services as discussed above. However, in response to increases in billing under Part D for drugs that may be for renal dialysis services but may also be prescribed for other conditions, we issued guidance in the CY 2014 Part D Call Letter to strongly encourage Part D sponsors to place beneficiary-level prior authorization edits on all drugs in the seven categories identified in the CY 2011 ESRD PPS final rule as drugs that ''may be'' ESRD-related for beneficiaries on dialysis (75 FR 49051). These include: Antiemetics, anti-infectives, antipruritics, anxiolytics, excess fluid management, fluid and electrolyte management including volume

expanders, and pain management (analgesics).

Since our new guidance took effect January 1, 2014, various stakeholders have raised concerns regarding the policy's impact on beneficiary access. We are considering various alternatives for dealing with this issue, as it has always been our intention to eliminate or minimize disruptions or delays for ESRD beneficiaries' receiving essential medications. We plan to issue guidance in the near future to address this issue.

Comment: A national industry organization commented that, prior to implementation of the ESRD PPS, most of the drugs that were listed as ''may be related to the treatment of ESRD were also prescribed for patients to take, at home, on non-dialysis treatment days. The commenter pointed out that CMS did not reflect Medicare payments for those oral drugs in calculating the ESRD PPS base rate. Therefore, CMS should continue to allow payment under Part D for those drug categories, that may be for the treatment of ESRD, but that are prescribed for non-dialysis days. The commenter requested that we revise the regulation text to provide that prescription drugs and biologicals that may be within the bundle are covered under the Part B bundle only when they are directly related to the provision of renal dialysis services.

Another commenter pointed out that a reasonable criterion regarding which medications are covered under the bundled payment should be if the medication is essential to perform dialysis or whether the dialysis treatment could be altered or intensified in some way that it would make the medication unnecessary. For instance, lidocaine cream for access site pain with cannulation would be included in the bundle, while an anti-pruritic agent taken twice daily for chronic pruritus that persists despite adequate dialysis would not be included in the bundle.

Response: In order to maintain the integrity of the ESRD PPS base rate and the payment bundle implemented in CY 2011, the drugs and biologicals that we consider to be renal dialysis services are those that are routinely given to patients ''for the treatment of ESRD'' and were billed separately to Part B prior to implementation of the ESRD PPS and where the payments for the injectable versions was included in the base rate. Therefore, if a facility would have furnished an injectable drug and received separate payment for that drug under Part B prior to the ESRD PPS, it would not be appropriate today to unbundle the oral versions of those injectable drugs by providing a prescription for a substitute drug to be taken on non-dialysis days and expect that drug to be covered under Part D. For more information regarding the injectable drugs included in the ESRD PPS base rate, please refer to Table C of the CY 2011 ESRD PPS Final Rule (75 FR 49205).

G. Low-Volume Payment Adjustment (LVPA)

1. Background

Section 1881(b)(14)(D)(iii) of the Act requires a payment adjustment that ''reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent.'' As a result of this provision and the regression analysis conducted for the ESRD PPS, effective January 1, 2011, the ESRD PPS provides a facility-level payment adjustment of 18.9 percent to ESRD facilities that meet the definition of a low-volume facility.

Under 42 CFR 413.232(b), a low-volume facility is an ESRD facility that: (1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and (2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year. Under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments equals the aggregate number of treatments furnished by other ESRD facilities that are both under common ownership and 25 road miles or less from the ESRD facility in question. This geographic proximity criterion is only applicable to ESRD facilities that were Medicare certified on or after January 1, 2011.

For purposes of determining eligibility for the low-volume payment adjustment (LVPA), ''treatments'' means total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis (PD) patients, one week of PD is considered equivalent to 3 HD treatments. In the CY 2012 ESRD PPS final rule (76 FR 70236), we clarified that we base eligibility on the three years preceding the payment year and those years are based on cost reporting periods. We further clarified that the ESRD facility's cost reports for the cost reporting periods ending in the three years preceding the payment year must report costs for 12-consecutive months.

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) that it qualifies as a low-volume ESRD facility and that it meets all of the requirements specified at 42 CFR 413.232. In the CY 2012 ESRD PPS final rule (76 FR 70236), we finalized a yearly November 1 deadline for attestation submission and we revised the regulation at § 413.232(f) to reflect this date. We noted that this timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria. Further information regarding the administration of the LVPA is provided in CMS Pub. 100–02, Medicare Benefit Policy Manual, chapter 11, section 60.B.1.

2. The United States Government Accountability Office Study on the LVPA

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required the United States Government Accountability Office (the GAO) to study the LVPA. The GAO examined (1) the extent to which the LVPA targeted low-volume, high-cost facilities that appeared necessary for ensuring access to care; and (2) CMS's implementation of the LVPA, including the extent to which CMS paid the 2011 LVPA to facilities eligible to receive the adjustment. To do this work, the GAO reviewed Medicare claims, facilities' annual cost reports, and data on dialysis facilities' locations to identify and compare facilities that were eligible for the LVPA with those that received the adjustment. The GAO published a report 13–287 on March 1, 2013, entitled, ''End-Stage Renal Disease: CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment''. The report found multiple discrepancies in the identification of low-volume facilities which are summarized below.

a. The GAO's Main Findings

The GAO found that many of the facilities eligible for the LVPA were located near other facilities, indicating that they might not have been necessary for ensuring access to care. They also identified certain facilities with relatively low-volume that were not eligible for the LVPA but had above-average costs and appeared to be necessary for ensuring access to care.

Lastly, they stated the design of the LVPA provides facilities with an adverse incentive to restrict their service provision to avoid reaching the 4,000 treatment threshold. The GAO calculated that Medicare overpaid an estimated $5.3 million for the LVPA to dialysis facilities that did not meet the eligibility requirements established by CMS. They indicated in their report that the guidance that CMS issued for implementation of the regulatory requirements was sometimes unclear and not always available when needed, and the misunderstanding of LVPA eligibility likely was exacerbated because CMS conducted limited monitoring of the Medicare contractors' administration of LVPA payments.

b. The GAO's Recommendations

In the conclusion of their study, the GAO provided Congress with the following recommendations: (1) To more effectively target facilities necessary for ensuring access to care, the Administrator of CMS should consider restricting the LVPA to low-volume facilities that are isolated; (2) To reduce the incentive for facilities to restrict their service provision to avoid reaching the LVPA treatment threshold, the Administrator of CMS should consider revisions such as changing the LVPA to a tiered adjustment; (3) To ensure that future LVPA payments are made only to eligible facilities and to rectify past overpayments, the Administrator of CMS should take the following four actions: require Medicare contractors to promptly recoup 2011 LVPA payments that were made in error; investigate any errors that contributed to eligible facilities not consistently receiving the 2011 LVPA and ensure that such errors are corrected; take steps to ensure that CMS regulations and guidance regarding the LVPA are clear, timely, and effectively disseminated to both dialysis facilities and Medicare contractors; and improve the timeliness and efficacy of CMS's monitoring regarding the extent to which Medicare contractors are determining LVPA eligibility correctly and promptly re-determining eligibility when all necessary data become available.

In response to the GAO's recommendations, we concurred with the need to ensure that the LVPA is targeted effectively at low-volume high-cost facilities in areas where beneficiaries may lack other dialysis care options. We also agreed to take action to ensure appropriate payment is made in the following ways: (1) Evaluating our policy guidance and contractor instructions to ensure appropriate application of the LVPA; (2) using multiple methods of communication to MACs and ESRD facilities to deliver clear and timely guidance; and (3) improving our monitoring of MACs and considering measures that provide specific expectations.

3. Clarification of the LVPA Policy

For CY 2015, we are not making changes to the adjustment or to the magnitude of the adjustment value. In accordance with section 632(c) of ATRA, for CY 2016 we will assess and address other necessary LVPA policy changes when we use updated data and reevaluate all of the patient- and facility-level adjustments together in a regression analysis similar to the analysis that is discussed in the CY 2011 ESRD PPS final rule (75 FR 49083). At this time, we are not changing the criteria in such a way that the number of low-volume facilities would deviate substantially from the number of facilities originally modeled to receive the adjustment in the first year of implementation. This is because of the interaction of the LVPA with other payment adjustments under the ESRD PPS. As discussed in the CY 2011 ESRD PPS final rule (75 FR 49081), we standardized the ESRD PPS base rate to account for the payment variables and it would not be appropriate to make changes to one variable in the regression when it could potentially affect the other adjustments or the standardization factor. However, there are two clarifications under the LVPA policy (discussed below) that we can address in this year's rulemaking that we believe are responsive to stakeholder's concerns and GAO's concern that the LVPA should effectively target low-volume, high cost-facilities.

a. Hospital-Based ESRD Facilities

As stated above, for purposes of determining eligibility for the LVPA, ''treatments'' means total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare) and for peritoneal dialysis (PD) patients, one week of PD is considered equivalent to 3 HD treatments. Once a MAC receives an attestation from an ESRD facility, it reviews the ESRD facility's cost reports to verify that the facility meets the low-volume criteria specified at 42 CFR 413.232(b). Specifically, the ESRD facility cost report is used to verify the total treatment count that an ESRD facility furnishes in its fiscal year, which includes Medicare and non-Medicare treatments. For independent ESRD facilities, this information is provided on Worksheet C of the Form CMS–265–11 form (previously Form CMS–265–94) and for hospital-based ESRD facilities, this information is on Worksheet I–4 of the Form CMS–2552–10.

After the LVPA was implemented, we began hearing concerns from multiple stakeholders, including members of Congress and rural hospital-based ESRD facilities, about the MACs' LVPA eligibility determinations. The stakeholders indicated that because hospital-based ESRD facilities are financially integrated with a hospital, their costs and treatment data are aggregated in the I-series of the hospital's cost report. This means that if there is more than one ESRD facility that is affiliated with a hospital, the cost and treatment data for all facilities are aggregated on Worksheet I–4, typically causing the facilities' treatment counts to exceed the 4,000-treatment criterion.

We have learned that some MACs accepted treatment counts from hospital-based ESRD facilities other than those provided on the hospital's cost report and, as a result, certain hospital-based ESRD facilities received the LVPA. Other MACs solely used the aggregated treatment counts from the hospital's cost report to verify LVPA eligibility, which resulted in denials for many hospital-based facilities that would have qualified for the adjustment if the MACs had considered other supporting documentation.

We agree with stakeholders that limiting the MAC review to the hospital cost reports for verification of LVPA eligibility for hospital-based ESRD facilities places these facilities at a disadvantage and does not comport with the intent of our policy. We believe it can be necessary for MACs to use other supporting data to verify the treatment counts for individual hospital-based facilities that would meet the eligibility criteria for the LVPA if their treatment counts had not been aggregated with one or more other facilities on their hospitals' cost reports. Because LVPA eligibility is based on cost report information and the individual hospital-based facility treatment counts is the source of the aggregated treatment counts reported in the cost report, however, we continue to believe that cost report data is an integral part of the process of verifying whether a hospital-based facility meets the LVPA eligibility criteria.

For these reasons, we are clarifying that MACs may consider other supporting data, such as a hospital-based facility's total treatment count, along with the facility's cost reports and attestation, to verify it meets the low-volume eligibility criteria provided at 42

CFR 413.232(b). The attestation should continue to be configured around the parent hospital's cost reports, that is, it should be for the same fiscal periods. The MAC can consider other supporting data in addition to the total treatments reported in each of the 12-consecutive month cost reports, such as the individual facility's total treatment counts, rather than the hospital's cost report alone, to verify the number of treatments that were furnished by the individual hospital-based facility that is seeking the adjustment. Consistent with this policy clarification, hospital-based ESRD facilities' eligibility for the LVPA should be determined at an individual facility level and their total treatment counts should not be aggregated with other ESRD facilities that are affiliated with the hospital unless the affiliated facilities are commonly owned and within 25 miles.

MACs have discretion as to the format of the attestation and any supporting data, however, the facility must provide the total number of Medicare and non-Medicare treatments for the three cost reporting years preceding the payment year for all of the hospital-based facilities for which treatment counts appear on the hospital's cost report. This will allow MACs to determine which treatments on the cost report were furnished by the individual hospital-based facility that is seeking the LVPA and which treatments were furnished by other affiliated facilities. Finally, we shall amend the regulation text by adding a new paragraph (h)(1) to § 413.232 to reflect this clarification of current policy under which MACs can verify hospital-based ESRD facilities' eligibility for the LVPA using supporting data in addition to hospital cost reports.

b. Cost Reporting Periods Used for Eligibility

In the CY 2012 ESRD PPS final rule (76 FR 70236), we clarified that for purposes of eligibility under 42 CFR 413.232(b), we base eligibility on the three years preceding the payment year and those years are based on cost reporting periods. We further clarified that the ESRD facility's cost reports for the cost reporting periods ending in the three years preceding the payment year must report costs for 12-consecutive months.

After the LVPA was implemented, we began hearing concerns from the industry that there is a conflict within our policy. Currently, our policy allows an ESRD facility to remain eligible for the LVPA when they have a change of ownership (CHOW) that does not result in a new Provider Transaction Access Number (PTAN). However, our regulations at § 413.232(b) suggest that MACs must verify treatment counts using cost reports for 12-consecutive month cost periods even though CHOWs often result in costs reports that are nonstandard, that is, longer or shorter than 12 months. In particular, the previous owner's final cost report may not coincide with the ESRD facility's cost report fiscal year end under its new ownership, resulting in two costs reports that are not 12-consecutive month cost reports. For example, where a CHOW occurs in the middle of the cost reporting period and the new owner wishes to retain the established cost report fiscal year end, the previous owner submits a final cost report covering their period of ownership and the new owner submits a cost report covering the remainder of the cost reporting period. Alternatively, a new owner could also choose not to retain the previous owner's established cost reporting fiscal year end, in which case the CHOW could result in a cost reports that exceed twelve months when combined. Further details regarding the policies for filing cost reports during a CHOW are available in the Provider Reimbursement Manual—Part 1, chapter 15, ''Change of Ownership.''

We are clarifying the policies governing LVPA that may prevent an otherwise qualified ESRD facility from receiving the adjustment. We have always intended that if an ESRD facility has a CHOW where the new owner accepts the previous owner's assets and liabilities by retaining the facility's PTAN, they should continue to be eligible for the LVPA. However, some MACs used a strict reading of the regulatory language and denied these ESRD facilities the LVPA. Other MACs added short cost reports together or prorated treatment counts for cost reporting periods spanning greater than 12 months.

In order to ensure consistent verification of LVPA eligibility, we are restating our intention that when there is a CHOW that does not result in a new PTAN but creates two non-standard cost reporting periods (that is, periods that are shorter or longer than 12 months) the MAC is either to add the two non-standard cost reporting periods together where combined they would equal 12-consecutive months or prorate the data when they would exceed 12-consecutive months to determine the total treatments furnished for a full cost reporting period as if there had not been a CHOW.

For example, prior to a CHOW, Facility A had a cost reporting period that spanned January 1 through December 31. Facility A had a CHOW mid-year that did not result in a new PTAN but caused a break in the cost reporting period. Consistent with the clarification of our policy, the MAC would add Facility A's cost report that spanned January 1 through May 31 to its cost report that spanned June 1 through December 31 to verify the total treatment count.

The other situation that could occur is when a CHOW results in a change of the original fiscal period. For example, prior to a CHOW, Facility B had a cost reporting period that spanned January 1 through December 31 and, based on its cost reports for 2012 and 2013; it met the LVPA eligibility criteria. Then, Facility B had a CHOW in the beginning of 2014 that did not result in a new PTAN, but changed its cost reporting period to that of its new owner, October 1, 2014 through September 30, 2015. This scenario would create a short and a long cost report that would not total 12 months that the MAC would need to review for verification. That is, Facility B would have a cost report that spanned January 1, 2014 through July 31, 2014 (7 months) and a cost report that spanned August 1, 2014 through September 30, 2015 (14 months).

In this situation, the MAC should combine the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorate the data to equal a full 12-consecutive month period. Finally, we shall amend the regulation text by adding a new paragraph (h)(2) to § 413.232 to clarify the verification process for ESRD facilities that experience a CHOW with no change in the PTAN.

Section 413.232(f) requires ESRD facilities to submit LVPA attestations by November 1 of each year. However, the changes we are finalizing to the LVPA regulation text would not be finalized in enough time to give the ESRD facilities the opportunity to learn about the policy clarifications and provide an attestation to their MAC by November 1, 2014. For these reasons, we are amending § 413.232(f) to extend the deadline for CY 2015 LVPA attestations until December 31, 2014. This timeframe would allow ESRD facilities to reassess their eligibility and apply for the LVPA for CY 2015. It would also give MACs an opportunity to verify any new attestations and reassess LVPA eligibility verifications made since 2011. We will issue guidance with additional detail regarding this policy clarification, which will include details about the process ESRD facilities should follow to seek the LVPA for past years.

Comment: Commenters were largely supportive of our policy clarification and proposed regulation changes regarding the facility eligibility requirements for the LVPA available under the ESRD PPS. A few commenter encouraged CMS to ''redesign'' the LVPA adjustment during the CY 2016 rulemaking, which will include refinements of the payment system. One commenter encouraged CMS to consider a facility's distance to the nearest facility and develop and rural adjustment factor as part of the adjustment. Other commenters urged CMS to implement the GAO recommendations. Some commenters encouraged CMS to consider travel time as well as distance in their consideration of the aggregate number of treatments furnished by ESRD facilities within 25 miles of each other under common ownership, and other commenters suggested that CMS identify critical access facilities and consider changes to the LVPA to protect access to isolated essential facilities. Another commenter asked that CMS consider a larger adjustment for those facilities that are more than 50 miles from the closest dialysis facilities, as closure of these facilities would create particular hardship for patients.

Response: We thank the commenters for their support of our policy clarification and supporting regulation changes. We will finalize these provisions as proposed. In addition, we thank the commenters for their suggestions in computing a low-volume payment adjustment in the future, and we will consider these comments for purposes of refinement in CY 2016.

Comment: A few commenters thanked CMS for extending the attestation filing deadline to December 31 so that affected facilities would have enough time to gather any supporting documentation necessary for determining a facility's total treatment count. Another commenter suggested that CMS further clarify what years a facility is able to re-attest for LVPA eligibility. One commenter cited an independent study claiming that over 1,000 facilities with treatment counts of less than 3,200 were not identified as low-volume facilities under the ESRD PPS.

Response: We thank the commenters for their support and agree that extending the deadline by 60 days will allow facilitates to gather any documentation that supports a facility's treatment count. In addition, we clarify that facilities that believe they have been denied the LVPA payment adjustment under the ESRD PPS may attest to any of the payment years since CY 2011. We thank the commenter who furnished independent data and plan to consider treatment count thresholds as part of our policy refinement in CY 2016.

Comment: One commenter recommended that CMS specify which years MACs will be required to reassess for incorrect determinations. In addition, as some MACs have advised ESRD facilities not to submit an application due to perceived ineligibility, they recommend CMS allow these facilities that did not file attestations to do so for prior years and receive a determination from the MAC.

Response: ESRD facilities that did not submit an attestation for CY 2011 through CY 2014 due to perceived ineligibility, but which now believe they qualify for the LVPA based upon our policy clarifications, should submit an attestation to their MAC for a determination. Likewise, facilities that submitted attestations and were denied, but now believe they qualify based upon the policy clarifications, should submit an attestation to their MAC for a redetermination.

Comment: One commenter supports allowing the submission of additional data for all types of facilities, not only those that are hospital-based, because the commenter indicated such data could help the contractors more effectively identify facilities that qualify for the LVPA. The commenter indicated that more can and should be done to make sure that MACs are appropriately evaluating facilities to ensure accurate determinations.

Response: We will consider this suggestion as part of the ESRD PPS refinement. In the meantime, we are planning to issue additional sub-regulatory guidance to MACs in an effort to ensure accurate LVPA determinations. We thank the commenter for their support and are finalizing the revision to § 413.232(f) to extend the deadline for CY 2015 LVPA attestations until December 31, 2014.

H. Continued Use of ICD–9–CM Codes and Corrections to the ICD–10–CM Codes Eligible for the Co-morbidity Payment Adjustment

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based upon case-mix that may take into account, among other things, patient co-morbidities. Co-morbidities are specific patient conditions that coexist with the patient's principal diagnosis that necessitates dialysis. The co-morbidity payment adjustments recognize the increased costs associated with co-morbidities and provide additional payment for certain conditions that occur concurrently with the need for dialysis. For a detailed discussion of our approach to developing the co-morbidity payment adjustment, see the CY 2011 ESRD PPS final rule (75 FR 49094 through 49108).

In the CY 2011 ESRD PPS final rule, we finalized six co-morbidity categories that are eligible for a co-morbidity payment adjustment, each with associated International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) diagnosis codes (75 FR 49100). These categories include three acute, short-term diagnostic categories (pericarditis, bacterial pneumonia, and gastrointestinal tract bleeding with hemorrhage) and three chronic diagnostic categories (hereditary hemolytic sickle cell anemia, myelodysplastic syndrome, and monoclonal gammopathy). The co-morbidity categories eligible for an adjustment and their associated ICD–9–CM codes were published in the Appendix of the CY 2011 ESRD PPS final rule as Table E: ICD–9–CM-Codes Recognized for the Comorbidity Payment Adjustment (75 FR 49211).

In the CY 2012 ESRD PPS final rule (76 FR 70252), we clarified that the ICD–9–CM codes eligible for the co-morbidity payment adjustment are subject to the annual ICD–9–CM coding updates that occur in the hospital IPPS final rule and are effective October 1st every year. We explained that any updates to the ICD–9–CM codes that affect the categories of co-morbidities and the diagnoses within the co-morbidity categories that are eligible for a co-morbidity payment adjustment would be communicated to ESRD facilities through sub-regulatory guidance. Together with the rest of the healthcare industry, CMS was scheduled to implement the 10th revision of the ICD coding scheme, that is, ICD–10–CM, on October 1, 2014. Hence, in the CY 2014 ESRD PPS (78 FR 72175 through 72179), we finalized a policy that ICD–10–CM codes will be eligible for a co-morbidity payment adjustment where they crosswalk from ICD–9–CM codes that are eligible for a co-morbidity payment adjustment, with two exceptions.

On April 1, 2014, PAMA was enacted. Section 212 of PAMA, titled ''Delay in Transition from ICD–9–CM to ICD–10–CM Code Sets,'' provides that ''[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10–CM code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and § 162.1002 of title 45, Code of Federal Regulations.'' On May

1, 2014, the Secretary announced that HHS expected to issue an interim final rule that would require use of ICD–10–CM beginning October 1, 2015 and continue to require use of ICD–9–CM through September 30, 2015. This announcement is available on the CMS Web site at *http://cms.gov/Medicare/Coding/ICD10/index.html.*

Since the publication of the CY 2015 ESRD PPS proposed rule on July 11, 2014, HHS finalized the new compliance date of October 1, 2015 for ICD–10–CM and ICD–10–PCS in an August 4, 2014 final rule titled ''Administrative Simplification: Change to the Compliance Date for the International Classification of Diseases, 10th Revision (ICD–10–CM and ICD–10–PCS).'' The rule also requires HIPAA covered entities to continue to use ICD–9 through September 30, 2015.

Before the passage of PAMA, our policy required facilities to utilize ICD–10–CM codes to identify co-morbidities eligible for the co-morbidity payment adjustment beginning October 1, 2014. However, in light of section 212 of PAMA and the Secretary's announcement of the new compliance date for ICD–10, we proposed to require use of ICD–10–CM to identify co-morbidities beginning on October 1, 2015, and, until that time, we would continue to require use of the ICD–9–CM codes to identify co-morbidities eligible for the co-morbidity payment adjustment. The ICD–9–CM codes that are eligible for the co-morbidity payment adjustment are listed in the crosswalk tables below.

Because facilities will begin using ICD–10–CM during the calendar year to which this rule applies, we are correcting several typographical errors and omissions in the Tables that appeared in the CY 2015 ESRD PPS final rule. First, we are correcting one ICD–9–CM diagnosis code that was incorrectly identified due to a typographical error in Table 1—ONE ICD–9–CM CODE CROSSWALKS TO ONE ICD–10–CM CODE (78 FR 72176). In Table 2—ONE ICD–9–CM CODE CROSSWALKS TO MULTIPLE ICD–10–CM CODES (78 FR 72177), we are correcting two ICD–10–CM codes because of typographical errors and finalizing two additional ICD–10–CM codes that were inadvertently omitted from the crosswalk. Lastly, in Table 3—MULTIPLE ICD–9–CM CODES CROSSWALK TO ONE ICD–10–CM CODE (78 FR 72178), we are including 9 additional ICD–10–CM crosswalk codes for eligibility for the comorbidity payment adjustment. These codes were omitted in error from the CY 2014 ESRD PPS final rule, and we have furnished an updated Table 15 below reflecting the additional codes.

We note that the ICD–10–CM codes that facilities will be required to use to identify eligible co-morbidities when ICD–10–CM becomes the required medical data code set on October 1, 2015 are those that were finalized in the CY 2014 ESRD PPS final rule at 78 FR 72175 to 78 FR 72179 with the corrections and proposed additions included below.

Table 15—ONE ICD–9–CM CODE CROSSWALKS TO ONE ICD–10–CM CODE (78 FR 72175 Through 78 FR 72176)

Table 15 lists all the instances in which one ICD–9–CM code crosswalks to one ICD–10–CM code. We finalized a policy in last year's rule that all identified ICD–10–CM codes would receive a co-morbidity adjustment with the exception of K52.81 Eosinophilic gastritis or gastroenteritis. We have since discovered that under the section titled Myelodysplastic Syndrome, ICD–9–CM code 238.7 Essential thrombocythemia was in accurately identified. The table below has been amended to accurately identify ICD–9–CM diagnostic code 238.71 Essential thrombocythemia.

TABLE 15—ONE ICD–9–CM CODE CROSSWALKS TO ONE ICD–10–CM CODE

ICD–9 Descriptor	ICD–10 Descriptor
Gastrointestinal Bleeding	
530.21 Descriptor Ulcer of esophagus with bleeding	K22.11 Descriptor Ulcer of esophagus with bleeding.
535.71 Eosinophilic gastritis, with hemorrhage	K52.81 Eosinophilic gastritis or gastroenteritis.
537.83 Angiodysplasia of stomach and duodenum with hemorrhage	K31.811 Angiodysplasia of stomach and duodenum with bleeding.
569.85 Angiodysplasia of intestine with hemorrhage	K55.21 Angiodysplasia of colon with hemorrhage.
Bacterial Pneumonia	
003.22 Salmonella pneumonia	A02.22 Salmonella pneumonia.
482.0 Pneumonia due to Klebsiella pneumonia	J15.0 Pneumonia due to Klebsiella pneumoniae.
482.1 Pneumonia due to Pseudomonas	J15.1 Pneumonia due to Pseudomonas.
482.2 Pneumonia due to Hemophilus influenzae [H. influenzae]	J14 Pneumonia due to Hemophilus influenzae.
482.32 Pneumonia due to Streptococcus, group B	J15.3 Pneumonia due to streptococcus, group B.
482.40 Pneumonia due to Staphylococcus, unspecified	J15.20 Pneumonia due to staphylococcus, unspecified.
482.41 Methicillin susceptible pneumonia due to Staphylococcus aureus.	J15.211 Pneumonia due to Methicillin susceptible Staphylococcus aureus.
482.42 Methicillin resistant pneumonia due to Staphylococcus aureus	J15.212 Pneumonia due to Methicillin resistant Staphylococcus aureus.
482.49 Other Staphylococcus pneumonia	J15.29 Pneumonia due to other staphylococcus.
482.82 Pneumonia due to escherichia coli [E. coli]	J15.5 Pneumonia due to Escherichia coli.
482.83 Pneumonia due to other gram-negative bacteria	J15.6 Pneumonia due to other aerobic Gram-negative bacteria.
482.84 Pneumonia due to Legionnaires' disease	A48.1 Legionnaires' disease.
507.0 Pneumonitis due to inhalation of food or vomitus	J69.0 Pneumonitis due to inhalation of food and vomit.
507.8 Pneumonitis due to other solids and liquids	J69.8 Pneumonitis due to inhalation of other solids and liquids.
510.0 Empyema with fistula	J86.0 Pyothorax with fistula.
510.9 Empyema without mention of fistula	J86.9 Pyothorax without fistula.
Pericarditis	
420.91 Acute idiopathic pericarditis	I30.0 Acute nonspecific idiopathic pericarditis.

TABLE 15—ONE ICD–9–CM CODE CROSSWALKS TO ONE ICD–10–CM CODE—Continued

ICD–9 Descriptor	ICD–10 Descriptor
Hereditary Hemolytic and Sickle Cell Anemia	
282.0 Hereditary spherocytosis	D58.0 Hereditary spherocytosis.
282.1 Hereditary elliptocytosis	D58.1 Hereditary elliptocytosis.
282.41 Sickle-cell thalassemia without crisis	D57.40 Sickle-cell thalassemia without crisis.
282.43 Alpha thalassemia	D56.0 Alpha thalassemia.
282.44 Beta thalassemia	D56.1 Beta thalassemia.
282.45 Delta-beta thalassemia	D56.2 Delta-beta thalassemia.
282.46 Thalassemia minor	D56.3 Thalassemia minor.
282.47 Hemoglobin E-beta thalassemia	D56.5 Hemoglobin E-beta thalassemia.
282.49 Other thalassemia	D56.8 Other thalassemias.
282.61 Hb-SS disease without crisis	D57.1 Sickle-cell disease without crisis.
282.63 Sickle-cell/Hb-C disease without crisis	D57.20 Sickle-cell/Hb-C disease without crisis.
282.68 Other sickle-cell disease without crisis	D57.80 Other sickle-cell disorders without crisis.
Myelodysplastic Syndrome	
238.71 Essential thrombocythemia	D47.3 Essential (hemorrhagic) thrombocythemia.
238.73 High grade myelodysplastic syndrome lesions	D46.22 Refractory anemia with excess of blasts 2.
238.74 Myelodysplastic syndrome with 5q deletion	D46.C Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality.
238.76 Myelofibrosis with myeloid metaplasia	D47.1 Chronic myeloproliferative disease.

Table 16—ONE ICD–9–CM CODE CROSSWALKS TO MULTIPLE ICD–10–CM CODES (78 FR 72177 Through 78 FR 72178)

Table 16 lists all of the instances in which one ICD–9–CM code crosswalks to multiple ICD–10–CM codes. We finalized a policy in last year's rule that all identified ICD–10–CM codes would receive a co-morbidity adjustment with the exception of D89.2 Hypergammaglobulinemia, unspecified. Under the section titled Gastrointestinal Bleeding, ICD–9–CM code 562 Diverticulosis of small intestine with hemorrhage was in accurately identified, as the complete code number is 562.02. The table below has been amended to accurately identify ICD–9–CM diagnostic code 562.02 Diverticulosis of small intestine with hemorrhage.

Also under the section titled Gastrointestinal Bleeding, ICD–9–CM diagnostic code 562.13 Diverticulitis of colon with hemorrhage did not include a complete crosswalk to ICD–10–CM diagnostic codes. Therefore, we are including ICD–10–CM diagnostic codes K57.81 Diverticulitis of intestine, part unspecified, with perforation and abscess with bleeding and K57.93 Diverticulitis of intestine, part unspecified, without perforation or abscess with bleeding, in addition to the ICD–10–CM diagnostic codes K57.21, K57.33, K57.41, and K57.53, as eligible for the co-morbidity payment adjustment when the use of ICD–10–CM is required, on October 1, 2015.

Under the section titled Pericarditis, ICD–10–CM code 130.1 Infective pericarditis was inaccurately identified. The table below has been amended to accurately identify the ICD–10–CM diagnostic code I30.1 Infective pericarditis as eligible for a co-morbidity payment adjustment when the use of ICD–10–CM is required, on October 1, 2015.

TABLE 16—ONE ICD–9–CM CODE CROSSWALKS TO MULTIPLE ICD–10–CM CODES

ICD–9 Descriptor	ICD–10 Descriptor
Gastrointestinal Bleeding	
562.02 Diverticulosis of small intestine with hemorrhage	K57.11 Diverticulosis of small intestine without perforation or abscess with bleeding. K57.51 Diverticulosis of both small and large intestine without perforation or abscess with bleeding.
562.03 Diverticulitis of small intestine with hemorrhage	K57.01 Diverticulitis of small intestine with perforation and abscess with bleeding. K57.13 Diverticulitis of small intestine without perforation or abscess with bleeding. K57.41 Diverticulitis of both small and large intestine with perforation and abscess with bleeding. K57.53 Diverticulitis of both small and large intestine without perforation or abscess with bleeding.
562.12 Diverticulosis of colon with hemorrhage	K57.31 Diverticulosis of large intestine without perforation or abscess with bleeding. K57.91 Diverticulosis of intestine, part unspecified, without perforation or abscess with bleeding. K57.51 Diverticulosis of both small and large intestine without perforation or abscess with bleeding.

TABLE 16—ONE ICD–9–CM CODE CROSSWALKS TO MULTIPLE ICD–10–CM CODES—Continued

ICD–9 Descriptor	ICD–10 Descriptor
562.13 Diverticulitis of colon with hemorrhage	K57.21 Diverticulitis of large intestine with perforation and abscess with bleeding. K57.33 Diverticulitis of large intestine without perforation or abscess with bleeding. K57.41 Diverticulitis of both small and large intestine with perforation and abscess with bleeding. K57.53 Diverticulitis of both small and large intestine without perforation or abscess with bleeding. K57.81 Diverticulitis of intestine, part unspecified, with perforation and abscess with bleeding. K57.93 Diverticulitis of intestine, part unspecified, without perforation or abscess with bleeding.
Bacterial Pneumonia	
513.0 Abscess of lung	J85.0 Gangrene and necrosis of lung. J85.1 Abscess of lung with pneumonia. J85.2 Abscess of lung without pneumonia.
Pericarditis	
420.0 Acute pericarditis in diseases classified elsewhere	A18.84 Tuberculosis of heart. I32 Pericarditis in diseases classified elsewhere. M32.12 Pericarditis in systemic lupus erythematosus.
420.90 Acute pericarditis, unspecified	I30.1 Infective pericarditis. I30.9 Acute pericarditis, unspecified.
420.99 Other acute pericarditis	I30.8 Other forms of acute pericarditis. I30.9 Acute pericarditis, unspecified.
Hereditary Hemolytic and Sickle Cell Anemia	
282.2 Anemias due to disorders of glutathione metabolism	D55.0 Anemia due to glucose-6-phosphate dehydrogenase [G6PD] deficiency. D55.1 Anemia due to other disorders of glutathione metabolism.
282.3 Other hemolytic anemias due to enzyme deficiency	D55.2 Anemia due to disorders of glycolytic enzymes. D55.3 Anemia due to disorders of nucleotide metabolism. D55.8 Other anemias due to enzyme disorders. D55.9 Anemia due to enzyme disorder, unspecified.
282.42 Sickle-cell thalassemia with crisis	D57.411 Sickle-cell thalassemia with acute chest syndrome. D57.412 Sickle-cell thalassemia with splenic sequestration. D57.419 Sickle-cell thalassemia with crisis, unspecified.
282.62 Hb-SS disease with crisis	D57.00 Hb-SS disease with crisis, unspecified. D57.01 Hb-SS disease with acute chest syndrome. D57.02 Hb-SS disease with splenic sequestration.
282.64 Sickle-cell/Hb-C disease with crisis	D57.211 Sickle-cell/Hb-C disease with acute chest syndrome. D57.212 Sickle-cell/Hb-C disease with splenic sequestration. D57.219 Sickle-cell/Hb-C disease with crisis, unspecified.
282.69 Other sickle-cell disease with crisis	D57.811 Other sickle-cell disorders with acute chest syndrome. D57.812 Other sickle-cell disorders with splenic sequestration. D57.819 Other sickle-cell disorders with crisis, unspecified.
Monoclonal Gammopathy	
273.1 Monoclonal paraproteinemia	D47.2 Monoclonal gammopathy. D89.2 Hypergammaglobulinemia, unspecified.
Myelodysplastic Syndrome	
238.72 Low grade myelodysplastic syndrome lesions	D46.0 Refractory anemia without ring sideroblasts, so stated. D46.1 Refractory anemia with ring sideroblasts. D46.20 Refractory anemia with excess of blasts, unspecified. D46.21 Refractory anemia with excess of blasts 1. D46.4 Refractory anemia, unspecified. D46.A Refractory cytopenia with multilineage dysplasia. D46.B Refractory cytopenia with multilineage dysplasia and ring sideroblasts.
238.75 Myelodysplastic syndrome, unspecified	D46.9 Myelodysplastic syndrome, unspecified. D46.Z Other myelodysplastic syndromes.

Table 17—MULTIPLE ICD–9–CM CODES CROSSWALK TO ONE ICD–10–CM CODE (78 FR 72178)

Table 17 displays the crosswalk where multiple ICD–9–CM codes crosswalk to one ICD–10–CM code. We finalized a policy in last year's rule that all of the ICD–10–CM codes listed in Table 3 would be eligible for the co-morbidity payment adjustment. Under the section titled Gastrointestinal Bleeding, nine ICD–10–CM codes (K25.0 Acute gastric ulcer with hemorrhage, K25.2 Acute gastric ulcer with both hemorrhage and perforation, K25.4 Chronic or unspecified gastric ulcer with hemorrhage, K25.6 Chronic or unspecified gastric ulcer with both hemorrhage and perforation, K26.0 Acute duodenal ulcer with hemorrhage, K26.2 Acute duodenal ulcer with both hemorrhage and perforation, K26.4 Chronic or unspecified duodenal ulcer with hemorrhage, K26.6 Chronic or unspecified duodenal ulcer with both hemorrhage and perforation, and K27.0 Acute peptic ulcer, site unspecified, with hemorrhage) and the corresponding ICD–9–CM codes were inadvertently omitted from the crosswalk. Therefore, we are finalizing ICD–10–CM diagnostic codes—K25.0, K25.2, K25.4, K25.6, K26.0, K26.2, K26.4, K26.6, K27.0—will be eligible for the comorbidity payment adjustment beginning October 1, 2015. We also finalize that the corresponding ICD–9–CM codes will be eligible for the comorbidity adjustment through September 30, 2015.

TABLE 17—MULTIPLE ICD–9–CM CODES CROSSWALK TO ONE ICD–10–CM CODE

ICD–9 Descriptor	ICD–10 Descriptor
Gastrointestinal Bleeding	
531.00 Acute gastric ulcer with hemorrhage, without mention of obstruction.	K25.0 Acute gastric ulcer with hemorrhage.
531.01 Acute gastric ulcer with hemorrhage, with obstruction.	
531.20 Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction.	K25.2 Acute gastric ulcer with both hemorrhage and perforation.
531.21 Acute gastric ulcer with hemorrhage and perforation, with obstruction.	
531.40 Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction.	K25.4 Chronic or unspecified gastric ulcer with hemorrhage.
531.41 Chronic or unspecified gastric ulcer with hemorrhage, with obstruction.	
531.60 Chronic or unspecified gastric ulcer with hemorrhage and perforation, without mention of obstruction.	K25.6 Chronic or unspecified gastric ulcer with both hemorrhage and perforation.
531.61 Chronic or unspecified gastric ulcer with hemorrhage and perforation, with obstruction.	
532.00 Acute duodenal ulcer with hemorrhage, without mention of obstruction.	K26.0 Acute duodenal ulcer with hemorrhage.
532.01 Acute duodenal ulcer with hemorrhage, with obstruction.	
532.20 Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction.	K26.2 Acute duodenal ulcer with both hemorrhage and perforation.
532.21 Acute duodenal ulcer with hemorrhage and perforation, with obstruction.	
532.40 Chronic or unspecified duodenal ulcer with hemorrhage, without mention of obstruction.	K26.4 Chronic or unspecified duodenal ulcer with hemorrhage.
532.41 Chronic or unspecified duodenal ulcer with hemorrhage, with obstruction.	
532.60 Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction.	K26.6 Chronic or unspecified duodenal ulcer with both hemorrhage and perforation.
532.61 Chronic or unspecified duodenal ulcer with hemorrhage and perforation, with obstruction.	
533.00 Acute peptic ulcer of unspecified site with hemorrhage, without mention of obstruction.	K27.0 Acute peptic ulcer, site unspecified, with hemorrhage.
533.01 Acute peptic ulcer of unspecified site with hemorrhage, with obstruction.	
533.20 Acute peptic ulcer of unspecified site with hemorrhage and perforation, without mention of obstruction.	K27.2 Acute peptic ulcer, site unspecified, with both hemorrhage and perforation.
533.21 Acute peptic ulcer of unspecified site with hemorrhage and perforation, with obstruction.	
533.40 Chronic or unspecified peptic ulcer of unspecified site with hemorrhage, without mention of obstruction.	K27.4 Chronic or unspecified peptic ulcer, site unspecified, with hemorrhage.
533.41 Chronic or unspecified peptic ulcer of unspecified site with hemorrhage, with obstruction.	
533.60 Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation, without mention of obstruction.	K27.6 Chronic or unspecified peptic ulcer, site unspecified, with both hemorrhage and perforation.
533.61 Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation, with obstruction.	
534.00 Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction.	K28.0 Acute gastrojejunal ulcer with hemorrhage.
534.01 Acute gastrojejunal ulcer, with hemorrhage, with obstruction.	
534.20 Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction.	K28.2 Acute gastrojejunal ulcer with both hemorrhage and perforation.
534.21 Acute gastrojejunal ulcer with hemorrhage and perforation, with obstruction.	

TABLE 17—MULTIPLE ICD–9–CM CODES CROSSWALK TO ONE ICD–10–CM CODE—Continued

ICD–9 Descriptor	ICD–10 Descriptor
534.40 Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction.	K28.4 Chronic or unspecified gastrojejunal ulcer with hemorrhage.
534.41 Chronic or unspecified gastrojejunal ulcer, with hemorrhage, with obstruction.	
534.60 Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction.	K28.6 Chronic or unspecified gastrojejunal ulcer with both hemorrhage and perforation.
534.61 Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, with obstruction.	
Bacterial Pneumonia	
482.30 Pneumonia due to Streptococcus, unspecified	J15.4 Pneumonia due to other streptococci.
482.31 Pneumonia due to Streptococcus, group A.	
482.39 Pneumonia due to other Streptococcus.	
482.81 Pneumonia due to anaerobes	J15.8 Pneumonia due to other specified bacteria.
482.89 Pneumonia due to other specified bacteria.	

We received no comments on our proposals to amend or modify our ICD–9–CM/ICD–10–CM crosswalk and, therefore, we are finalizing these changes as proposed.

III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

A. Background

For more than 30 years, monitoring the quality of care provided by dialysis facilities to patients with end-stage renal disease (ESRD) has been an important component of the Medicare ESRD payment system. The ESRD Quality Incentive Program (QIP) is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS. The ESRD QIP is authorized by section 1881(h) of the Social Security Act (the Act), which was added by section 153(c) of the Medicare Improvements for Patients and Providers Act (MIPPA).

Specifically, section 1881(h) requires the Secretary to establish an ESRD QIP by (i) selecting measures; (ii) establishing the performance standards that apply to the individual measures; (iii) specifying a performance period with respect to a year; (iv) developing a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; and (v) applying an appropriate payment reduction to facilities that do not meet or exceed the established Total Performance Score (TPS). The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' (79 FR 40208 through 40315), (hereinafter referred to as the CY 2015 ESRD PPS Proposed Rule), was published in the **Federal Register** on July 11, 2014, with a comment period that ended on September 2, 2014. In that proposed rule, we made proposals for the ESRD QIP, including adding new measures, revising existing measures; refining the scoring methodology; modifying the program's public reporting requirements; continuing the data validation pilot program for CROWNWeb and introducing a validation feasibility study for the NHSN Bloodstream Infection clinical measure. We received 46 public comments on the ESRD QIP proposals, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients; manufacturers; health care systems; and nurses.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the program. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section of this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section of this final rule.

B. Considerations in Updating and Expanding Quality Measures Under the ESRD QIP

Throughout the past decade, Medicare has been transitioning from a program that pays for healthcare based on particular services furnished to a beneficiary to a program that bases payments to providers and suppliers on the quality of services they furnish. By paying for the quality of care rather than simply the quantity of care, and by focusing on better care and lower costs through improvement, prevention and population health, expanded healthcare coverage, and enterprise excellence, we are strengthening the healthcare system while also advancing the National Strategy for Quality Improvement in Health Care (that is, the National Quality Strategy (NQS)). We are also working to update a set of domains and specific quality measures for our Value Based Purchasing (VBP) programs, and to link the aims of the NQS with our payment policies on a national scale. We are working in partnership with beneficiaries, providers, advocacy groups, the National Quality Forum (NQF), the Measures Application Partnership, operating divisions within the Department of Health and Human Services (HHS), and other stakeholders to develop new measures where gaps exist, refine measures where necessary, and remove measures when appropriate. We are also collaborating with stakeholders to ensure that the ESRD QIP serves the needs of our beneficiaries and also advances the goals of the NQS to improve the overall quality of care, improve the health of the U.S. population, and reduce the cost of quality healthcare.[3]

We believe that the development of an ESRD QIP that is successful in supporting the delivery of high-quality healthcare services in dialysis facilities is paramount. We seek to adopt measures for the ESRD QIP that promote better, safer, and more coordinated care. Our measure development and selection activities for the ESRD QIP take into account national priorities such as those established by the HHS Strategic Plan (*http://www.hhs.gov/strategic-plan/priorities.html*), the NQS (*http://*

[3] 2013 Annual Progress Report to Congress: National Strategy for Quality Improvement in Health Care, *http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm.*

www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm), and the HHS National Action Plan to Prevent Healthcare Associated Infections (HAIs) (*http://www.hhs.gov/ash/initiatives/hai/esrd.html*). To the extent feasible and practicable, we have sought to adopt measures that have been endorsed by a national consensus organization; recommended by multi-stakeholder organizations; and developed with the input of providers, beneficiaries, health advocacy organizations, and other stakeholders.

We received a number of general comments on our proposals, which we summarize and respond to here.

Comment: Some commenters were concerned about the number of measures used in the ESRD QIP. Commenters stated that as the number of measures in the ESRD QIP grows, so do the costs to providers and CMS. Commenters also stated that implementing too many measures dilutes the impact of poor performance on individual measures in the ESRD QIP. Commenters recommended that CMS ''strive to include measures that address multiple domains of CMS's VBP programs and are not duplicative.''

Response: We understand that there are a number of measures we proposed to be added to the ESRD QIP. One of the reasons we proposed to adopt measures for both PY 2017 and PY 2018 in the CY 2015 ESRD PPS Proposed Rule this rule (and why the majority of the new measures were proposed for adoption in PY 2018) was to provide facilities with a sufficient amount of time to implement processes that would enable them to successfully report the measure data and achieve high scores on the measures. Although we recognize that adopting more measures in the ESRD QIP increases costs to facilities as well as CMS, we believe these increased costs are outweighed by the benefits to patients of incentivizing quality care in the domains that the measures cover. We further note that the new measures adopted for the ESRD QIP will not dilute the weight of the PY 2017 clinical measure set or the PY 2018 clinical measure set, as compared to the weights that we assigned to the PY 2016 clinical measure set. The PY 2017 program contains the same amount of clinical measures as the PY 2016 program, and the clinical measure sets receive the same weight in both programs. Additionally, the weight of the clinical measures in the PY 2018 program will be increased from 75 percent of a facility's TPS (as specified in the PY 2017 program) to 90 percent, and we believe that this added weight will preserve the program's strong incentives for facilities to achieve high scores on the clinical measures. Finally, we agree with commenters who recommend that, where possible, individual ESRD QIP measures should span multiple domains. We agree that adopting measures that span multiple domains, such as the SRR measure, allows us to address multiple aspects of quality, reduces the total number of measures in the ESRD QIP, and presents less burden for facilities than adopting multiple measures that each address a single domain. Going forward, we will continue to strive to ensure that the ESRD QIP measure set is as parsimonious as possible.

Comment: Some commenters requested that CMS explore new methods of adjusting quality metrics for patient case mix, because ESRD QIP measures, as currently specified, place facilities treating sicker patients at a disadvantage. For example, dialysis patients who are admitted to nursing homes and long-term care hospitals (LTCHs) often still receive their ESRD treatment at the dialysis facility. These patients are ''inherently sicker and require more care than the general dialysis population.'' Therefore, dialysis facilities that only treat patients who are admitted to LTCHs or nursing homes are at a disadvantage under the current methodology. Commenter stated that comparing facilities with similar case mixes would be a fairer way to evaluate facility performance.

Response: We appreciate the commenters' concerns regarding the exploration of new methods of adjusting for patient case mix to ensure facilities are not penalized for caring for sicker patients. The SRR and STrR clinical measures are risk-adjusted on the basis of patient case mix. We make an effort to adjust for case mix where clinical evidence and methodological rigor indicate doing so is appropriate, and we consider the appropriateness of risk-adjusting for case mix as part of our ongoing reevaluation of quality measures implemented in the ESRD QIP.

Comment: A commenter was concerned that many ESRD QIP measures include patients who are only treated at a facility for a short period of time in the facility. The commenter believes that outcomes for these patients should be attributed to other facilities (that is, other dialysis facilities and hospitals), rather than a facility that had a limited opportunity to provide care for a patient.

Response: We believe the measure specifications appropriately account for patients seen at a facility for a limited period of time by implementing exclusion criteria specific to quality measures as deemed appropriate. For example, the STrR measure excludes all patients who have not received treatment at a facility for 60 days. The Hypercalcemia measure requires 30 days of treatment in the facility. The Kt/V dialysis adequacy measures exclude patient-months where fewer than 7 treatments are billed for the patient, and the vascular access measures require a minimum of 4 months of claims. An analogous exclusion is not appropriate for the SRR, where facility attribution is defined by a hospital discharge, and not time in treatment at a facility.

Comment: One commenter recommended that CMS include the Standardized Mortality Ratio (SMR) in the ESRD QIP, because the ''medical literature has shown SMR is more indicative of the quality of care received at a facility than Standardized Readmissions Ratio (SRR) or Standardized Transfusion Ratio (STrR).''

Response: We thank the commenter for the input. We will consider proposing to adopt the SMR measure for future payment years.

Comment: One commenter recommended that CMS include a measure of the percent of eligible patients on the transplant wait-list in the ESRD QIP, because this indicator of patient status ''is under the immediate auspices of the dialysis team.'' Other commenters recommended that CMS develop one or more measures on fluid management because this area is a high priority concern for clinicians, patients, and facilities. Another commenter recommended that CMS develop a measure evaluating the employment rate among ESRD patients ages 18–54, because the ability to maintain regular employment is an indicator of both positive clinical and psychosocial outcomes in the ESRD population. Commenter stated that monitoring employment statistics among the ESRD population will shift facility focus toward patients' overall well-being rather than just clinical outcomes.

Response: We thank the commenters for their input and will take their recommendations into consideration as we proceed with our measure development work.

Comment: One commenter recommended CMS fully test its system for calculating ESRD QIP scores because in the past 2 years scores on the National Health Safety Network (NHSN) Bloodstream Infection and Dialysis Adequacy measures have been miscalculated.

Response: We agree that it is essential to calculate ESRD QIP measure scores correctly. The purpose of the annual

Preview Period process is to give facilities the opportunity to identify scoring issues and request score changes. We further note that scoring issues related to the NHSN and Dialysis Adequacy measures were resolved via the Preview Period processes, and we take this as an indication that the process is working as intended.

Comment: One commenter supported CMS's goal of improving coordination of care for ESRD patients, but stated that the adoption of measures that may implicate providers outside of the dialysis facility should be delayed until renal-specific accountable care organizations can be established because without an incentive to cooperate, other healthcare providers may not share necessary information with dialysis facilities. Commenters also stated that many facilities lack the tools necessary to effectively address care coordination. Commenters supported the Comprehensive ESRD Care Initiative currently in development, and recommended that CMS delay the adoption of any care coordination measures until results are available from that model.

Response: We appreciate stakeholder support of the ESRD Seamless Care Organization (ESCO) model. However, we do not believe that the ESCO's focus on coordination of care should preclude the ESRD QIP from implementing measures intended to improve care coordination, because collecting and analyzing results from the model will take a number of years, and it may not be possible to extrapolate results obtained from the small sample of facilities included in the model to all facilities nationwide. In addition, by including measures on coordination of care in the ESRD QIP before the ESCOs are in place, we will be able to positively impact care coordination for a large percentage of ESRD patients in the near future, and will be able to collect important data on care coordination from a wide array of facilities, which would better inform its future model development efforts.

Comment: One commenter recommended that CMS develop new measures on anemia management because transfusions have increased as facilities' utilization of ESAs has declined.

Response: We agree with the commenter than anemia management is a major concern among patients with ESRD, and will continue to take this into account in future measure development. We also note that the ESRD QIP currently includes a measure on anemia management and ESA dosage, the Anemia Management reporting measure, and that the intention of the STrR measure we are adopting for the PY 2018 program is to monitor and prevent transfusions related to underutilization of ESAs.

Comment: Many commenters recommended modifying the Vascular Access Type measures such that facilities are not penalized when grafts are placed in certain patients (for example, diabetics with intrinsic vascular disease). Commenters stated that outcomes for these patients are comparable when grafts or fistulae are used, and that the absence of a graft measure in the Vascular Access Type measure topic disincentivizes a clinically appropriate access that is selected after consultation with patients. As an intermediate step, some commenters recommended assigning the catheter and fistula measures, respectively, two-thirds and one-third the weight of the Vascular Access Type measure topic.

Response: The current NQF-endorsed vascular access quality measures adopted for use in the program (NQF #0257: Hemodialysis Vascular Access—Maximizing Placement of Arterial Venous Fistula (AVF) and NQF #0256: Hemodialysis Vascular Access—Minimizing Use of Catheters as Chronic Dialysis Access) consider Arterial Venous (AV) fistula use as a positive outcome, prolonged use of tunneled catheter as a negative outcome, and incorporates the clinical equipoise regarding AV grafts, effectively creating three categories of outcome (AV fistula = positive; AV graft = neutral; prolonged use of tunneled catheter = negative). We believe this paradigm to be generally appropriate. Positive incentives are provided for AV fistula creation, but dialysis providers must remain cognizant of the clinical impact of prolonged use of tunneled catheters because of the negative incentive provided for that outcome. This paired incentive structure reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First Project over the last decade. Furthermore, a recent large meta-analysis demonstrates poorer survival with AV graft compared to AV fistula, raising important questions about the commenter's assertion of clinical appropriateness of AV graft as an alternative to AV fistula.[4] We appreciate the commenters' suggestion to revise the relative weights of the catheter and fistula components of the Vascular Access Type measure topic to increase the focus on ''catheter last''. We will take this into consideration in as we continue to revise and refine the ESRD QIP measure set, and we may use future rulemaking to propose changes to the measures' relative weights.

Comment: One commenter recommended that CMS exclude patients with a limited life expectancy from the Vascular Access Type: Catheter ≥90 days clinical measure.

Response: We appreciate the commenters' suggestion to exclude patients with a limited life expectancy from the measure denominator and will consider whether this type of revision is feasible and appropriate for this measure.

Comment: Some commenters recommended that CMS consider making incentive payments to facilities meeting and/or exceeding benchmarks in the ESRD QIP in addition to penalizing facilities that do not meet or make progress toward the standards, because the current incentive program only withholds funding from the nation's kidney care infrastructure. One commenter recommended working to find ways, within the statutory authorities of the Act, to provide facilities with payment incentives for high performance in the ESRD QIP. The commenter stated that doing so is consistent with the principle that value-based purchasing programs should ''redistribute to providers all of the funding that was set aside in accordance with their performance on the quality measures.''

Response: We do not believe that we have the statutory authority to provide facilities with incentive payments for high performance on ESRD QIP measures.

Comment: One commenter recommended that CMS revise the nomenclature it uses to categorize measures in the ESRD QIP because the current terminology is confusing and may contribute to a lack of patient understanding. The commenter stated that the use of the terms ''clinical'' and ''reporting'' do not align with the commonly accepted meaning of those words. The commenter recommended that CMS replace the term ''clinical measures'' with ''accountability measures'' and replace the term ''reporting measures'' with ''required data submission.''

Response: We disagree that the terms ''clinical measure'' and ''reporting measure'' are confusing. Specifically, the term ''clinical'' indicates that the clinical measures pertain to clinical care and aspects of the clinical environment that improve patient care. Furthermore, the term ''reporting'' indicates that reporting measures pertain to how well

[4] Ravani, J Am Soc Nephrol 24: 465–473, 2013.

a facility meets requirements for reporting data to CMS. Accordingly, we do not believe it is necessary to revise the nomenclature used to categorize measures in the ESRD QIP.

Comment: Some commenters were concerned that the ESRD QIP lacks a strategic vision and encouraged CMS to consult with the ESRD community to establish a clear set of principles and goals for the program. Commenter stated that the program currently seems to be focusing on adding new measures without considering whether each measure will drive improvements in dialysis care.

Response: The goals of the ESRD QIP closely align with the goals of the CMS Quality Strategy (the CMSQS). The CMSQS is designed to guide the activities of various components throughout the Agency and is aligned with the Department of Health and Human Services' (HHS') National Quality Strategy (the NQS). The six goals of the CMSQS are organized around NQS' three broad aims and drive and orient all of CCSQ's quality improvement programs, including the ESRD QIP, insofar as these aims align with the statutory goals of the program. The following figure illustrates the six goals of the CMSQS, which have been informed by extensive consultation with stakeholders across the country:

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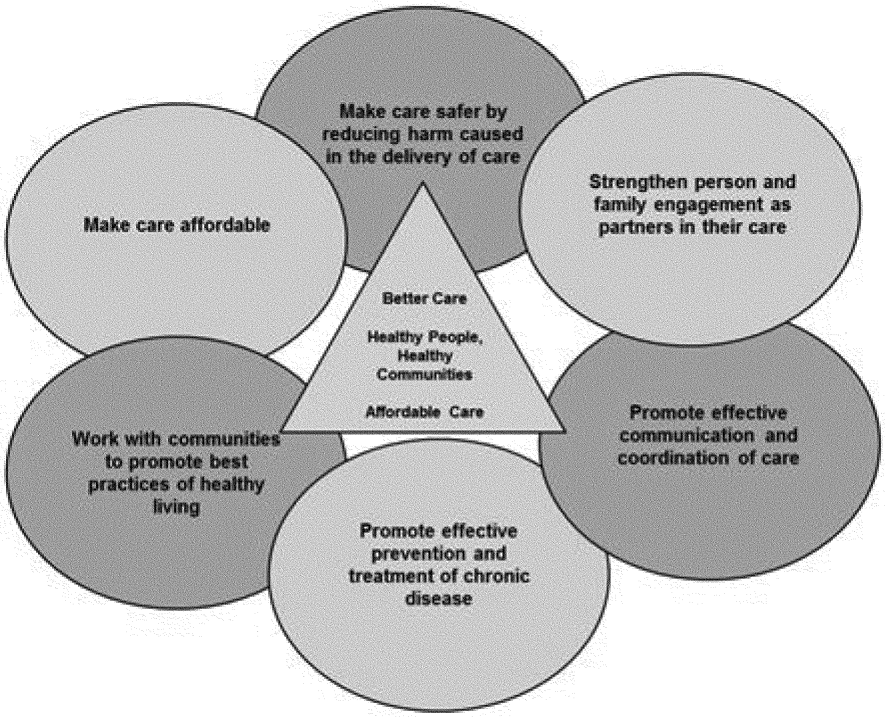

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The strategic vision of the ESRD QIP is to adopt measures that address each of these goals. The following table illustrates the program's efforts to implement this strategic vision:

TABLE 18—ESRD QIP ALIGNMENT WITH CMSQS QUALITY STRATEGY GOALS

CMSQS Goal	Measure	
Promote effective prevention and treatment of chronic disease	Kt/V Measure Topic	Hemodialysis. Peritoneal Dialysis. Pediatric Hemodialysis. Pediatric Peritoneal Dialysis.
	Vascular Access Type Measure Topic.	Fistula. Catheter for at Least 90 Days.
	Mineral Metabolism Reporting. Anemia Management Reporting. Hypercalcemia. Standardized Transfusion Ratio. Screening for Depression and Follow Up reporting. Pain Assessment and Follow-Up reporting.	
Strengthen person and family engagement as partners in their care	ICH CAHPS Reporting (*PY 2017*) and Clinical (PY 2018).	
Promote effective communication and coordination of care	Standardized Readmissions Ratio.	
Make care safer by reducing harm caused in the delivery of care	NHSN Bloodstream Infection in Hemodialysis Outpatients. NHSN Healthcare Personnel Influenza Vaccination reporting.	
Work with communities to promote best practices of healthy living	None.	
Making care affordable	None.	

As the table above illustrates, the ESRD QIP has not proposed or finalized measures for the following quality goals:

- Work with communities to promote the best practices of healthy living.
- Making care affordable.

We will evaluate these remaining goals, particularly the goal of making care affordable, to assess their appropriateness as policy goals for the ESRD QIP. In addition to evaluating the ESRD QIP measure set in terms of how well it addresses legislative mandates, NQS and CMSQS goals, we are also evaluating how well the measure set addresses policy priorities that stakeholders have brought to our attention. We continue to engage both external and internal stakeholders on a regular basis, to communicate the strategic vision of the program as well as to engage in dialogue useful to the development and implementation of policy that will effectively create improvements in the quality of care provided to ESRD beneficiaries.

Comment: Some commenters were concerned that CMS is proposing to adopt a number of measures that have not been reviewed or endorsed by NQF. One commenter stated that the Social Security Act authorizes the program to adopt measures that have not been endorsed by NQF, but the commenter recommended that this authority should only be exercised rarely.

Response: As described above, we may adopt non-NQF-endorsed measures under the ESRD QIP exception authority in section 1881(h)(2)(B)(ii) of the Act. This provision provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, 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. Although we proposed some measures that are not currently NQF-endorsed, they are pending NQF endorsement, and we are actively seeking this endorsement. We also considered other available measures that have been endorsed by the NQF and found no other feasible and practical measures. In addition, the MAP has supported or conditionally supported all of the measures proposed for the PY 2017 and PY 2018 ESRD QIP.

Comment: Some commenters were concerned about the process CMS uses to develop measures for ESRD. Commenters stated that the measure development process does not consider the day-to-day operations of a dialysis facility, appears to be pre-determined and closed to influence from the ESRD community, is insufficiently transparent, and is not focused on areas that are of concern to the ESRD community.

Response: Our development process makes use of the CMS Measures Management System Blueprint, which is publicly available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html.* The CMS Blueprint guides measure development through all stages in order to prepare the measures for public comment, and submission to NQF. Development work begins with an extensive review of relevant literature, which is then presented to a panel of technical experts (members of which are selected after a public call for nominations) convened for the purpose of providing guidance to our quality measure development contractor. These panels typically include practicing nephrologists and nurses, ESRD researchers, and other experts who may meaningfully contribute to the content area under discussion. The results of their deliberations are posted publicly on a CMS Web site, and any measures developed through this process undergo a 30-day public comment period prior to being considered for inclusion in the ESRD QIP. We have additionally submitted most of our measures to NQF for endorsement, and as part of that process, we must submit extensive documentation supporting the measure specifications, and the measure is scrutinized extensively by a steering committee to assess measure importance, scientific acceptability, feasibility, and usability. Furthermore, we propose the measures through our annual notice and comment rulemaking process to allow for public comments.

Comment: One commenter recommended CMS ensure the integrity of the data used to develop measures and score facilities on measures in the ESRD QIP. Other commenters did not support the use of multiple data sources in the ESRD QIP.

Response: We are continuing to work diligently to ensure the validity and reliability of data that is used to calculate facility scores and to develop measures for the ESRD QIP. We believe that our efforts to solicit stakeholder feedback through the CROWNWeb Users Group have dramatically accelerated our efforts on this, and we looking forward to the continued collaboration.

We believe that our measures are currently valid and reliable, and use a variety of tools to assess reliability and validity. We base our measure specifications on rigorous clinically peer-reviewed findings, convene technical expert panels of clinicians and statistical experts, run medical record reliability pilot tests, and submit measures to the Secretary's consensus-based endorsement entity and the Measures Application Partnership for review. We use these tools as appropriate and feasible to ensure validity and reliability.

We believe that it is appropriate to use more than one data source to collect ESRD QIP measure data because the use of multiple data sources ensures that measure scores are calculated using the most reliable data source available, and that data from one source can be validated against data from another source.

Comment: A commenter recommended that CMS align measurement methodologies and reporting requirements across CMS ESRD quality programs. Commenter stated that current misalignments are creating confusion and are burdening facility staff.

Response: The ESRD QIP, Dialysis Facility Compare program, and the Dialysis Facility Reports program have different purposes, which in certain cases necessitates divergent measure specifications and scoring methodologies. We are currently in the process of reviewing measure specifications and scoring methodologies across the three programs, and we will continue to create alignments where appropriate.

Comment: A number of commenters recommended applying six exclusion criteria to all measures in the ESRD QIP unless there is a clinical or operational reason not to do so: (1) Beneficiaries who die within the applicable month; (2) Beneficiaries who receive fewer than 7 treatments in a month; (3) Beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented good faith effort to have them participate in such a visit during the applicable month; (4) Transient dialysis patients; (5) Pediatric patients (unless the measure is specific to pediatric patients); and (6) Kidney transplant recipients with a functioning graft. Commenter also recommended that patients should only be attributed to a facility after being assigned to the facility for 60 days, and that the dialysis adequacy measures should exclude patients with fewer than four eligible claim months.

Response: We considered applying these six global exclusion criteria in response to comments on the CY 2014 ESRD PPS proposed rule (78 FR 72192). We agree with commenters that exclusion criteria for the ESRD QIP measures should be consistent, where feasible. We further believe, however, that exclusions also need to take into account the population to which a measure applies and the settings for which the measures were developed (for example, in-center hemodialysis as opposed to home hemodialysis). As stated in previous rules, we will continue to look for ways to align exclusion criteria for measures in the ESRD QIP, as long as there is evidence to support such consistency.

Comment: Commenter stated that measures in the ESRD QIP predominantly focus on in-center dialysis. Commenter recommended developing new measures, and modifying existing measures, to take greater account of peritoneal and home hemodialysis. Commenter further recommended that measure development activities should utilize data from patients on home dialysis, rather than extrapolating data from patients on in-center dialysis. Commenter stated that this is particularly important for measures of dialysis adequacy, because patients on home hemodialysis receive four to six treatments per week, while patients on in-center hemodialysis receive three treatments per week on average. Other commenters recommended that CMS increase home hemodialysis patients' representation in current ESRD QIP measures, particularly in measures directly assessing quality of care and patient experience, such as the ICH CAHPS survey. These commenters stated that home hemodialysis patients represent 10 percent of the ESRD population and are excluded from most measures currently used in the program.

Response: We appreciate commenters' interest in ensuring that home dialysis patients are appropriately included in the ESRD QIP. Because home hemodialysis patients currently comprise a small percentage of the ESRD population, we have confronted challenges in developing quality measures that can meaningfully distinguish facility performance in the quality of care furnished to these patients, and many of our existing measures specifically exclude home hemodialysis patients from the denominator for this reason. However, we remain interested in exploring ways to capture these patients in the ESRD QIP, including developing measures that would assess their quality of care.

Comment: Some commenters recommended that CMS reevaluate the Dialysis Adequacy measure topic, because the measures assess the quantity and sufficiency of dialysis, but do not account for the patient's overall health. Commenters stated that this results in a focus on meeting the measure standard, rather than achieving the Kt/V level that is best for the individual patient.

Response: The current measure specifications are informed by the KDOQI clinical practice guidelines and the current body of evidence about respective clinical thresholds. These minimum standards do not specifically preclude individualization of care, but treatment should not fall below the minimum standards supported by evidence and guidelines.

Comment: One commenter was concerned that the ESRD QIP overemphasizes laboratory-based measures and stated that measures that assess a patient's quality of life are more meaningful.

Response: We recognize that the majority of the measures that we previously adopted for the ESRD QIP involve laboratory measurements (for example, the Hypercalcemia and Dialysis Adequacy clinical measures). However, we also note that we are finalizing many measures in this final rule that are not laboratory-based measures, such as the SRR, STrR, and ICH CAHPS clinical measures, as well as the Screening for Depression and Follow-Up and the Pain Assessment and Follow-Up reporting measures. These non-laboratory based measures are intended to address patients' quality of life by assessing patient and family engagement in their care, the clinical care patients receive, and conditions impacting patients' ability to participate in activities of daily living.

Comment: One commenter recommended CMS develop a ''palliative care exclusion'' to avoid unfairly penalizing facilities for tailoring a very ill patient's care to the patient's informed preferences. Another commenter stated that the ESRD QIP does not meet the needs of patients pursuing palliative care because it does not include measures that assess improvements in quality of life or whether care is consistent with patients' treatment goals. The commenter recommended that CMS develop measures that prioritize patient comfort and align the care furnished with patient preferences and goals. Commenter also recommended that CMS develop measures on reducing the social and psychological impact of ESRD, advanced care planning, facility documentation of surrogate decision-makers, facility assessment of patients' needs on first visit after hospitalization, and medication reconciliation.

Response: We recognize that some patients may seek palliative care, and that it is important to take this into account when developing robust clinical quality measures for patients with ESRD. Through our ongoing measure maintenance work, we will consider this and other potential exclusion criteria, and their role in measure specifications. We will also consider the commenter's recommendations as we establish priorities for future measure development.

Comment: One commenter recommended that CMS reinstate the Hemoglobin Less than 10 g/dL clinical measure, because it protects patients from anemia under-treatment. Commenter stated that since the removal of the Hemoglobin Less than 10 g/dL clinical measure, mean hemoglobin levels among dialysis patients have declined and transfusions have increased, indicating that facilities are not adequately addressing anemia in this population. Commenter further stated that a Hemoglobin Less than 10g/dL measure is consistent with FDA labeling of Erythropoiesis stimulating agents (ESAs) because ESA treatment should be initiated when patients reach a hemoglobin level of 10 g/dL. Commenter also states that the goal of maintaining a hemoglobin level of at least 10 g/dL is appropriate because the risk of receiving a transfusion increases four-fold when hemoglobin levels fall below 10 g/dL.

Response: We appreciate commenter's recommendation to re-adopt the Hemoglobin < 10 g/dL clinical measure in the ESRD QIP. As discussed in the proposed rule, we share commenter's concerns about adequate maintenance of patients' hemoglobin levels. In addition, FDA guidance advises that treatment of anemia should minimize the occurrence of transfusions among ESRD dialysis patients, and we believe that the STrR is consistent with the guidance, and will serve to guard against underutilization of ESAs among patients. For this reason, we proposed to implement the STrR clinical measure in Payment Year 2018.

Comment: Some commenters stated that patient-months indicating a Kt/V value greater than 2.5 should not be excluded from the Hemodialysis measures, because patients on nocturnal dialysis may achieve such values, and they should be included in the measure.

Response: As stated in the CY 2013 ESRD PPS Final Rule, ''We do not currently have the ability to identify

patients who are receiving thrice weekly in-center nocturnal hemodialysis and do not have a measure specific to this population . . . Patients with HD spKt/V values greater than 2.5 are excluded from the measure calculation as these values are considered implausible for most hemodialysis patients'' (77 FR 67488). As part of our measure re-evaluation process, we are considering alternatives to the 2.5 cut-off for spKt/V values, as well as avenues for identifying patients receiving in-center nocturnal hemodialysis. We will continue to pursue both avenues of inquiry in our ongoing effort to provide as comprehensive and accurate an assessment of dialysis adequacy in the QIP as is possible.

Comment: One commenter recommended that CMS use raw data to independently calculate Kt/V values for the Dialysis Adequacy clinical measure topic, because this will improve the measures' accuracy.

Response: As stated in the CY 2013 ESRD PPS Final Rule, ''We choose to collect reported Kt/V, rather than the data elements for Kt/V, due to the limitations of collecting data on Medicare claims and to minimize burden on facilities'' (77 FR 67489). This is still true because the measure continues to be based on data reported on Medicare claims. We continue to believe that Medicare claims are a reliable data source for this purpose because instructions for submission of Kt/V on Medicare Claims are very specific in the requirement to report Kt/V calculated from either Daugirdas II or urea kinetic modeling, the two most reliable methods for determining Kt/V, consistent with the most recent NKF KDOQI consensus recommendations and supported by a recent Technical Expert Panel convened in 2013.

Comment: Commenter recommended converting the Hypercalcemia clinical measure to a reporting measure, because the ESRD PPS will not be including oral-only drugs until 2024. Commenter stated that this provision of the ESRD PPS will delay the economic incentives for facilities to underutilize oral-only drugs, so the hypercalcemia measure is not needed to protect patient safety.

Response: We believe it is important to retain Hypercalcemia as a clinical measure in the ESRD QIP because this measure is the only clinical outcome measure endorsed by NQF for bone mineral metabolism, and issues related to bone mineral metabolism are tremendously important for patients with ESRD. The anticipated addition of oral medications in the ESRD PPS may incentivize the use of less costly calcium-based phosphorus binders and less use of cinacalcet, which may lead to increased hypercalcemia in the ESRD dialysis population. We further note that the measure's clinical significance has already been accounted for in the scoring methodology that was finalized for the PY 2016 program and proposed for PY 2017–2018, wherein the Hypercalcemia measure is given less weight than other measures.

Comment: Some commenters recommended that CMS work with the kidney community to develop a composite phosphorous/calcium/PTH measure, because a composite measure would be more likely to improve patient outcomes than a measure evaluating one of the individual components.

Response: We welcome an opportunity for collaboration on this and other projects. We note, however, that in 2010, a Technical Expert Panel discussed the possibility of developing measures for phosphorus, and was unable to come to a consensus regarding a phosphorus measure that assesses appropriate levels of phosphorus due to a lack of evidence supporting a clinical threshold. A reporting measure was developed and originally endorsed by the NQF in 2007, and forms the basis of the Mineral Metabolism reporting measure implemented in the ESRD QIP. In 2011, NQF reviewed two phosphorus measures, establishing one with an upper limit (hyperphosphatemia) and one with a lower limit (hypophosphatemia). NQF did not endorse either measure. A recent 2013 Technical Expert Panel recommended the development of a reporting measure for PTH, which we have specified, and are currently working to test prior to submitting it to NQF for endorsement. However, the panel concluded that there was insufficient evidence to develop a clinical measure. We are unaware of more recent evidence that makes it likely that consensus around such a clinical performance measure would be reached in new measure development efforts at this time, but we would be interested in discussing any such evidence with stakeholders.

Comment: One commenter recommended aligning the dates used for calculating patient censuses under the Vascular Access Type measure topic and NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure to reduce administrative burden. Commenter stated that the Vascular Access Type measure topic is based on the last treatment of the month, while the NHSN census is based on the ESRD facility's first two working days of the month.

Response: We appreciate the recommendation. Because these measures serve different purposes, and because the methods used to calculate the measures have shown to be reliable, we do not believe there is sufficient technical rationale to justify aligning these administrative tasks at this time.

Comment: One commenter recommended that CMS consider coordinating occupational therapy with dialysis treatments.

Response: We thank the commenter for the input.

Comment: One commenter stated their concern that the ESRD QIP does not adequately account for the challenges faced by acute hospital-based programs that occasionally treat chronic patients. Commenter recommended that CMS reevaluate the exclusion criteria for ESRD QIP measures and exclude these facilities, because patients are already sicker when entering care at these facilities and will not remain there long enough for the patient's improvement to be attributed to the facility.

Response: We thank commenters for the recommendation. Some of our proposed measures, such as the SRR and STrR, do seek to address patient comorbidities through risk-adjustment. Other measures, such as the Dialysis Adequacy and Vascular Access Type measures, identify the types of patients who should be excluded as determined by available evidence. We welcome specific recommendations regarding new exclusion criteria for our measures, which we can address through our ongoing measure re-evaluation process.

Comment: One commenter recommended that when calculating all of the ESRD QIP measures, CMS should identify an alternative first ESRD service date for individuals who resume dialysis.

Response: We thank commenters for the recommendation. All measures in the ESRD QIP only include patients on dialysis, so an alternate first service date for those resuming dialysis would only potentially affect measures that exclude patients for some initial period. The original 90-day rule following beginning of ESRD was implemented to allow time for patients to stabilize and to ensure that a patient is a chronic dialysis patient (that is, did not receive temporary dialysis therapy). Currently, we use the Medical Evidence Form 2728 to capture the date of first dialysis in order to help determine patient exclusions for the Dialysis Adequacy and Hypercalcemia clinical measures. For future payment years, we will explore the appropriateness of using the date of return to regular dialysis for those individuals who resume dialysis after transplant for the Dialysis

Adequacy and hypercalcemia clinical measures.

For the STrR measure, time at risk begins at the start of the facility treatment period (starting with day 91 after onset of ESRD after a patient has been treated at the facility for 60 days) and continues until the earliest occurrence of the following: a Medicare claim indicating a diagnosis on the exclusions list, three days prior to a kidney transplant, death, end of facility treatment, or December 31 of the year. Upon discharge from a facility, the patient continues to be attributed to that facility for 60 days. Patients who resume dialysis after transplant resume time at risk once they have been back at a dialysis facility for 60 days. Therefore, we believe this recommendation may be of less concern for the STrR.

The SRR, the vascular access measures, the NHSN Bloodstream Infection measure, the ICH CAHPS measure, and the reporting measures in the ESRD QIP measure set do not have exclusion criteria related to the first ESRD service date and so are unaffected by the first ESRD service date.

Comment: Some commenters requested that CMS reevaluate the Hemodialysis Adequacy clinical measures' inclusion of patients who are treated at a facility at least twice in a month, because facilities experience difficulties in obtaining Kt/V measurements for patients receiving a small number of treatments during the time they are at the facility. Specifically, commenters recommended that instead of excluding patients seen at a facility two times or fewer in a month, the measure should exclude patients seen fewer than seven times. Commenter stated that it may not be possible for a facility to draw the blood needed to determine a Kt/V value if a patient is seen fewer than seven times in a month. Commenter further stated that 9.99 is reported on Medicare claims for patients receiving less than six treatments at a facility in a month, because patients receiving so few treatments may have changed modalities, received transplantation, or undergone long hospitalizations. Commenters also stated that it would be inappropriate for a facility to change a patient's hemodialysis prescription if the facility only treated the patient two times in a month. Commenter further stated that it is not possible to monitor patient conditions, modify treatment protocols, and evaluate the impact of such changes when patients are treated fewer than seven times in a month. Commenter recommended not including patient-months in the denominator if the Kt/V value reported on Medicare claims is 9.99, and that facilities should submit four months of claims for a patient before the patient is included in the measure.

Response: We disagree with commenters' assertion that that 9.99 is reported on claims for patients receiving six or fewer treatments per month. We note that this is inconsistent with the instructions in the Claims Processing Manual, which does not direct providers to use 9.99 for claims with fewer than seven treatments in the billing period, but instead provides the following guidance:

> ''Value Code D5—Result of last Kt/V reading. For in-center hemodialysis patients this is the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis this may be before the current billing period but should be within 4 months of the claim date of service.
>
> Hemodialysis: For in-center and home-hemodialysis patients prescribed for three or fewer treatments per week, the last Kt/V obtained during the month must be reported. Facilities must report single pool Kt/V using the preferred National Quality Forum (NQF) endorsed methods for deriving the single pool Kt/V value: Daugirdas II or Urea Kinetic Modeling (UKM). The reported Kt/V should not include residual renal function.
>
> A value of 8.88 shall be entered on the claim if the situation exists that a patient is prescribed and receiving greater than three hemodialysis treatments per week for a medically justified and documented clinical need. The 8.88 value is not to be used for patients who are receiving ''extra'' treatments for a temporary clinical need (for example, fluid overload). A medical justification must be submitted for patients receiving greater than 13 treatments per month.
>
> This code (D5) is effective and required on all ESRD claims with dates of service on or after July 1, 2010. In the event that no Kt/V reading was performed providers must report the D5 with a value of 9.99.''

Despite the fact that Medicare claims do not require facilities to report a Kt/V value of 9.99 on claims with fewer than seven times, we agree with commenters who stated that it is difficult to alter patients' Kt/V values if they are seen infrequently during a month. We also agree with commenters who stated that it is inappropriate for a facility to change a patient's hemodialysis prescription if the patient is typically treated at a different facility. For these reasons, beginning with the PY 2017 program, we will change the exclusion criteria of the Adult and Pediatric Hemodialysis Adequacy measures, such that patients treated at a facility fewer than seven times in a month are excluded from the measures for the month. This revision will appear in the finalized measure specifications for the PY 2017 and PY 2018 programs, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We also disagree that requiring that a patient be treated at a facility for four months before the patient is included in the measure is appropriate. As noted above, we are now requiring that a patient receive at least seven treatments at a facility during a month before being included in the Hemodialysis Adequacy measures for that month. We believe this modification sufficiently addresses commenters' concerns about facilities ability to impact patients' Kt/V levels when they only treat the patient a limited number of times.

C. Web Sites for Measure Specifications

In an effort to ensure that facilities and the general public are able to continue accessing the specifications for the measures that were proposed for and have been adopted in the ESRD QIP, we are now posting these measure specifications on a CMS Web site, instead of posting them on *www.dialysisreports.org* as we have in the past. Measure specifications from previous years, as well as those for the PY 2017 and PY 2018 programs, can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We did not receive any comments on this change.

D. Updating the NHSN Bloodstream Infection in Hemodialysis Outpatients Clinical Measure for the PY 2016 ESRD QIP and Future Payment Years

The NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure (that is, NHSN Bloodstream Infection clinical measure) that we adopted beginning with the PY 2016 ESRD QIP is based on NQF #1460. At the time we adopted it, the measure included a risk adjustment for patients' vascular access type but did not include any reliability adjustments to account for differences in the amount of exposure or opportunity for healthcare associated infections (HAIs) among patients. On April 4, 2014, in response to a measure update proposal submitted by CDC, NQF endorsed a reliability adjustment for volume of exposure and unmeasured variation across facilities to NQF #1460. This reliability adjustment is called the Reliability-Adjusted Standardized Infection Ratio or Adjusted Ranking Metric (ARM). As a result of this change to the NQF-endorsed measure specifications, a facility's performance on NQF #1460 can be adjusted towards the mean (that

is, facilities with low exposure volume can be adjusted more than facilities with high exposure volume, and the performance rate can be adjusted up or down depending on the facility estimate and mean) to account for the differences in the reliability of the infection estimates based on the number of patient-months at a facility and any unmeasured variation across facilities. Because the adjustment can be based on the volume of exposure, facility scores can be adjusted more if there are fewer patient-months in the denominator, and facility scores can be adjusted less if there are many patient-months in the denominator.

We proposed to adopt the same reliability adjustment for purposes of calculating facility performance on the NHSN Bloodstream Infection clinical measure, beginning with the PY 2016 ESRD QIP. We believe that the inclusion of this reliability adjustment, in addition to the risk factor adjustment, will enable us to better differentiate among facility performance on this measure, because it accounts not only for the variation in patient risk by vascular access type, but also for variation in the number of patients a facility treats in a given month. The ARM will be incorporated into the existing risk-adjustment methodology, which will also continue to include a risk adjustment for patient vascular access type. Further information about the reliability adjustment, and the NHSN Bloodstream Infection measure specifications can be found at *http://www.cdc.gov/nhsn/PDFs/dialysis/NHSN–ARM.pdf, http://www.cdc.gov/nhsn/dialysis/dialysis-event.html,* and *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on this proposal. The comments and our responses are set forth below:

Comment: One commenter supported the proposal to calculate the NHSN Bloodstream Infection measure with the Adjusted Ranking Metric because this adjustment ''will provide a more reliable SIR, and better reflect the differences in opportunity for HAI prevention in ESRD facilities.'' The commenter also recommended monitoring and ongoing assessment of this ranking.

Response: We thank the commenter for their support.

Comment: Some commenters did not support using the Adjusted Ranking Metric to calculate performance rates for the NHSN Bloodstream Infection measure because the public has not been provided with sufficient details about the adjustment's methodology to offer informed comments on the proposal, so the proposal does not meet the requirements of the Administrative Procedures Act. The commenter also stated that although NQF #1460 (the measure upon which the NHSN Bloodstream Infection measure is based) remains endorsed, even with the revised specifications to include the ARM adjustment, an NQF Steering Committee still has yet to review the revised specifications, and this has limited public scrutiny. Another commenter did not support the use of the Adjusted Ranking Metric in the NHSN Bloodstream Infection measure, because the adjustment imposes a rank order on facilities that is not appropriate for quality improvement and is not mandated by the Act.

Response: We have reviewed the information we made publicly available regarding the ARM methodology for the CY 2015 ESRD PPS comment period, and we agree with commenters that greater detail would have allowed commenters to more meaningfully analyze and comment on the proposed revision to the NHSN Bloodstream Infection clinical measure. Therefore, we are not finalizing the proposal to adopt the ARM reliability adjustment for purposes of calculating facility performance on the NHSN Bloodstream Infection clinical measure. Instead, facility performance on this measure will be calculated as finalized in the CY 2014 ESRD PPS final rule, using the Standardized Infection Ratio (78 FR 72204 through 72207).

Comment: One commenter did not support the adoption of the NHSN Bloodstream Infection clinical measure in the ESRD QIP because apparent differences in performance are actually an artifact of reporting practices. Accordingly, facilities that diligently monitor and report infections receive lower scores than those that do not, and this creates a perverse incentive for facilities to not report dialysis events to NHSN. As an alternative to including the NHSN Bloodstream Infection measure as a clinical measure, another commenter recommended including it as a reporting measure.

Response: We understand commenter's concern regarding differences in performance as an artifact of reporting practices, and agree that reporting rates in the NHSN Bloodstream Infection measure are subject to detection bias. This is one of the concerns that prompted us to propose the NHSN data validation study for the NHSN Bloodstream Infection clinical measure in CY 2015. In addition, CDC is working to assist facilities and groups to evaluate the quality of their submitted data, and we recognize that support for a more systematic means of assessing and ensuring data quality and completeness is needed. Because including a clinical measure on bloodstream infections will provide stronger incentives for facilities to monitor and reduce these infections, as compared to a reporting measure on the same topic, we continue to believe that it is essential to maintain the measure as a clinical measure.

Comment: Some commenters did not support the continuation of the NHSN Bloodstream Infection measure in the ESRD QIP, because sufficient information about how the measure is adjusted for access type is not available to the public.

Response: The specifications for the NHSN Bloodstream Infection in Hemodialysis Outpatients measure (NQF #1460) include the methodology used to stratify the NHSN Bloodstream Infection measure by vascular access type. These specifications include the following information about how the measure is adjusted for access type: ''Both the numerator and denominator are stratified by vascular access type since vascular access type is the single greatest risk factor for bloodstream infection in this population. The vascular access variables that are collected and included in this analysis are: Arteriovenous (AV) fistula, AV graft, other access device, tunneled central line, and nontunneled central line. If more than one access type is present in a patient, the bloodstream infection event is attributed to the access type with the greatest risk (that is, AV fistula < AV graft < other access device < tunneled central line < nontunneled central line). During denominator collection, the user is asked to count each patient as having only 1 vascular access type, following the algorithm described. During numerator collection, all vascular access types present at the time of the bloodstream infection event are reported and the algorithm is applied during analysis of the data.

This information appears on the specifications, which were posted at *http://www.cdc.gov/nhsn/nqf/* on August 12, 2014, have been available through the NQF Web site since the measure was endorsed in August 2011.

Comment: One commenter recommended that CMS and CDC consider adjusting the patient counting methodology for the NHSN Bloodstream Infection clinical measure such that all patients treated in the facility in a month are included in the patient count for that month, rather than the current

method, which includes only counts of patients that are in the unit on the first two treatment days of the month.

Response: CDC has conducted pilot validation work with a group of dialysis facilities and found that the census on the first two working days of the month was a satisfactory predictor of the entire month's patient treatment count. The alternative of counting denominator data on a daily basis has been required in inpatient settings, but was determined by CDC to be unacceptably burdensome for dialysis facilities conducting manual data collection.

Comment: Some commenters did not support the NSHN Bloodstream Infection measure as a clinical measure in PY 2016, because performance standards were not identified prior to the measure's expansion to a clinical measure.

Response: We appreciate the commenters' concerns about establishing values for the NHSN Bloodstream Infection clinical measure performance standards before the beginning of the PY 2016 performance period. However, we stated in the CY 2014 ESRD PPS Final Rule that we wanted to begin assessing facilities on the number of these events as soon as possible, rather than merely assessing whether facilities report these events, because of the abnormally large impact HAIs have upon patients and the healthcare industry. We believe these safety concerns justified the adoption of the NHSN Bloodstream Infection clinical measure before collecting all of the baseline data needed to apply the traditional achievement and improvement scoring methodologies. We also note that, in recognition of the fact that we would not initially be able to award improvement points to facilities, we set the minimum TPS low enough that a facility can meet it even if it receives zero achievement points on the NHSN Bloodstream Infection clinical measure, as long as it meets or exceeds the performance standard for each of the other finalized clinical measures.

Comment: One commenter did not support the continuation of the NHSN Bloodstream Infection measure in the ESRD QIP, because determining whether a positive blood culture is a true bloodstream infection is a subjective exercise.

Response: As stated in the CY 2015 ESRD PPS final rule, ''The NHSN Bloodstream Infection clinical measure is an objective measure based solely on the presence of a positive blood culture. Although NHSN collects information on access-relatedness to provide additional information that is of use for prevention purposes, the NHSN Bloodstream Infection clinical measure does not rely upon assessments of whether the bloodstream infection was access-related'' (78 FR 72207).

Comment: One commenter recommended modifying the NHSN Bloodstream Infection measure to focus on event-specific indicators, beginning with access-related bloodstream infections. Commenter stated that focusing on specific indicators would help facilities develop prevention plans and would be a more appropriate benchmark for assessing dialysis-related infections.

Response: We thank the commenter for their recommendation. As discussed in the CY 2014 ESRD PPS Final Rule (78 FR 72205), NQF endorsed a bloodstream infection measure (that is, NQF #1460, the measure upon which the NHSN Bloodstream Infection clinical measure is based) because positive blood cultures (the reported event under the bloodstream infection measure) can be objectively identified. Although the measure focuses on the presence of a positive blood culture, event-specific indicators (that is, counts and rates of access related bloodstream infections) are available in NHSN. Both CDC and CMS encourage facilities to review and utilize this data, together with overall bloodstream infection rates, for prevention purposes. As we continue to further develop and refine the measure, we may consider a greater focus on event-specific indicators (for example, access-relatedness) in the future.

Comment: Commenter recommended that CMS should require facilities to implement CDC's core interventions for dialysis bloodstream infection prevention, particularly interventions 7 and 8, which the commenter stated should be made into a clinical measure.

Response: We thank the commenter for their recommendation. As stated in the CY 2014 ESRD PPS final rule, ''We continue to encourage facilities to adopt all of CDC's core prevention interventions. However, they are not required under the ESRD QIP because we do not believe it is feasible at this time to design a performance measure that would accurately evaluate facility compliance'' (78 FR 72206).

For these reasons, we are not finalizing the proposal to adopt the ARM reliability adjustment for purposes of calculating facility performance on the NHSN Bloodstream Infection clinical measure. Instead, facility performance on this measure will be calculated as finalized in the CY 2014 ESRD PPS final rule, using the Standardized Infection Ratio (78 FR 72204–72207). The technical specifications for this finalized measure can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

E. Oral-Only Drug Measures in the ESRD QIP

Section 217(d) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, amends section 1881(h)(2) of the Act to require the Secretary, for PY 2016 and subsequent years, to adopt measures (outcome-based, to the extent feasible) in the ESRD QIP that are specific to the conditions treated with oral-only drugs. We believe that the Hypercalcemia clinical measure adopted beginning with the PY 2016 program (78 FR 72200 through 72203) meets this new statutory requirement because hypercalcemia is a condition that is treated with oral-only drugs. The Hypercalcemia clinical measure is not an outcome-based measure, and we have considered the possibility of adopting outcomes-based measures that pertain to conditions treated with oral-only drugs. However, we have determined that it is not feasible to propose to adopt an outcome-based measure on this topic at this time because we are not aware of any outcome measures developed on this topic.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: One commenter supported CMS's interpretation of the requirements of the Protecting Access to Medicare Act of 2014 (PAMA) to delay the adoption of measures (preferably outcomes-based) related to conditions treated by oral-only drugs.

Response: We appreciate the commenter's support, but clarify that PAMA requires that for 2016 and subsequent years, the measures included in the ESRD QIP include measures that are specific to the conditions treated with oral-only drugs, and that such measures, to the extent feasible, be outcome-based.

Comment: Some commenters stated that the Hypercalcemia measure does not meet the Protecting Access to Medicare Act of 2014 (PAMA) requirement for the ESRD QIP to include a measure ''specific to conditions treated with oral-only drugs.'' One commenter stated that it is not an effective measure for oral-only drugs because it is strongly influenced by parenteral vitamin D. Another commenter stated that current oral-only drugs are intended reduce elevated levels of parathyroid hormone and phosphorus, and that the Hypercalcemia

measure is not related to either condition. Commenters recommended that CMS adopt measures related to these conditions for adoption in the PY 2018 program, not the PY 2016 program, in accordance with the requirements of PAMA.

Response: While we do not agree with these comments, we recognize that we could, consistent with PAMA, adopt measures as late as for PY 2018 that are specific to the conditions treated with oral-only drugs. We will take these comments into account as we evaluate what measures, including the Hypercalcemia clinical measure, might satisfy this new statutory requirement in the future.

F. Requirements for the PY 2017 ESRD QIP

1. Revision to the Expanded ICH CAHPS Reporting Measure

For the ICH CAHPS reporting measure, we proposed one change to the reporting requirements finalized in the CY 2014 ESRD PPS Final Rule for PY 2017. In the CY 2014 ESRD PPS final rule, we finalized that facilities would be eligible to receive a score on the measure if they treated 30 or more survey-eligible patients during the performance period (78 FR 72220 through 72221). Subsequently, we were made aware that facilities may not know whether they will have enough survey-eligible patients during the performance period to be eligible for the ICH CAHPS measure when they are making decisions about whether or not they will contract with a vendor to administer the survey. We agree that it would be preferable if facilities knew at the beginning of the performance period if they will be eligible to receive a score on the ICH CAHPS measure, because this would allow facilities to make informed decisions about whether they should contract with a vendor to administer the survey. For this reason, we proposed that beginning with the PY 2017 program, facilities will be eligible to receive a score on the ICH CAHPS measure if they treat 30 or more survey-eligible patients during the ''eligibility period,'' which we define as the CY before the performance period. However, even if a facility is eligible to receive a score on the measure because it has treated at least 30 survey-eligible patients according to the ICH CAHPS Survey measure specifications during the calendar year prior to the performance period, we proposed that the facility will still not receive a score for performance during the performance period if it cannot collect 30 survey completes during the performance period. We believe that facilities should be able to determine quickly the number of survey-eligible patients that they treated during the eligibility period, and that reaching this determination should not impact facilities' ability to contract with a vender in time to meet the semiannual survey administration requirements. Technical specifications for the ICH CAHPS reporting measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Many commenters did not support the requirement to conduct the ICH CAHPS survey on a semiannual basis, because it is an unfunded mandate and does not provide facilities with sufficient time to make changes to the facility environment based on survey responses. Commenters also requested further evidence that a semiannual survey administration improves patient outcomes. For these reasons, some commenters requested that CMS reduce the ICH CAHPS survey to one administration per year, until it can be determined that survey fatigue does not result in lower ICH CAHPS scores. Other commenters recommended allowing facilities to coordinate with the Networks, such that the facilities field the survey once during the performance period, and the Networks field the survey a second time.

Response: Several options were considered for the frequency of administering the survey. A Technical Expert Panel that we convened suggested that quarterly administration was too frequent due to the low turnover in facilities. Annual collections might result in outdated information for public reporting and quality monitoring purposes as well as a decrease in respondent recall. By surveying twice a year, we capture a diverse range of patients within their care cycle, some fairly new patients along with others with more longevity on dialysis. With semiannual administration, facilities will learn first-hand about issues concerning the care offered and where there may be gaps in providing care to this vulnerable population.

Semiannual administration of the survey improves reliability of results that will be useful for quality improvement interventions. These more reliable results will lead to quality improvement and improve the patient experience.

Comment: Some commenters did not support the adoption of the ICH CAHPS measure in the ESRD QIP because the survey instrument consists of 58 core questions, and this is burdensome for patients, particularly if facilities are required to have the survey administered on a semiannual basis. In order to reduce the burden on patients, these commenters recommended allowing venders to administer only one of the survey's three domains to each patient in the sample.

Response: While we understand that the ICH CAHPS survey may be time consuming for some patients, we believe its value as a tool for assessing the patient's experience of care outweighs this concern. In-center hemodialysis patients spend up to 12 hours a week in treatment, and are therefore the best source of information about the quality of care provided in the facility. Furthermore, the protocol for the ICH CAHPS survey allows patients to receive assistance on the survey from family members or a caregiver not associated with the dialysis facility. In addition, we note that a patient need only answer 29 of the 58 core questions for the survey to be considered complete. Looking at results from the recent CMS Mode Experiment, less than 1 percent of the sampled patients submitted incomplete surveys. Anecdotally, we found that patients were eager to complete the survey, as evidenced by calls to the ICH CAHPS hotline upon receipt of the pre-notification letter regarding the survey administration.

Comment: Some commenters stated that the ICH CAHPS measure should not include homeless people, because vendors have trouble administering the survey to this population, and facilities are penalized for incomplete surveys.

Response: We are aware that it might be difficult to contact homeless persons to perform the ICH CAHPS survey; however, we are interested in ensuring that all patients, regardless of housing status, receive high quality care from the multidisciplinary team at their facility. We are particularly concerned about the needs of homeless patients because they may have different concerns than other patients that need to be addressed by the facility. We further note that under the ICH CAHPS survey administration and ESRD QIP scoring methodology, facilities are not penalized if they are either (1) unable to contact a patient for the survey administration, or (2) receive incomplete survey responses, provided that the survey vendor followed the administration protocol.

Comment: Some commenters stated that facilities should not be held accountable for low response rates when they do not have an opportunity to

review patient contact information used by survey vendors. One commenter also recommended increasing the minimum number of qualifying patients because small and rural facilities often have high non-response rates.

Response: As noted above, facilities with high non-response rates, regardless of their location or population size, are not penalized on the basis of their survey response rate. Instead, scores on the ICH CAHPS reporting measure are based on whether the facility administers the survey on a twice-yearly basis using a third-party, CMS-approved vendor and submits these survey results to CMS via that third-party vendor. We therefore disagree that high non-response rates for small and rural facilities justify increasing the minimum number of qualifying patients for this measure, and we note that doing so would effectively discount (for the purposes of the ESRD QIP) the experiences of a substantial number of patients. In addition, the ICH CAHPS survey administration specifications include methods of confirming that patient contact information is as up-to-date as possible. ICH CAHPS survey vendors are required to verify the contact information provided by the ICH CAHPS Coordination Team from CROWNWeb by using a commercial address update service. Survey vendors are permitted to ask facilities to provide updated addresses and telephone numbers for all patients they served during the sampling window. To maintain and protect the identity of the patients sampled, survey vendors cannot give the list of sample patients to the facility when they request updated patient addresses and contact information.

Comment: Some commenters stated that versions of the survey used for patients who do not speak English as their first language are mistranslated, particularly the Chinese version.

Response: We appreciate commenter's input regarding the translated versions of the ICH CAHPS survey. Recent corrections to the Chinese language versions of the ICH CAHPS survey have been made to reflect changes to the English version of the instrument. Our language specialists assure us that we are using translations which the majority of people speaking a given language will understand, but we are open to concerns and feedback about the translated versions of the ICH CAHPS survey. Please send any questions or comments to *ichcahps@rti.org.*

Comment: One commenter stated that the ICH CAHPS survey should be expanded to include all patients with ESRD, such as those who dialyze at home, instead of being restricted to in-center hemodialysis patients.

Response: We appreciate the commenter's recommendation that we develop additional questions or surveys intended to capture a larger proportion of the ESRD population. While the current survey is specific to in-center hemodialysis patients, we will look into opportunities to capture other patients, such as home hemodialysis and peritoneal dialysis patients, in the future.

Comment: One commenter sought clarification as to how many times a patient must be treated at a facility before he or she becomes eligible for the ICH CAHPS measure.

Response: Patient eligibility for the ICH CAHPS measure is not determined on the basis of a set number of treatments, but rather on the amount of time a patient is treated at a facility. Nevertheless, assuming that a typical hemodialysis patient receives three treatments per week, and given that a patient must be seen at a facility for three months to be eligible for the ICH CAHPS survey, an average survey-eligible patient will receive 36 treatments before becoming eligible for the measure.

Comment: One commenter was concerned that the ICH CAHPS survey is of limited use in the ESRD population, because its administration excludes patients who die or are too sick to complete the survey, and the survey does not ask patients about advance care planning. Commenter recommended CMS continue to work on the ICH CAHPS survey so that it provides more actionable information about whether the care patients receive is consistent with patients' goals.

Response: We understand commenter's concerns about the ICH CAHPS survey excluding patients who are deceased or physically or mentally incapable of completing the survey. We believe that in a patient experience of care survey, patients are most qualified to evaluate their experience. While we agree that those who are capable of completing the survey but require assistance to do so should receive the necessary assistance, we do not believe that a survey administered to a family member or proxy on behalf of a patient is a satisfactory substitute for patient input. Therefore, we do not believe it is appropriate to include patients who are deceased or are mentally or physically incapable of completing the survey in the ICH CAHPS survey at this time. We appreciate commenter's recommendation to modify or include new elements in the survey aimed at providing actionable information about whether a patient's care is consistent with the patient's goals for care, and will take this into consideration in the future.

For these reasons, we are finalizing the expanded ICH CAHPS reporting measure as proposed for the PY 2017 ESRD QIP and for future payment years. The technical specifications for this finalized measure can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.*

2. Measures for the PY 2017 ESRD QIP

a. PY 2016 Measures Continuing in PY 2017 and Future Payment Years

We previously finalized 11 measures in the CY 2014 ESRD PPS Final Rule for the PY 2016 ESRD QIP, and these measures are summarized in Table 19 below. In accordance with our policy to continue using measures unless we propose to remove or replace them (77 FR 67477), we will continue to use 10 of these 11 measures in the PY 2017 ESRD QIP. As we discuss in more detail below, we proposed to remove one measure, Hemoglobin Greater than 12 g/dL, beginning with the PY 2017 measure set (see Table 20 below).

TABLE 19—PY 2016 ESRD QIP MEASURES BEING CONTINUED IN PY 2017

NQF #	Measure title and description
0249	Hemodialysis Adequacy: Minimum delivered hemodialysis dose. Percent of hemodialysis patient-months with spKt/V greater than or equal to 1.2.
0318	Peritoneal Dialysis Adequacy: Delivered dose above minimum. Percent of peritoneal dialysis patient-months with spKt/V greater than or equal to 1.7 (dialytic + residual) during the four month study period.
1423	Pediatric Hemodialysis Adequacy: Minimum spKt/V. Percent of pediatric in-center hemodialysis patient-months with spKt/V greater than or equal to 1.2.

TABLE 19—PY 2016 ESRD QIP MEASURES BEING CONTINUED IN PY 2017—Continued

NQF #	Measure title and description
0257	Vascular Access Type: AV Fistula. Percentage of patient-months on hemodialysis during the last hemodialysis treatment of the month using an autogenous AV fistula with two needles.
0256	Vascular Access Type: Catheter ≥ 90 days. Percentage of patient-months for patients on hemodialysis during the last hemodialysis treatment of month with a catheter continuously for 90 days or longer prior to the last hemodialysis session.
N/A[1]	National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients. Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.
1454	Hypercalcemia. Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.
N/A[2]	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration. Facility administers, using a third-party CMS-approved vendor, the ICH CAHPS survey in accordance with survey specifications and submits survey results to CMS.
N/A[3]	Mineral Metabolism Reporting. Number of months for which facility reports serum phosphorus for each Medicare patient.
N/A	Anemia Management Reporting. Number of months for which facility reports ESA dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient.

[1] We note that this measure is based on a current NQF-endorsed bloodstream infection measure (NQF #1460).
[2] We note that a related measure utilizing the results of this survey has been NQF-endorsed (#0258). We are proposing to adopt NQF #0258 in the PY 2018 program.
[3] We note that this measure is based upon a current NQF-endorsed serum phosphorus measure (NQF #0255).

TABLE 20—MEASURE PROPOSED FOR REMOVAL BEGINNING WITH THE PY 2017 ESRD QIP

NQF #	Measure title
N/A	Anemia Management: Hgb >12 Percentage of Medicare patients with a mean hemoglobin value greater than 12 g/dL.

b. Policy for Determining When a Measure Is ''Topped-Out'' in the ESRD QIP, and the Removal of a Topped-Out Measure From the ESRD QIP, Beginning With PY 2017

In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized a list of seven criteria we would consider when making determinations about whether to remove or replace a measure:

''(1) measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made; (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative unintended consequences.''

In the CY 2014 ESRD PPS final rule (78 FR 72192), we stated that we were in the process of evaluating all of the ESRD QIP measures against the criteria. Subsequent to the publication of the CY 2014 ESRD PPS final rule, we completed our evaluation and determined that none of the measures finalized in the PY 2016 ESRD QIP met criteria 2 through 7, as listed above. With respect to the first criterion, we proposed to more specifically define when performance on a clinical measure is so high and unvarying that the measure no longer reflects meaningful distinctions in improvements or performance. The statistical definitions that we proposed to adopt will align our methodology with that used by the Hospital VBP program to determine when a measure is topped out (76 FR 26496 through 26497). Under this methodology, a clinical measure is considered to be topped out if national measure data show (1) statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) a truncated coefficient of variation (CV) of less than or equal to 0.1.

To determine whether a clinical measure is topped out, we initially focused on the top distribution of facility performance on each measure and noted if their 75th and 90th percentiles were statistically indistinguishable. Then, to ensure that we properly accounted for the entire distribution of scores, we analyzed the truncated coefficient of variation (CV) for each of the clinical measures.

The CV is a common statistic that expresses the standard deviation as a percentage of the sample mean in a way that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual facility scores, with large and presumably meaningful differences between hospitals in relative performance. A small CV would indicate that the distribution of individual facility scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual facility performance scores. We used a modified version of the CV, namely a truncated CV, for each clinical measure, in which the 5 percent of facilities with the lowest scores, and the 5 percent of facilities with the highest scores were first truncated (set aside) before calculating the CV. This was done to avoid undue effects of the highest and lowest outlier facilities; if included, they would tend to greatly widen the dispersion of the distribution and make the clinical measure appear to be more reliable or discerning. For example, a clinical measure for which most facility scores are tightly clustered around the mean value (a small CV) might actually reflect a more robust dispersion if there were also a number of facilities with extreme outlier values, which would greatly increase the perceived variance in the measure. Accordingly, the

truncated CV of less than or equal to 0.10 was added as a criterion for determining whether a clinical measure is topped out.

We evaluated each of the clinical measures finalized in the PY 2016 ESRD QIP against these proposed statistical conditions. The full analysis is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* The results of that analysis appear below in Table 21.

TABLE 21—PY 2016 CLINICAL MEASURES USING CROWNWEB AND MEDICARE CLAIMS DATA FROM JANUARY 2013–DECEMBER 2013

Measure	N	75th percentile	90th percentile	Std. error	Statistically indistinguishable	Truncated CV	TCV <0.10
Adult HD Kt/V	5665	96.1	97.4	0.13	No	0.04	Yes.
Adult PD Kt/V	1176	92.9	94.8	0.55	No	0.15	No.
Pediatric HD Kt/V	10	94.5	97.1	2.71	Yes	0.08	Yes.
Hgb >12	5521	0.0	0.0	0.02	Yes	<0.01	Yes.
Fistula Use	5561	72.3	77.0	0.16	No	0.14	No.
Catheter Use	5586	5.9	2.8	0.10	No	≤0.01	Yes.
Hypercalcemia	5685	0.3	0.0	0.04	No	≤0.01	Yes.

As the information presented in Table 21 suggests, the Hemoglobin Greater than 12 g/dL measure meets the proposed criteria for determining when a clinical measure is topped-out in the ESRD QIP. Accordingly, we proposed to remove the Hemoglobin Greater than 12 g/dL measure from the ESRD QIP, beginning with the PY 2017 program. We recognize that the Pediatric Hemodialysis Adequacy measure also meets the conditions for being a topped-out clinical measure in the ESRD QIP. However, we did not propose to remove the Pediatric Hemodialysis Adequacy measure from the ESRD QIP because we determined that removing the measure will not be useful for dialysis facilities. There are currently very few measures available that focus on the care furnished to pediatric patients with ESRD, and we are reticent to remove a measure that addresses the unique needs of this population. In addition, although only 10 facilities were eligible to receive a score on the Pediatric Hemodialysis Adequacy measure (based on CY 2013 data), we believe that the publicly reported performance of these facilities can influence the standard of care furnished by other facilities that treat pediatric patients, even if a facility does not treat a sufficient number of pediatric patients to be eligible to be scored on the measure.

For these reasons, we believe that the drawbacks of removing a topped out clinical measure could be outweighed by the other benefits to retaining the measure. Accordingly, we proposed that even if we determine that a clinical measure is topped out according to the statistical criteria we apply, we would not remove or replace it if we determine that its continued inclusion in the ESRD QIP measure set will continue to set a high standard of care for dialysis facilities.

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: One commenter supported removal of the Hemoglobin Greater than 12 g/dL clinical measure, because there is little variation in facilities' performance. The commenter additionally supported this proposal ''because under the PPS, facilities no longer have an incentive to overuse erythropoietin stimulating agents.'' Several commenters recommended continuing to publicly report facility scores to ensure that patients' hemoglobin levels are properly monitored.

Response: We thank the commenters for the support. We further note that the Dialysis Facility Compare program will continue to publically report facility scores on the Hemoglobin Greater than 12 g/dL measure, and that this will help ensure that patients' hemoglobin levels are properly monitored.

Comment: Some commenters did not support the proposal to remove the Hemoglobin >12 g/dL clinical measure from the ESRD QIP, because the measure is clinically important, and removing this measure could lead to a lapse in anemia monitoring in this patient population. One commenter recommended that CMS keep the Hemoglobin >12 g/dL clinical measure, but reduce its weight for QIP scoring purposes in order to maintain facilities' focus on anemia management while decreasing this measure's impact on facility scores.

Response: We agree that maintaining patients' hemoglobin levels below 12 g/dL is clinically important. For this reason, the Dialysis Facility Compare program will continue to publically report facility scores on the Hemoglobin Greater than 12 g/dL measure, and we believe that this will help ensure that patients' hemoglobin levels are properly monitored. Nevertheless, based on the statistical criteria for determining when a measure is topped out in the ESRD QIP, we have determined that performance on this measure is so high and unvarying that meaning distinctions in facility performance cannot be made. Accordingly, we do not believe it is appropriate to use the measure in a value-based purchasing program, such as the ESRD QIP, because the measure is not an effective tool for incentivizing facilities to further improve the quality of care provided to patients with ESRD.

Comment: One commenter recommended that CMS reevaluate the Hemoglobin >12 g/dL clinical measure, because it does not account for the differences in ''average'' hemoglobin levels among dialysis patients of different ages, genders, and overall health. For example, the commenter stated that while a hemoglobin of 12–14 g/dL is ''normal'' for women, the range for men is 14–18 g/dL, and that male patients may be denied access to treatments that would raise their hemoglobin levels to ''normal'' because their facility is concerned about its score on the hemoglobin >12 g/dL clinical measure.

Response: We appreciate the commenter's input and note that we are removing the Hemoglobin Greater than 12 g/dL clinical measure from the ESRD QIP beginning in the PY 2017 program. However, we will consider the commenter's recommendation as we continue to evaluate the use of the measure in other CMS ESRD quality programs, such as Dialysis Facility Compare.

Comment: One commenter sought clarification as to whether the Anemia Management reporting measure is sufficient to meet CMS's statutory requirements regarding measures on

anemia management if CMS chooses to remove the Hemoglobin >12 g/dL clinical measure from the ESRD QIP.

Response: Based on the FDA's evolving position on ESAs, we believe the Anemia Management reporting measure meets the statutory mandate to include such measures in the ESRD QIP. The FDA labeling for ESAs previously included a hemoglobin level target range of 10 to 12 g/dL for chronic kidney disease patients. In 2011, the FDA released a modified drug recommendation for the use of ESAs in chronic kidney disease patients, removing these hard cutoffs and replacing them with more generalized guidance to ''individualize dosing and use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions.'' We therefore believe the Anemia Management reporting measure's requirement that providers report ESA dosages, rather than prescribing a course of action, aligns with the current FDA labeling regarding ESA usage. Additionally, we note that the STrR clinical measure, finalized for the PY 2018 ESRD QIP, meets the statutory requirement for measures on anemia management.

Comment: One commenter did not support the proposal to remove the Hemoglobin >12 g/dL clinical measure from the ESRD QIP, because its removal and the inclusion of the proposed Standardized Transfusion Ratio may lead facilities to revert to higher ESA doses in an effort to avoid transfusions.

Response: Evidence currently suggests that ESA doses have declined sharply since 2011, due in large part to the FDA label change for ESAs. Since that time, the Hemoglobin Greater than 12 g/dL clinical measure has become topped out as fewer patients have hemoglobin levels that exceed 12 g/dL, and we believe that current payment incentives (i.e., the inclusion of ESAs in the ESRD PPS) will minimize the risk of excessive utilization of ESAs. However, we intend to continue monitoring hemoglobin levels through the Anemia Management reporting measure and the Dialysis Facility Compare program.

Comment: Many commenters supported the proposed statistical criteria for determining when a measure is topped-out in the ESRD QIP. However, one commenter recommended modifying the criteria used to determine when to remove a measure from the ESRD QIP, and further recommended that a measure should not be removed from the program if the measure uniquely ''addresses the needs of a specific population within the ESRD program.'' Another commenter supported the statistical criteria, but also recommended that CMS should consider lowering the thresholds for determining when a measure is topped out.

Response: We agree with commenters that a measure should not be removed from the ESRD QIP if it uniquely addresses the needs of a specific population within the ESRD population. We are finalizing the proposed statistical criteria for determining that a measure is topped-out and should be removed from the ESRD QIP. However, for the reasons explained below, we are not finalizing our proposal to retain a clinical measure that is statistically topped-out if we determine that its continued inclusion in the ESRD QIP measure set will continue to set a high standard of care for dialysis facilities. Instead, based on comments received, we are finalizing a policy that allows us to retain a topped-out clinical measure if it addresses the unique needs of a subset of the ESRD population, because we believe that this criterion is clearer and more transparent than the one proposed. Additionally, we agree with the commenter that statistically topped out measures should be retained in the ESRD QIP measure set if they address the unique needs of a subset of the ESRD population, because we believe that the drawbacks associated with scoring a topped out measure are less significant than the benefits of including as many subsets of the ESRD population as possible.

Comment: One commenter sought clarification as to why CMS is not proposing to remove the Pediatric Hemodialysis Adequacy measure, despite the fact that it meets the statistical criteria for being a topped-out measure in the ESRD QIP.

Response: We originally proposed to retain the Pediatric Hemodialysis Adequacy clinical measure for two reasons: (1) There are few measures available that focus on the care furnished to pediatric patients; and (2) we believed that the small number of facilities that are eligible to receive a score on the measure should properly set a standard of care for all facilities treating pediatric hemodialysis patients, even if these other facilities are not eligible to a receive a score on the measure. As explained above, and based on public comments, we are not finalizing a policy that would allow us to retain a topped-out clinical measure on the basis that its continued inclusion in the ESRD QIP measure set will continue to set a high standard of care for dialysis facilities, because we agree with the commenter that this standard may be difficult to apply.

Comment: Commenter did not support the use of the first statistical criterion for determining when a measure is topped out in the ESRD QIP, because in a sample size of roughly 5600 facilities, measure scores will appear to be statistically indistinguishable, even though the truncated coefficient of variation is less than 0.1.

Response: The two proposed statistical criteria were selected to create alignments between the ESRD QIP and other CMS quality-reporting and VBP programs, such as the Hospital Inpatient Quality Reporting program, the Hospital VBP program, and the Hospital Outpatient Quality Reporting program. We recognize that using both of the statistical criteria instead of just the second (that is, truncated coefficient of variation is less than 0.1) raises the threshold a measure must reach before it is considered topped out. Nevertheless, we believe that this elevated threshold appropriately differentiates topped-out measures from measures that reliably distinguish facility performance, whereas the use of only the second criterion would inaccurately classify reliable measures as being topped out.

Comment: Commenter stated that there is little room for facilities to improve on the dialysis adequacy measures. For this reason, commenter recommended that the adequacy measures should be removed from the ESRD QIP, and that performance on these measures should be monitored through other means.

Response: As illustrated in Table 21 above, the Adult Hemodialysis and the Adult Peritoneal Adequacy measures do not meet the statistical criteria for being a topped out measure in the ESRD QIP. Although performance rates are high overall, there is still room for facility improvement on the measures, and we therefore do not think it is appropriate to remove the measures from the ESRD QIP. As explained above, even though the Pediatric Hemodialysis Adequacy measure meets the statistical criteria for being a topped out measure in the ESRD QIP, we have decided not to remove it because it addresses the unique needs of a specific subset of the ESRD population.

For these reasons, we are finalizing the removal of the Hemoglobin Greater than 12 g/dL measure from the ESRD QIP, beginning with the PY 2017 program. We are also finalizing as proposed the statistical criteria for determining when a measure is topped out in the ESRD QIP. We are not finalizing our proposal to retain a clinical measure that is statistically

topped-out if we determine that its continued inclusion in the ESRD QIP measure set will continue to set a high standard of care for dialysis facilities. Instead, we are finalizing that we will not remove a statistically topped-out measure if the measure addresses the unique needs of a specific subset of the ESRD population.

c. New Measures for PY 2017 and Future Payment Years

As the program evolves, we believe it is important to continue to evaluate and expand the measures selected for the ESRD QIP. Therefore, for the PY 2017 ESRD QIP and future payment years, we proposed to adopt one new clinical measure that addresses care coordination (see Table 22).

TABLE 22—NEW MEASURE PROPOSED FOR THE PY 2017 ESRD QIP

NQF #	Measure title
N/A [1]	Standardized Readmission Ratio, a clinical measure. Risk-adjusted standardized hospital readmissions ratio.

[1] We note that this measure is currently under review at NQF.

i. Standardized Readmission Ratio (SRR) Clinical Measure

Background

At the end of 2011, 615,899 patients were being dialyzed, 115,643 of whom were new (incident) patients with ESRD.[5] The SRR measure assesses the rate of unplanned readmissions of ESRD patients to an acute care hospital within 30 days of an index discharge from an acute care hospital, thereby identifying potentially poor or incomplete quality of care in the dialysis facility. In addition, the SRR reflects an aspect of ESRD care that is especially resource-intensive. In 2011, the total amount paid by Medicare for the ESRD program was approximately $34.3 billion, a 5.4 percent increase from 2010.[2] In particular, Medicare paid more than $10.5 billion for costs associated with hospitalized ESRD patients in 2011. In 2011, ESRD dialysis patients were admitted to the hospital twice on average, and spent an average of 12 total days in the hospital over the year, accounting for approximately 38 percent of Medicare expenditures for patients with ESRD.[2] Furthermore, a substantial percentage (30 percent) of ESRD patients discharged from the hospital have an unplanned readmission within 30 days.[2] In the non-ESRD population, clinical studies have demonstrated that improved care coordination and discharge planning may reduce readmission rates. The literature also reports a wide range of estimates of the percentage of readmissions that may be preventable. One literature review of more than 30 studies found the median proportion of readmissions that may be preventable was 27%, with a range of 5% to 79%.[6] Preventability varied widely across diagnoses. Readmissions were more likely to be preventable in patients with more severe conditions. Therefore, a systematic measure on unplanned readmissions is essential for controlling escalating medical costs; it can identify where readmission rates are unusually high, and help facilities to provide cost-effective healthcare.

Overview of Measure

The SRR is a one-year risk-standardized measure of a facility's 30-day, all-cause rate of unplanned hospital readmissions among Medicare-covered ESRD dialysis patients. The number of expected readmissions is determined by a risk-adjustment model that accounts for the hospital where the index discharge took place, certain patient characteristics (including age, sex, and comorbidities), and the national median expected performance for all dialysis facilities, given the same patient case mix.

We proposed to adopt the SRR measure currently under review by NQF (NQF #2496). Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iv) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (that entity currently is NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, 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, so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We have given due consideration to endorsed measures, as well as those adopted by a consensus organization, and we are proposing this measure under the authority of 1881(h)(2)(B)(ii) of the Act. Although the NQF has endorsed an all-cause hospital readmission measure (NQF #1789), we did not believe it was feasible to adopt this measure in the ESRD QIP because NQF #1789 is specified for use in hospitals, not dialysis facilities. In addition, NQF #1789 is intended to evaluate readmissions across all patient types, whereas the proposed SRR measure is specified for the unique population of ESRD dialysis patients, which have a different risk profile than the general population captured in NQF #1789. Because the proposed SRR measure has been developed specifically for the dialysis-facility setting, and because the measure has the potential to improve clinical practice and decrease healthcare costs, we believe it is appropriate to adopt the SRR in the ESRD QIP at this time.

We have analyzed the measure's reliability, the results of which are provided below and in greater detail in the SRR Measure Methodology report, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* The Inter-Unit Reliability (IUR) was calculated for the proposed SRR using data from 2012 and a ''bootstrap'' approach, which uses a resampling scheme to estimate the within-facility variation that cannot be directly estimated by the analysis of variance (ANOVA). The SRRs that we calculated for purposes of this analysis were for dialysis facilities that had at least 11 patients who had been discharged from a hospital during 2012. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by ''random noise,'' indicating the measure would not be a

[5] United States Renal Data System, USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2013.

[6] van Walraven C, Bennett C, Jennings A, Austin PC, Forster AJ. Proportion of hospital readmissions deemed avoidable: a systematic review. CMAJ. 2011; 183(7): E391–E402.

reliable characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real differences between facilities. The IUR for the proposed SRR measure was found to be 0.49, indicating that about one-half of the variation in the SRR can be attributed to between-facility differences, and about half to within-facility variation. This value of IUR indicates that an average-size facility would achieve a moderate degree of reliability for this measure. This level of reliability is consistent with the reliability of other outcome measures in CMS quality-reporting and VBP programs, such as the 30-day Risk-Standardized All-Cause Acute Myocardial Infarction, Heart Failure, and Pneumonia Readmission and Mortality measures used in the Hospital IQR and VBP Programs. We therefore believe that facilities can be reliably scored on the proposed SRR measure.

We convened a technical expert panel (TEP) in May 2012 for the purpose of evaluating this measure, but the TEP did not reach a final consensus and declined to support the measure. Some members of the TEP were concerned that we did not risk-adjust for the nephrologist treating the patients, because actions taken by nephrologists can impact readmission rates. After reviewing the TEP's arguments, we determined that the suggested risk adjustment for nephrologist care would constitute a reversal of CMS policy not to risk adjust for factors related to care for which the provider is responsible. We do not think that it is appropriate to risk-adjust the measure for the nephrologist because the nephrologist is part of the facility's multi-disciplinary team, and medical directors, as employees of the dialysis facilities, are responsible for ensuring that appropriate care is provided by a multi-disciplinary team. The Measures Application Partnership reviewed this measure in February 2013 and supported the direction of the measure, advising CMS that the measure would require additional development prior to implementation. Subsequently, we released draft specifications for the measure to the public for a 30-day comment period and, based on comments received, finalized measure specifications in September 2013. We also, on a voluntary basis, provided individual dialysis facilities with a facility-specific report that calculated their SRR measure results and compared those results to SRR measure results at the state and national level, as well as discharge-level data upon request. Facilities also had an opportunity to submit questions to CMS regarding the measure and their reports. We therefore believe that the proposed SRR measure risk-adjusts appropriately for patient condition and comorbidities at the start of care for which the facility is not responsible. We also believe that the measure is ready for adoption because, as explained above, it achieves a moderate degree of reliability.

Data Sources

The data we will use to calculate the proposed SRR measure come from various CMS-maintained data sources for ESRD patients including the CROWNWeb database, the CMS Annual Facility Survey (Form CMS–2744), Medicare claims, the CMS Medical Evidence Form (Form CMS–2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS–2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. These data sources include all Medicare-covered patients with ESRD. Information on hospitalizations is obtained from Medicare Inpatient Claims Standard Analysis Files (SAFs) and past-year comorbidity is obtained from Medicare Claims SAFs (inpatient, outpatient, physician/supplier, home health, hospice, and skilled nursing facility claims).

Outcome

The outcome for this measure is 30-day all-cause, unplanned readmission defined as a hospital readmission for any cause beginning within 30 days of the discharge date of an index discharge, with the exclusion of planned readmissions. This 30-day readmission period is consistent with other publicly reported readmission measures endorsed by NQF and currently implemented in the Hospital Inpatient Quality Reporting Program and Hospital Readmission Reduction Program, and reflects an industry standard.

Cohort

All discharges of Medicare ESRD dialysis patients from an acute care hospital in a calendar year are considered eligible for this measure, with the exception of the exclusions listed in the next section.

Inclusion and Exclusion Criteria

The proposed SRR measure excludes from the measure cohort hospitalizations: (1) Where the patient died during the index hospitalization; (2) where the patient dies within 30 days of the index discharge with no readmission; (3) where the patient is discharged against medical advice; (4) where the patient was admitted with a primary diagnosis of certain conditions related to cancers, mental health conditions, or rehabilitation procedures (because these patients possess radically different risk profiles, and therefore cannot reasonably be compared to other patients discharged from hospitals); (5) where the patient is discharged from a PPS-exempt cancer hospital (because these hospitals care for a unique population of patients that cannot reasonably be compared to the patients admitted to other hospitals); (6) where the patient is transferred to another acute care hospital; and (7) where the patient has already been discharged 12 times during the same calendar year (to respond to concerns raised by the TEP that patients who are hospitalized this frequently during a calendar year could unduly skew the measure rates for small facilities).

Risk Adjustment

The measure adjusts for differences across facilities with regard to their patient case mix. Consistent with NQF guidelines, the model does not adjust for socioeconomic status or race, because risk adjusting for these characteristics would hold facilities with a large proportion of patients who are minorities and/or who have low socioeconomic status to a different standard of care than other facilities. One goal of this measure is to illuminate quality differences that such risk adjustment would obscure. As with the Hospital-Wide Readmission measure employed by the Hospital Readmissions Reduction program, the SRR employs a hierarchical logistic regression model to estimate the expected number of readmissions to an acute care hospital, taking into account the performance of all dialysis facilities, the discharging hospital, and the facility's patient case-mix.

Although the SRR risk-adjustment model is generally aligned with the Hospital-Wide Readmission measure risk-adjustment methodology, we proposed to modify it to account for comorbidities and patient characteristics relevant to the ESRD population. The proposed SRR measure includes the following patient characteristics as risk adjustors, which are obtained from the following data sources:

Risk adjustor	Data source
Sex	CMS Form 2728.
Age	REMIS database.
Years on ESRD	CMS Form 2728.
Diabetes as cause of ESRD	CMS Form 2728.
BMI at incidence of ESRD	CMS Form 2728.
Days hospitalized during index admission	Part A Medicare Inpatient Claims SAFs.
23 past-year comorbidities (for example, cardiorespiratory failure/shock; drug and alcohol disorders)..	Medicare Claims SAFs: Part A Inpatient, home health, hospice, and skilled nursing facility; and Part B Outpatient.
Discharged with any of 11 high-risk conditions (for example, cystic fibrosis, and hepatitis).	Part A Medicare Inpatient Claims SAFs.

More details on the risk-adjustment calculations, and the rationale for selecting these risk adjustors and not others, can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.* We proposed to risk adjust the proposed SRR measure based on sex, because we have determined that patients' sex affects the measure in ways that are beyond the control of dialysis facilities. We reached this determination by examining the effects of the risk adjusters, both independently and in combination, on rates of unplanned readmissions. This analysis yielded two conclusions. First, the analysis indicated that females are generally more likely than males to experience an unplanned readmission, even when accounting for the other risk adjustors. Second, the disparate effects of gender were substantially impacted by the effects of age: Females aged 15 to 45 were much more likely to experience an unplanned readmission than males of the same age, but this disparity was significantly reduced for men and women younger than 15 and older than 45. Based on these two conclusions, we believe that women in the 15–45 age range face a greater risk of experiencing an unplanned readmission, as compared to men of the same age with similar risk profiles. This does not appear to be a consequence of facility performance, however, because the disparity is not generally applicable to women, but only to a limited age group. We therefore believe it is essential to risk-adjust for sex to ensure that facilities with larger numbers of women aged 15 to 45 are not inappropriately disadvantaged, because not risk-adjusting for sex would potentially incentivize facilities to deny access to these individuals.

As indicated in the table above, the measure is risk-adjusted, in part, based on 23 comorbidities that develop in the year prior to the index hospitalization, as well as 11 high-risk conditions that are present at the time of the index discharge. These data are taken from Medicare claims submitted by hospitals, dialysis facilities, and other types of long-term and post-acute care facilities.

We believe that this proposed approach to risk-adjusting the SRR measure is consistent with NQF guidelines for measure developers. NQF evaluates measures on the basis of four criteria: Importance, scientific acceptability, feasibility, and usability. The validity and reliability of a measure's risk-adjustment calculations fall under the ''scientific acceptability'' criterion, and Measure Evaluation Criterion 2b4 specifies NQF's preferred approach for risk-adjusting outcome measures (*http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx#scientific*). This criterion states that patient comorbidities should only be included in risk-adjustment calculations if they are (1) present at the start of care and (2) not indicative of disparities or deficiencies in the quality of care provided. As indicated in the ''Inclusion and Exclusion Criteria'' subsection above, as well as the measure specifications that are currently under review at NQF, the start of care is defined as the index hospitalization. Accordingly, we believe that NQF Measure Evaluation Criterion 2b4 supports risk adjusting the proposed SRR measure on the basis of patient comorbidity data collected in the year prior to the index hospitalization, because these comorbidities are likely present at the start of care (that is, the date(s) that the patient spends in the hospital during the index hospitalization). For these reasons, we believe that the risk-adjustment methodology for the proposed SRR measure is consistent with NQF guidelines for measure developers and is appropriate for this measure.

Full documentation of the SRR risk-adjustment methodology is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

Calculating the SRR Measure

The SRR measure is calculated as the ratio of the number of observed unplanned readmissions to the number of expected unplanned readmissions. Facilities that have more unplanned readmissions than would be expected for an average facility with a similar case-mix would have a ratio greater than one. Facilities having fewer unplanned readmissions than would be expected for an average facility with a similar case mix would have a ratio less than one. This ratio calculation is consistent with that employed by one NQF-endorsed outcome measure for ESRD, the Standardized Hospitalization Ratio (NQF #1463).

Hospitalizations are counted as events in the numerator if they meet the definition of unplanned readmission—which is that they (a) occurred within 30 days of the index discharge and (b) are not preceded by a ''planned'' readmission that also occurred within 30 days of the index discharge. Planned readmissions are defined as readmissions that do not bear on the quality of care furnished by the dialysis facility, that occur as a part of ongoing appropriate care of patients, or that involve elective care. Building on the algorithm developed for the Hospital-Wide Readmission measure (NQF #1789), the proposed planned readmission list incorporates minor changes appropriate to the ESRD population as suggested by technical experts. The full planned readmission list and algorithm are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* In general, a readmission is considered ''planned'' under two scenarios.

1. The patient undergoes a procedure that is always considered planned (example, bone marrow transplant) or has a primary diagnosis that always indicates the hospitalization is planned (for example, maintenance chemotherapy).

2. The patient undergoes a procedure that *may* be considered planned if it is not accompanied by an acute diagnosis. For example, a hospitalization involving a heart-valve procedure accompanied by

a primary diagnosis of acute myocardial infraction would be considered unplanned, whereas a hospitalization involving a heart-valve procedure accompanied by a primary diagnosis of diabetes would be considered planned (because acute myocardial infraction is a plausible alternative acute indication for hospitalization).

The expected number of readmissions is calculated using hierarchical logistic modeling (HLM). This approach accounts for the hospital from which the patient was discharged and the patient case mix (as defined by factors such as age, sex, and patient comorbidities), as well as the national median performance of all dialysis facilities. The HLM is an appropriate statistical approach to measuring quality based on patient outcomes when patients are clustered within facilities (and therefore the patients' outcomes are not statistically independent), and when the number of qualifying patients for the measure varies from facility to facility. The HLM approach is also currently used to calculate readmission and mortality measures that are used in several quality-reporting and VBP programs by CMS, such as the Heart Failure and Pneumonia Mortality measures in the Hospital IQR and Hospital VBP Programs.

The proposed SRR measure is a point estimate—the best estimate of a facility's readmission rate based on the facility's case mix. For more information on the proposed calculation methodology, please refer to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: One commenter supported the proposal to adopt the Standardized Readmission Ratio clinical measure, because ''hospital readmissions may be an indicator of poor access to follow-up primary care or missed opportunities for inpatient and ambulatory care providers to better coordinate care.''

Response: We thank the commenter for the support.

Comment: Some commenters did not support the proposal to adopt the SRR measure because it could harm patients. Specifically, commenters stated that the measure could lead facilities to deny care to high-risk populations, particularly in urban settings where patients have more than one option for dialysis treatment. One commenter further stated that the measure's risk-adjustment methodology will not completely remove this incentive to ''cherry-pick'' patients, which would be detrimental to patient health and waste healthcare resources. Commenter was also concerned that facilities may delay needed hospital admissions if the SRR measure were to be adopted in the ESRD QIP.

Response: We agree that the concern for unintended consequences is a serious one with outcome measures. Access to care is particularly important and we continue to seek ways to ensure that access is unabated. This is part of the reason we proposed to adopt the SRR measure, which incorporates a risk-adjustment methodology that levels the playing field for facilities with different case-mixes and counters the incentive for cherry-picking patients. We also have the capacity to monitor and evaluate for some types of unintended consequences. For example, we currently assess rates of mortality at the facility level in the Dialysis Facility Compare program. This is an approach similar to that used on Hospital Compare, which publicly reports both mortality and readmissions rates for hospitals. In general, we note that mortality and readmission rates are positively correlated among dialysis facilities and in other settings, suggesting that reducing readmissions does not create increased risk to patients through ''cherry-picking''. We also note that similar measures have been implemented in other post-acute care settings for quality reporting and value-based purchasing, including long-term care hospitals, inpatient rehabilitation facilities, and nursing homes. The SRR risk adjustment is consistent with these measures. We intend to monitor whether the implementation of this measure leads to unintended consequences.

Comment: Many commenters did not support the proposal to adopt the SRR measure because it is not a fair way to evaluate facility performance. Specifically, commenters stated that unplanned readmissions are beyond the control of dialysis facilities, and that cultural factors can make patients noncompliant with treatment protocols, leading to hospital admissions.

Response: We disagree with assertion that unplanned readmissions are beyond the control of dialysis facilities. While the causes of readmissions are multifactorial, our analyses support that the facility exerts an influence on readmissions roughly equivalent to that exerted by the discharging acute care hospital. We believe that coordination of care requires interaction between multiple providers, including those discharging the patient, and those continuing patient care following discharge. While cultural factors and patient noncompliance can lead to hospital admissions, this is no less true for the acute care hospitals, long-term care hospitals, inpatient rehabilitation facilities, nursing homes, and home health agencies, and it does not negate the deleterious consequences readmissions can have for those patients.

Comment: Some commenters stated that facilities are typically not notified when a patient is discharged from a hospital, that many patients are discharged from and readmitted to a hospital before they return to their dialysis facility. Commenters also stated that facilities cannot compel nephrologists to see patient immediately after the patients are discharged from a hospital. Commenters recommended that patients with a readmission within one to five days of an index discharge should be excluded from the measure, because facilities typically do not have a chance to see these patients before they are readmitted to a hospital, and 17 percent of hospitalized patients with ESRD are readmitted to a hospital within three days of the index discharge.

Response: We recognize that a disproportionate number of readmissions may occur during the days immediately following discharge. We believe this reflects an important opportunity for quality improvement that may be missed if these readmissions are excluded from the readmission measure. While it is true that several days may pass between discharge and a patient's first regularly scheduled appointment at a dialysis facility, we submit that if this pattern of practice results in excessive levels of readmissions, then it represents a failure to successfully manage a patient's care from the acute to non-acute setting. Additionally, under the Conditions for Coverage, a dialysis facility must have a medical director whose responsibilities include a quality assessment and improvement program (CfC § 494.150). Therefore, facilities can compel nephrologists to see a patient immediately after the patients are discharged from the hospital, because improving on quality issues, such as care coordination, is part of the medical director's responsibilities.

Comment: Many commenters stated that facilities should not be placed in the position of managing comorbid conditions that typically accompany ESRD, and commenters preferred a measure that was limited to readmissions that are related to ESRD and dialysis. Commenters stated that the measure should be limited to

readmissions associated with ESRD (as opposed to focusing on all readmissions, irrespective of cause), because the majority of readmissions for patients with ESRD are not attributable to diagnoses related to ESRD and dialysis, and this could penalize facilities for readmissions beyond their scope of control. One commenter stated it may be difficult to distinguish readmissions related to dialysis and ESRD from those that are not, so the commenter recommended addressing this issue with further adjustments to the measure's statistical models, and by adding additional adjustments for case mix.

Response: A Technical Expert Panel (TEP) that we convened for the purpose of developing this measure considered the issue of whether dialysis facility readmission measures should be all-cause, or limited to a specific set of readmissions related to ESRD and dialysis. The TEP concluded that an all-cause measure was appropriate for the SRR because it could not come to a consensus of what specific causes for readmissions did or did not fall within the control of dialysis facilities or could be considered to be related to ESRD and dialysis. This approach is consistent with readmission measures implemented for other quality programs, and is augmented using a planned readmissions algorithm that excludes readmissions identified as having been planned, with the rationale that such readmissions do not reflect poor quality of care. This algorithm was originally developed for hospital readmissions measures, and has been adapted for use in the dialysis facility setting, as well as nursing homes, home health agencies, inpatient rehabilitation facilities, and long-term care hospitals.

Comment: Many commenters expressed a number of technical concerns with the specifications for the SRR measure. Specifically, commenters stated that using the 2728 form as the data source for determining patient comorbidities is inappropriate because the form is not used to track comorbidities that develop after the initiation of ESRD; commenters therefore recommend obtaining a reliable data source for comorbidities before adopting the measure. Commenters further stated that the measure relies on too many data sources to be specific to ESRD, and that facilities do not have ready access to hospital data, which they could use to design quality improvement programs.

Response: Although we do incorporate some information from the 2728 form in the risk adjustment model, the comorbidities are identified using Medicare Claims data. We use many data sources to construct our quality measures, but the data are derived from ESRD dialysis patients, and are therefore relevant to the care of this patient population. We recognize that dialysis facilities do not have access to hospital claims data, and that they believe they could benefit from such access in developing quality improvement programs. Providing such data is fraught with difficulty, such as logistical delays in the availability of the data, concerns about patient privacy across providers, and the lack of an effective delivery system for such data. While we continue to consider how such data may be provided in a way that is meaningful and as actionable as possible, we believe implementing a quality measure based on claims data is appropriate and consistent with the implementation of readmission measures in other settings. Additionally, we have implemented measures in the LTCH, IRF, and Home Health quality reporting programs even though hospital and other claims data are not currently available to these providers. Even if we could find a feasible way to make the hospital data available, there would be a substantial delay between the time we receive it and the time we could make it available to facilities. It is therefore not feasible for us to provide facilities hospital data in a short timeframe.

Comment: Some commenters stated that sickle cell trait, angiodysplasia, myelodysplasia, diverticular bleeding, asthma and nursing home/rehab status should be included as risk-factors in the measure calculations. Some commenters did not support the proposal to adopt the SRR measure, because it does not risk-adjust for patients' socioeconomic status. Commenters recommended that CMS incorporate this risk adjustment into the SRR measure, because otherwise facilities serving a high percentage of low-income patients may be subject to unnecessary and inappropriate payment reductions. One commenter further recommended that the SRR measure adjust for patient race, language, life circumstances, and environmental factors, because these factors have an impact on health outcomes and are beyond the control of the facility. One commenter also recommended that CMS institute a peer-grouping system in order to compare dialysis facilities that are similarly situated and treat similar patient populations before incorporating any further outcome measures into the ESRD QIP.

Response: The SRR already includes risk adjustment for the prior-year comorbidities as supported by a TEP and analysis of data. The suggested comorbidities were not included in the risk adjustment model following input from the TEP and a 30-day public comment period. We are aware that there are differing opinions regarding our current approach in risk-adjusting measures in the QIP for socioeconomic status (SES). We note that risk-adjusted outcome measures aim to reveal differences related to the quality of care provided. We believe that quality of care received by patients of lower SES contributes at least in part to the observed association between SES status and the readmissions rate. We continue to have concerns about holding dialysis facilities to different standards for the outcomes of their patients of low SES—we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations.

Concerns that facilities treating large numbers of low socioeconomic status patients are disproportionately penalized by quality measure performance may be addressed through risk adjustment, but other alternatives exist that would first need to be considered, such as peer grouping stratification. Peer group stratification involves stratifying hospitals by the hospital's proportion of low-SES patients, as a method to correlate readmission rates and penalties with patient income. We may consider incorporating such a peer-grouping stratification or an alternate method of addressing socioeconomic status in the future, as we continue to revise and refine the SRR clinical measure.

Comment: Some commenters stated that the measure's specifications are inappropriate because the denominator is defined in terms of index discharges, as opposed to the number of eligible patients at a facility. Commenters recommended using the latter method because under the proposed method a facility's score could be disproportionately reduced if one or two patients had high readmission rates, even if the facility had a low readmission rate overall.

Response: The same issue was discussed by the TEP in the course of their evaluation of the SRR. As a consequence of those deliberations, we have structured the SRR measure to account for frequently hospitalized patients in two ways: first, it excludes all hospitalizations following a patient's 12th admission (note that 1 percent of all patients are admitted more than six times in a calendar year) and, second, the model that defines the expectation of readmission adjusts for

hospitalizations that involve high risk diagnoses that are rare but very likely to result in a 30-day readmission (for example, sickle-cell anemia, HIV/AIDS).

The measure is focused on the process of readmission following a hospital discharge, and for this purpose the denominator is appropriate. Each hospital discharge is an opportunity for success or failure in managing the transition of a patient's care from the acute care facility to the dialysis facility. Allowing for risk-adjustment, the SRR assesses the rate of success at a given dialysis facility, and compares it to the rate of success at other facilities. It is true that a facility that has relatively fewer hospitalizations will have a smaller denominator, but what portion of those hospitalizations are followed by a readmission within 30 days is still a valid indicator of the successful management of care transitions. If one took as the denominator the set of all patients at the facility, we might be led to conclude that this facility with relatively few hospital discharges had a reasonable rate of readmissions even though, for the condition of the patient being discharged, we would have expected significantly fewer readmissions.

Furthermore, we proposed in the CY 2015 ESRD PPS Proposed Rule to account for variability in small facilities' SRR scores by excluding facilities with fewer than 11 discharges, and by applying a small facility adjustor (which ''gives facilities the benefit of the doubt when measure scores can be unduly influenced by a few outlier patients'') for facilities with 11 to 41 index discharges. We believe that this aspect of the ESRD QIP scoring methodology will mitigate the impact of one or two outlier patients on a small facility's SRR score.

Comment: Some commenters sought clarification as to why the proposed SRR measure is not limited to patients on chronic dialysis for 90 days, when this exclusion is included in the Standardized Mortality Ratio and Standardized Hospitalization Ratio measures. One commenter stated that this specification should align across the three measures.

Response: The original 90-day exclusion following the start of ESRD dialysis was implemented to allow time for patients to stabilize; as a result, hospitalizations and deaths in this period did not count against the dialysis facility when computing the SHR and the SMR. The SRR diverges on this point because the readmissions function differently. The SRR measure addresses the question as to how well the patient is managed once discharged from an acute-care hospital and assesses the outcome of the discharge. The start of dialysis defines the point in time when patients begin to be at risk for hospitalization or death while in the care of a dialysis facility (for the purposes of calculating the SMR and SHR measures). By contrast, risk for readmission begins upon discharge from an acute care hospital when calculating the SRR measure. As SRR is a measure of care coordination, there is no expected need for a stabilization period. Applying one would limit the measure's efficacy at assessing coordination of care for the discharged patient.

Comment: Some commenters were concerned that the proposal to exclude index hospitalizations that occur after a patient's 12th readmission in a calendar year will unduly impact small facilities, because these facilities' scores are disproportionately impacted by outliers. Commenters sought clarification as to why this criterion was raised from 6 readmissions to 12 readmissions.

Response: We initially considered allowing a maximum of six readmissions per patient-year (95th percentile of the 2009 test population). We made the change since we were concerned that there might be seasonal exclusions—that is, that this exclusion might disproportionately exclude hospitalizations occurring later in the reporting period and that these hospitalizations might, in some way, be different from hospitalizations occurring earlier in the reporting period (that is, in the calendar year).Variants of the measure that include either the cap of 6 or 12 readmissions are highly correlated (97.8 percent). Since increasing the exclusion criteria to 12 admissions made only a small difference, we felt comfortable applying this criterion in the hope of reducing the likelihood of bias.

Comment: Some commenters stated that the Hospital-Wide All-Cause Unplanned 30-Day Readmission Ratio measure (NQF #1789) excludes patients who have an incomplete claims history from the past year. Commenters sought clarification as to why this criterion was not included in the proposed SRR measure.

Response: We considered adopting this exclusion for the SRR measure but decided against doing so because it would exclude approximately one-third of ESRD dialysis patients who are discharged from the hospital during their first year of ESRD treatment. Many ESRD beneficiaries are not Medicare eligible at the initiation of dialysis but may still be likely to experience a hospitalization within the first year of dialysis treatment. As a consequence, the exclusion criterion would effectively eliminate accountability for readmissions within the first year of dialysis for patients who were not Medicare eligible prior to being diagnosed with ESRD, and we believe that the measure should assess all eligible unplanned readmissions of ESRD dialysis patients.

Comment: Some commenters stated that risk-adjusting for the discharging hospital does not sufficiently account for geographic variability in admission and readmission rates. Commenters also recommended risk-adjusting for the admitting physician because physicians decide when to admit and re-admit patients to a hospital.

Response: We decided not to propose a physician adjustment for three reasons—our general goal of encouraging the facility's coordination with its physicians; harmonization with readmission measures implemented in quality programs for other settings; and issues with attribution of discharges and readmissions to specific nephrologists or other care providers.

Variations in practice patterns may result in undesirable practices that this and other ESRD measures are seeking to improve. In view of the concept of shared accountability, adjusting for physician practice also removes a potential role for the dialysis facility in modifying physician practice.

Under our regulations (42 CFR 494.150(c)(2)(i)), dialysis facilities are responsible for overseeing the provision of care by a multi-disciplinary team, including the nephrologist treating the patient. Oversight of individual staff nephrologist care, including, ensuring adherence to facility policies and Medicare regulations, is primarily the responsibility of the site Medical Director, a paid employee of the dialysis facility, and, additionally, the responsibility of the facility governing body. Risk adjusting for physician would place CMS in the position of suggesting that a dialysis facility is not responsible for health consequences experienced by patients as the result of business or policy decisions by the facility administration.

We designed the SRR measure to be aligned as closely as possible with the existing Hospital-Wide Readmission Measure (NQF# 1789). Adjusting for physician effects in this measure would be inconsistent with similar readmission measures in other care settings where we assume that like dialysis facilities, the physicians treating the patients fall under the facility's responsibility.

Risk-adjusting for the nephrologist would also create issues with

attribution. First, ESRD patients are often under the care of multiple physicians and attribution to a particular physician would be difficult. Second, it is not clear whether it is more appropriate to hold responsible the nephrologist seeing the patient immediately before the index admission, or the nephrologist seeing the patient immediately after the discharge, or both.

We do not adjust our readmission measures to account for regional hospitalization practices. We believe that regional variation in hospital utilization that is related to that hospital's case mix does not justify differences in dialysis facility readmission rates because this variation is modifiable by provider behavior.

Comment: One commenter was concerned that the double random effects model used in stage 1 of the proposed SRR measure is biased against rural facilities, because these facilities are likely to be the only major ones available, and they are likely to be served by one major hospital. Commenter requested data on the measure's differential impact before adopting the measure. Commenter also recommended adjusting the measure to account for the distance patients travel from their homes to their dialysis facility and to the admitting hospital, because this could influence patient choices to utilize health care resources.

Response: The risk adjustment methodology uses a mixed model, with fixed effects estimated for the dialysis facilities' contribution to readmissions, and random effects estimated for the hospitals' contribution to risk for readmissions. In the event that a rural facility is paired only with a single hospital, the associated (random) hospital effect is estimated by borrowing information from all the other hospitals nationwide. There is no reason to believe that rural facilities (or any facilities) would be penalized with this approach. As in the case of care coordination measures for other settings, responsibility for outcomes is shared between the facility and the hospital.

Comment: Commenter stated that using a fixed effects model in the proposed SRR measure is inconsistent with the use of a random effects model in the NHSN Bloodstream Infection's Adjusted Ranking Metric. Commenter stated that the random effects model is more appropriate for the dialysis facility setting.

Response: Using random effects and fixed effects requires different statistical assumptions when estimating the contribution of a risk factor to patient outcomes of care. While we recognize that using fixed effects, along with random effects, in the risk-adjustment methodology for the SRR measure is different than the model we use to risk-adjust the Bloodstream Infection measure, our risk-adjustment methodology for the SRR measure is consistent with the use of fixed effects models developed for the SMR and SHR. We also note that the NQF has endorsed both approaches to risk-adjustment. The SRR measure incorporates both fixed and random effects in its adjustment model for particular purposes. When there is only one hospital and one dialysis facility serving a community, the random effects approach basically assumes that the hospital is drawn at random from the population of hospitals, as is the underlying assumption in a random effects model. Thus, the adjustment for the hospital in that case would be essentially that of a randomly selected hospital. In other instances, where the same hospital is paired with two or more dialysis facilities, the overall rate of readmissions is used in the model to determine the hospital adjustment. In either case, the random variation due to the hospital contributes to the standard error of the estimated facility response. There are no additional assumptions in the fixed effects for facilities, as opposed to the additional statistical assumptions required of a random effect.

Comment: One commenter stated that the validity of the SRR measure is called into question by the high number of risk-adjustments included. Specifically, commenter stated that risk-adjusting for BMI at incidence of chronic dialysis is inappropriate because the recorded values may have been incorrectly documented, and because a patient's BMI is likely to change significantly between the initiation of chronic dialysis and an index hospitalization.

Response: Our risk adjustment is intended to fairly compare a given facility to the national level of performance after properly adjusting for the case-mix in that facility. Thus, the adjustments were chosen to reflect important comorbidities and characteristics of patients in a given facility, and were assessed with respect to their association with the readmission outcome. We have, however, avoided risk-adjusting for facility practices that reflect choices in care provided and that may result in better or worse outcomes. We did this to avoid adjusting away care choices made by providers that may account for important differences in facility outcomes. We are not aware of a particular standard defining the number of risk adjustors in a model that would call its validity into question, but we carefully consider the risk model's parsimony during its development, evaluating components for redundancy, and removing those that are either redundant or do not contribute to the model. We continuously re-evaluate our quality measures for appropriateness, and our analyses indicate that incident BMI is a significant and appropriate predictor of health outcomes in the ESRD dialysis population.

Comment: One commenter stated that claims codes used in a non-ESRD population should not be used to determine planned readmissions in the ESRD population, as it the case for the proposed SRR measure.

Response: The list of acute diagnoses and planned procedures—both of which were initially developed for the Hospital-Wide Readmission Measure (NQF #1789)—were reviewed by a nephrologist, by members of the Technical Expert Panel convened in April 2012, and by stakeholders during the CMS public comment period in May 2013 for the purpose of determining whether they were appropriate for the SRR measure. This process resulted in the planned readmissions algorithm as it is currently specified for the SRR. We believe the systematically excluded claims codes identify readmissions that are planned, and therefore do not reflect a failure in the transition of care for the ESRD population. These codes are applicable to the ESRD population insofar as they are submitted by hospitals for ESRD and non-ESRD patients alike, and are therefore appropriate for exclusion from the SRR.

Comment: One commenter stated that claims data is not sufficient to reliably estimate actual and expected readmission rates. Commenter recommended that the proposed SRR measure should use data from facilities' electronic medical records.

Response: A key advantage for claims-based risk-adjustment is the availability of standardized data elements for all Medicare beneficiaries. There is currently no set standard of medical record compatibility and no national electronic medical record system across dialysis provider organizations.

Comment: Some commenters did not support the adoption of the proposed SRR measure, because the measure only has a ''moderate'' degree of reliability.

Response: We believe that the SRR clinical measure captures important quality data for the purposes of the ESRD QIP program. We believe the SRR is sufficiently reliable for inclusion in the ESRD QIP because it meets the

NQF's moderate degree of reliability standard, and particularly in light of our policies to set the case minimum for this measure at 11 index discharges and apply the small-facility adjuster to facilities with between 11 and 41 index discharges. We provide detailed analysis of the reliability of the SRR at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/AnalysisoftheReliabilityoftheProposedSRRandSTrRMeasures.pdf.* From 2009 through 2012, the SRR has an inter-unit reliability ranging from 0.49 to 0.54, which indicates a moderate degree of reliability. For context, the standard of an acceptable level of reliability is 0.40 or higher.

Comment: One commenter sought clarification as to how the proposed SRR measure will count hospital stays less than 24 hours, observation days, and same-day surgical procedures.

Response: The SRR measure assesses the risk of readmission to an acute care hospital within 30 days of discharge from an acute care hospital. Patients who are not admitted to an acute care hospital within 30 days of discharge are not included in the measure. Patients who are admitted will be included in the measure, even in cases (such as same-day surgical procedures) where admission and discharge occur within a 24-hour period. Such instances account for 1.3 percent of hospitalizations eligible to serve as index discharges in the SRR in 2012.

Comment: One commenter sought clarification on how the proposed SRR measure will address unsuccessful kidney transplants in the six months following the transplant. Commenter recommended that the measure exclude these transplant failures.

Response: As specified, the measure does not exclude patients who are hospitalized after a failed kidney transplant. We realize that this detail was not clear in the measure methodology report and we will edit the report to ensure clarity. As part of our ongoing quality measure re-evaluation process, we will examine this issue and consider how best to explicitly account for failed transplants in the SRR.

Comment: One commenter sought clarification on whether ''poisoning by nonmedical substances'' encompasses chronic substance abuse.

Response: We clarify that ''poisoning by non-medicinal substances'' does not include ICD–9 codes for ongoing alcohol or drug abuse. Please refer to the breakdown of this CCS group on AHRQ's Web site: *http://www.hcup-us.ahrq.gov/toolssoftware/ccs/AppendixASingleDX.txt.*

Comment: Some commenters stated that adopting the SRR measure would penalize two facilities for the same readmission: hospitals through the Hospital Readmissions Reduction Program and dialysis facilities through the ESRD QIP. Other commenters stated that readmissions measures are not an effective way to increase care coordination because different types of facilities (for example, dialysis facilities and hospitals) are paid separately.

Response: We agree that it is possible that a hospital and a dialysis facility could be penalized simultaneously for the same readmission event. We believe that both the hospital and the facility should be held accountable for ensuring that ESRD patients transition successfully from the hospital to post-acute care in the facility. Although different types of facilities are paid separately, we believe that all providers involved in the transition of care from acute to non-acute settings share responsibility for avoiding excessive rates of unplanned readmissions.

Comment: One commenter stated that facilities will experience difficulty in explaining facility scores on the SRR clinical measure to patients, and that doing so may be ''politically challenging'' when the dialysis facility is affiliated with the admitting hospital system.

Response: The CY 2015 ESRD PPS Proposed rule includes a link to a measure methodology report (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*) which provides an extensive discussion of how to interpret scores on the SRR measure. Simply put, a readmission ratio of greater than 1.0 reflects that a facility's patients are at higher risk for readmissions than they would be at an average facility. A score below 1.0 reflects that a facility's patients are at lower risk for readmissions than they would be at an average facility. A lower ratio is preferable because it indicates that a facility is doing a better job of managing patient transitions from a hospital back to the dialysis facility.

Comment: Some commenters recommended that CMS should delay the adoption of this measure until it provides facilities with reports documenting their performance with patient-level data, so that facilities can identify root causes and implement improvement plans. Commenters also recommended delaying the adoption of the proposed SRR measure until it has been endorsed by NQF.

Response: From March through April 2014, we conducted a dry run of the SRR, in which facilities were given the opportunity to view a quality report that provided their readmission measure results. At facility request, we also made patient-level data available for their review and entertained facility comments regarding the measure and the reporting process. We acknowledge the desire to delay implementation until after endorsement by NQF, and the reasoning behind such a suggestion. However, we believe that readmissions represent an important outcome of care for dialysis patients, given the population has a readmission rate of around 36 percent, which is twice that of the Medicare population.

Comment: One commenter recommended that CMS continue to exclude pediatric patients from the proposed SRR measure and any future readmission measures, because the pediatric population is so small that a single readmission can skew the unit's results and may incentivize facilities to deny admission to pediatric patients.

Response: We thank the commenter for the recommendation and will take it into account in future measure development work.

Comment: One commenter stated that the SRR measure should exclude planned readmissions.

Response: We appreciate the commenter's support for the SRR's exclusion of planned readmissions. This is an approach we have incorporated into measures of readmissions across multiple settings, and we agree that it is appropriate for this measure because planned readmissions do not reflect failures in care transitions and if not excluded, could bias SRR results for facilities that treat patients who receive certain kinds of in-patient hospital care.

Comment: One commenter recommended that CMS require hospitals to provide facilities with data concerning a patient's dry weight, dialysis prescription changes, and continuing antibiotics on the day a patient is discharged. Commenter stated that CMS could require hospitals to provide this data using the hospital Conditions for Coverage or the Hospital Value-Based Purchasing Program, and that this information is crucial for facilities to identify problems that lead to unplanned readmissions.

Response: We thank commenters for the suggestions, which capture an important issue of care coordination. We believe all providers should communicate and coordinate the care of patients transitioning from one setting of care to another. We agree that effective communication of clinically relevant data is an important goal. We are exploring means by which to

encourage the transfer of relevant information between providers.

For these reasons, we are finalizing the SRR clinical measure as proposed for the PY 2017 ESRD QIP and for future payment years. The technical specifications for this finalized measure can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

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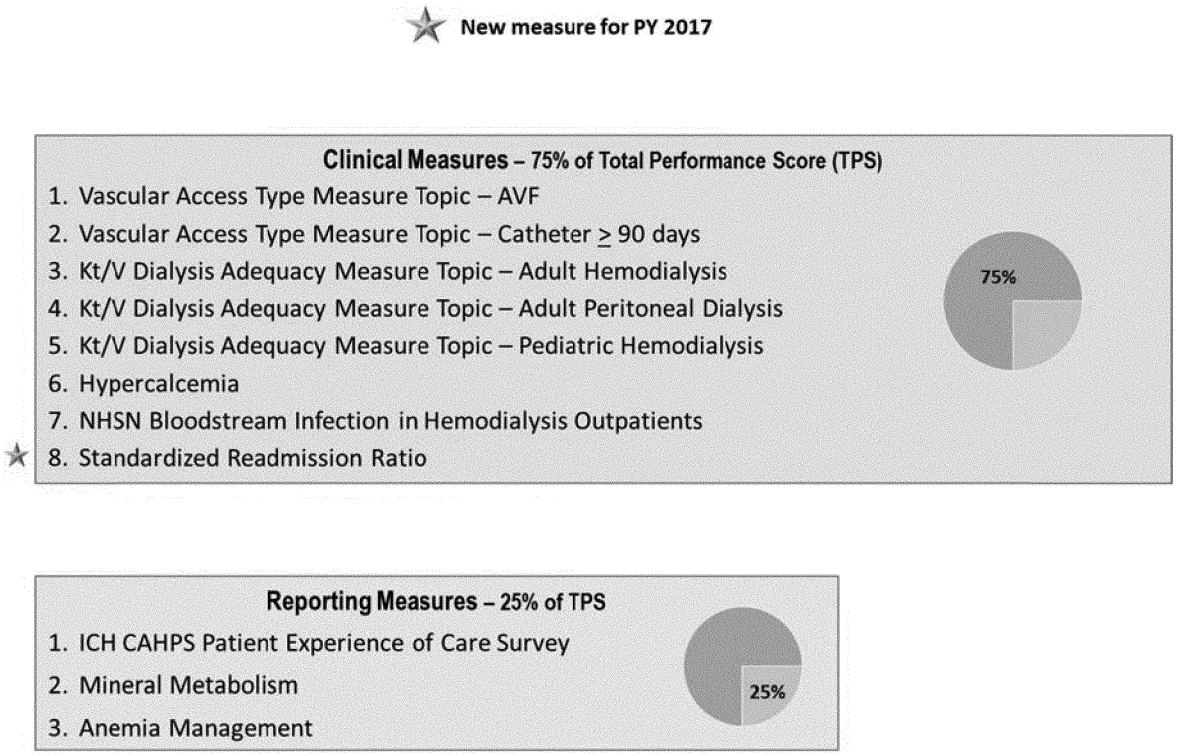
Summary of Finalized PY 2017 Measure Set



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3. Performance Period for the PY 2017 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish the performance period with respect to a payment year, and that the performance period occur prior to the beginning of such year. In the CY 2013 ESRD PPS Final Rule (77 FR 67500), we stated our belief that, for most measures, a 12-month performance period is the most appropriate for the program because this period accounts for any potential seasonal variations that might affect a facility's score on some of these measures, and also provides adequate incentive and feedback for facilities and Medicare beneficiaries. CY 2015 is the latest period of time during which we can collect a full 12 months of data and still implement the PY 2017 payment reductions. Therefore, we proposed to establish CY 2015 as the performance period for PY 2017 ESRD QIP.

We sought comments on this proposal. We did not receive any comments and are finalizing it as proposed.

4. Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2017 ESRD QIP

We proposed to adopt performance standards for the PY 2017 ESRD QIP measures similar to those we finalized for PY 2016 (78 FR 72211 through 72213). Section 1881(h)(4)(A) of the Act provides that ''the Secretary shall establish performance standards with respect to measures selected . . . for a performance period with respect to a year.'' Section 1881(h)(4)(B) of the Act further provides that the ''performance standards . . . shall include levels of achievement and improvement, as determined appropriate by the Secretary.'' We use the performance standards to establish the minimum score a facility must achieve to avoid a Medicare payment reduction. We use achievement thresholds and benchmarks to calculate scores on the clinical measures.

a. Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures in the PY 2017 ESRD QIP

With the exception of the NHSN Bloodstream Infection clinical measure, we proposed to set the performance standards, achievement thresholds, and benchmarks for the PY 2017 clinical measures at the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2013, because this would give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2017 program prior to the beginning of the performance period. We continue to believe that these standards will provide an incentive for facilities to continuously improve their performance, while not reducing incentives to facilities that score at or above the national performance rate for the clinical measures. As stated in the CY 2014 ESRD PPS Final Rule (78 FR 72213 through 72215), CY 2014 is the first year for which we will have data

for the NHSN Bloodstream Infection clinical measure. Accordingly, we proposed to set the performance standard, achievement threshold, and benchmark for the NHSN Bloodstream Infection clinical measure based on the 50th, 15th, and 90th percentiles, respectively, of national performance in CY 2014.

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: One commenter supported CMS's use of benchmarks to drive quality improvement in the ESRD QIP, and the scoring methodology proposed for the PY 2017 program, because it aligns with the methodology used in the Hospital Value-Based Purchasing program.

Response: We thank the commenter for the support.

Comment: One commenter was concerned with the proposed benchmarks for PY 2017, stating that these benchmarks are ''unrealistic'' because the increasingly high thresholds for achievement are making it harder for facilities to score well, even though they may be delivering high-quality care to patients. Commenter stated that for some measures, circumstances beyond a facility's control, such patient eligibility for a fistula and patient choice, will impact facility scores.

Response: We disagree that the proposed benchmarks for PY 2017 are unrealistic or unachievable. Benchmarks for clinical measures are pegged to national performance rates, such that 15 percent of facilities met the benchmarks two years before the performance period. Accordingly, the benchmarks represent a high level of achievement, but they are not unrealistic because they have been met by 15 percent of facilities nationwide, and because they represent past (and typically lower) standards of practice.

Comment: One commenter supported the use of benchmarks to drive quality improvement in the ESRD facility setting, but stated that pegging benchmarks to national performance rates creates a ''continually moving target.'' The commenter further stated that without an adjustment for facility location, population, or demographics, these benchmarks may penalize a facility that is performing well in comparison to its peers. The commenter recommended that CMS determine standards for each individual measure using evidence-based practices and provide these standards to facilities. Another commenter recommended CMS carefully evaluate established benchmarks to ensure that the high standards established do not create an incentive for facilities to deny care to sicker patients.

Response: We thank the commenter for the support. We recognize that pegging benchmarks to national performance rates creates a continually moving target for facilities, because facility performance on clinical quality metrics typically improves over time. We believe it is appropriate for benchmarks to increase, in line with improvements in national performance rates, because not increasing the benchmarks would hold facilities to a lower standard of care and would diminish incentives for improvement. We discussed above the possibility of using a peer group stratification system for dialysis facilities as a feasible approach to risk adjustment. We welcome input on how such a system might function, and will consider its utility for future years of the ESRD QIP.

Comment: One commenter stated that it is inappropriate for the ESRD QIP to base payment reductions on retroactive performance, and recommended that CMS should finalize measures and performance standards in a timely manner, in order to ensure facilities are made aware of appropriate standards.

Response: The current achievement scoring methodology generally compares facility performance in the performance period to national performance two years before the performance period, except in cases where there is a compelling patient safety reason to accelerate the adoption of a clinical measures (for example, the NHSN measure in the PY 2016 ESRD QIP). If facility performance during the performance period were to be compared to national performance during the performance period, this would place facilities on a ''forced curve'' and ensure that fifty percent of facilities fell below the performance standard. Additionally, we appreciate that facilities want to learn as soon as possible what the ESRD QIP measure set will be for a given CY. For this reason, we are finalizing measures the PY 2018 program in this final rule, 14 months before the beginning of the performance period for those measures. Finally we publish numerical values for performance standards as soon as data reflecting current national facility performance become available.

Comment: Commenter stated that facilities should not be scored on a forced normal curve. Commenter stated that this practice is not mandated by the Act, that it has been dismissed as invalid in quality improvement initiatives used in other professions, and that this penalizes facilities for providing patient-centered care when it is inconsistent with measure goals and targets.

Response: We appreciate commenter's concerns; however, the ESRD QIP does not use a normal curve to score facilities, nor have we proposed to adopt such a methodology in the proposed rule.

For these reasons, we are finalizing the performance standards for the PY 2017 ESRD QIP as proposed.

b. Finalized Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures in the PY 2017 ESRD QIP

Upon the publication of the CY 2015 ESRD PPS Proposed Rule, we did not have the necessary data to assign numerical values to the proposed performance standards, achievement thresholds, and benchmarks for the clinical measures, because we did not yet have complete data from CY 2013. Since that time, we have collected the data needed to calculate finalized performance standards for the PY 2017 ESRD QIP. For all of the clinical measures, including the SRR clinical measure, this data comes from the period of January through December 2013. Table 23 lists the finalized numerical values for all of the finalized PY 2017 ESRD QIP clinical measures except the NHSN Bloodstream Infection clinical measure.

TABLE 23—NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2017 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Performance standard	Achievement threshold	Benchmark
Vascular Access Type:			
%Fistula	64.46	52.42	78.56
%Catheter	9.92	18.36	3.23
Kt/V:			
Adult Hemodialysis	96.89	91.08	99.35

TABLE 23—NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2017 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA—Continued

Measure	Performance standard	Achievement threshold	Benchmark
Adult Peritoneal Dialysis	87.10	70.19	95.20
Pediatric Hemodialysis	94.44	84.15	99.06
Hypercalcemia	1.30	4.78	0.00
NHSN Bloodstream Infection	50th percentile of eligible facilities' performance during CY 2014.	15th percentile of eligible facilities' performance during CY 2014.	90th percentile of eligible facilities' performance during CY 2014
Standardized Readmission Ratio	0.996	1.325	0.555

We believe that the ESRD QIP should not have lower performance standards than in previous years. In accordance with our statements in the CY 2012 ESRD PPS final rule (76 FR 70273), if the final numerical value for a performance standard, achievement threshold, and/or benchmark is worse than it was for that measure in the PY 2016 ESRD QIP, then we proposed to substitute the PY 2016 performance standard, achievement threshold, and/or benchmark for that measure.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: One commenter supported the proposal to use performance standards from the previous year if the current year's standards are lower.

Response: We thank the commenter for the support. For this reason, we will finalize our proposal to utilize previous years' performance standards if they are higher than those of the next year. The performance standards for the measures used in previous years of the ESRD QIP have not declined. Therefore, for PY 2017, we will use the performance standards in the above table.

c. Performance Standards for the PY 2017 Reporting Measures

In the CY 2014 ESRD PPS Final Rule, we finalized performance standards for the Anemia Management, Mineral Metabolism, and ICH CAHPS reporting measures (78 FR 72213). We proposed to continue to use these performance standards for these measures in the PY 2017 ESRD QIP. We sought comments on this proposal. We did not receive any comments on this proposal.

5. Scoring the PY 2017 ESRD QIP Measures

a. Scoring Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). In determining a facility's achievement score for each measure under the PY 2017 ESRD QIP, we proposed to continue using this methodology for all clinical measures. Under this methodology, facilities receive points along an achievement range based on their performance during the proposed performance period for each measure, which we define as a scale between the achievement threshold and the benchmark.

b. Scoring Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). In determining a facility's improvement score for each measure under the PY 2017 ESRD QIP, we proposed to continue using this methodology for all clinical measures. Under this methodology, facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We proposed to define the improvement threshold as the facility's performance on the measure during CY 2014. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2015 (the proposed performance period) to its performance rate on the measure during CY 2014.

We sought comments on this proposal. We did not receive any comments and are finalizing it as proposed.

6. Weighting the Total Performance Score

We continue to believe that while the reporting measures are valuable, the clinical measures evaluate actual patient care and therefore justify a higher combined weight (78 FR 72217). We therefore did not propose to change our policy, finalized most recently in the CY 2014 ESRD PPS (78 FR 72217), to weight clinical measures as 75 percent and reporting measures as 25 percent of the TPS. We did not propose any changes to the policy that facilities must be eligible to receive a score on at least one reporting measure and at least one clinical measure to be eligible to receive a TPS, or the policy that a facility's TPS will be rounded to the nearest integer, with half of an integer being rounded up.

7. Minimum Data for Scoring Measures for the PY 2017 ESRD QIP and Changing the Attestation Process for Patient Minimums

For the same reasons described in the CY 2013 ESRD PPS final rule (77 FR 67510 through 67512), for PY 2017 we proposed to only score facilities on clinical and reporting measures for which they have a minimum number of qualifying patients during the performance period. Our current policy is that a facility must treat at least 11 qualifying patients during the performance period in order to be scored on a clinical measure (77 FR 67510 through 67511). We did not propose any changes to this policy.

However, with respect to the proposed SRR measure, we proposed that facilities with fewer than 11 index discharges will not be eligible to receive a score on that measure. We considered proposing to adopt the 11 qualifying patient minimum that we use for the other clinical measures. We decided, however, to base facility eligibility for the measure on the number of index discharges attributed to a facility, because the measure calculations are determined by the number of index discharges, adjusted for patient case-mix. We decided to set the minimum number of index discharges at 11 because this is consistent with reporting for the proposed SRR measure during the dry run conducted earlier this year, as well as with the implementation of outcome measures in the Hospital Readmission Reduction Program, which base case minimums on the number of index discharges attributable to the facility.

Additionally, for the proposed SRR measure, we proposed to apply the small-facility adjuster to facilities that treat 41 or fewer index discharges because we determined that this was the minimum number of index discharges needed to achieve an IUR of 0.4 (that is,

moderate reliability) for the proposed SRR measure. Because the small-facility adjuster gives facilities the benefit of the doubt when measure scores can be unduly influenced by a few outlier patients, we believe that setting the threshold at 41 index discharges will not unduly penalize facilities that treat small numbers of patients.

In the CY 2014 ESRD PPS Final Rule, we finalized that the case minimum for the Mineral Metabolism and Anemia Management reporting measures is one, and that facilities that treat one qualifying patient could attest to this in CROWNWeb in order to avoid being scored on the measures (78 FR 72197 through 72199 and 72220 through 72221). In the process of responding to questions from facilities about the attestation requirements for the PY 2015 program, however, we found that facilities were confused by this requirement. For this reason, we proposed to remove the option for facilities to attest that they did not meet the case minimum for these measures. Accordingly, facilities that meet the case minimum of one qualifying patient would be scored on these measures, facilities with between 2 and 11 qualifying patients would be required to report data for all but one qualifying patient, and facilities with 11 or more qualifying patients would be required to report data for all patients. Due to facility confusion with the attestation process, we also proposed to remove the option for facilities to attest that they did not meet the case minimum for the ICH CAHPS survey reporting measure. As we stated above, we did not propose any further changes to the 30 survey-eligible case minimum for this measure. We proposed that the ESRD QIP program will determine facility eligibility for these measures based on available data submitted to CROWNWeb, in Medicare claims, and to other CMS administrative data sources.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Many commenters did not support the proposed data minimum requirements for the reporting measures because the commenters stated that the requirements unfairly penalize facilities that may not be able to legitimately report data for a few patients. As an alternative, the commenters recommended applying a consistent case minimum of 26 for all measures in the ESRD QIP.

Response: We agree with commenters that requiring facilities with small patient populations to report data for all but one eligible patient may unfairly penalize small facilities, because failing to report data for two or more patients will have a greater impact on small facility than on larger facilities. However, we disagree that it is appropriate to set the case minimum at 26 for these reporting measures, because doing so would not allow CMS to collect baseline data for a large percentage of patients. We believe that setting the case minimum at 11 for the Anemia Management and Mineral Metabolism reporting measures strikes the appropriate balance between the need to maximize data collection and the need to not unduly penalize small facilities that are unable, for legitimate reasons, to report data on all but one patient. We further believe that setting the case minimum at 11 is appropriate, because this would align with the case minimum policy for the clinical measures in the ESRD QIP. Therefore, we are finalizing a case minimum policy of 11 for the Anemia Management and Mineral Metabolism reporting measures.

Comment: One commenter did not support the proposed minimum data requirements for the ICH CAHPS measure, because small facilities will have difficulty obtaining 30 completed surveys. Commenter recommended CMS use actual response rates from the CY 2014 survey to determine eligibility criteria for this measure in PY 2017 and PY 2018.

Response: Under the minimum data requirements proposed for the ICH CAHPS reporting measure for PY 2017, a facility that (1) treats fewer than 30 survey-eligible patients during the eligibility period (that is., CY 2014); or (2) receives fewer than 30 completed surveys during the performance period (that is., CY 2015) is not eligible to receive a score on the ICH CAHPS measure. We are finalizing below that these data minimum requirements also apply to the ICH CAHPS clinical measure for PY 2018. Therefore, if a small facility treats more than 30 ICH CAHPS eligible patients during the eligibility period but receives fewer than 30 completed surveys total from the two survey administrations for the performance period, that facility will receive an ''N/A'' on the ICH CAHPS measure for that Payment Year. We disagree with commenter's recommendation to use CY 2014 response rates to determine survey eligibility criteria for the ICH CAHPS measure because actual response rates are susceptible to a number of biases, including facility case-mix, response propensity, and the mode of survey administration. We believe the current minimum data requirement avoids the possibility of unfairly penalizing facilities based on these response biases by relying solely on the number of patients treated and the number of surveys completed to determine ICH CAHPS scoring eligibility.

Comment: One commenter did not support calculating clinical measure performance rates for facilities with between 11 and 25 eligible patients, and then applying the small facility adjuster to these facilities' scores. One commenter stated that including facilities with small numbers of eligible patients, and compensating (via the small facility adjuster) for the random effects that inevitably appear, is not consistent with the NQS goal of applying consistent approaches to quality measurement.

Response: We recognize that measures using a patient-minimum of 11 are somewhat less reliable than measures using a patient-minimum of 26. Despite this modest decline in the measures' reliability, we continue to believe that it is essential to score facilities with between 11 to 25 eligible patients on the clinical measures. Based on data from CY 2013, we have determined that applying a 26-patient-minimum to all of the clinical measures (as compared with continuing the current 11-patient-minimum) would result in the exclusion of an additional 562 facilities from the ESRD QIP, or 9.2 percent of facilities overall. Given the inherent tradeoff between a modest decline in measure reliability and including these 562 facilities in the ESRD QIP, we believe that on balance it is more important to include these facilities. Additionally, we recognize that the small facility adjuster is an imperfect mechanism for accounting for the possibility that a small number of outlier patients will disproportionately diminish a facility's score on a clinical measure. Nevertheless, given the program's commitment to the 11-patient minimum, using the adjuster is preferable to not using any adjustment, because the adjuster gives small facilities the benefit of the doubt. We further believe that this methodology is consistent with the NQS goal of a consistent approach to quality measurement because it is applied to all clinical measures in the ESRD QIP.

Comment: One commenter did not support the use of the small facility adjuster in the ESRD QIP, because adjustments are haphazardly applied to facilities with similar numbers of eligible patients and patient-months in the numerator. For example, and with respect to the Peritoneal Dialysis Adequacy clinical measure, a facility with 18 eligible patients that misses the threshold for 3 patients would not

receive an adjustment, whereas a facility with 17 eligible patients that misses the threshold for 3 patients would, as would a facility with 19 eligible patients that misses the threshold for 3 patients. If the small facility adjuster remains in the ESRD QIP, commenter recommended rounding the measure score after applying the adjustment, as opposed to beforehand, which the commenter states is the current practice.

Response: The small facility adjustment is applied consistently to facilities' performance rates (for example, 87.5 percent for the Adult Peritoneal Dialysis clinical measure), such that facilities with fewer eligible patients receive more of an adjustment than facilities with more eligible patients. With respect to the example provided by the commenter, we recognize that the impact of the small facility adjustment on measure scores can be different for facilities with the same or similar numbers of eligible patients for each facility. This variable impact on facility measure scores is attributable to the achievement and improvement scoring methodologies used in the ESRD QIP. Scores on the clinical measures are determined by selecting the higher of the facility's achievement and improvement scores. The achievement score is determined by comparing the adjusted performance rate to the achievement threshold and benchmark, and the facility's improvement score is determined by comparing the adjusted performance rate to the facility's baseline rate. Accordingly, the impact of the small facility adjustment on a measure score (as opposed to a performance rate) will depend upon whether a measure is scored on the basis of achievement or improvement, as well as the facility's improvement threshold. Therefore, the variable impact of the small facility adjustment is not inherent to the small facility adjuster, but rather an intentional artifact of the ESRD QIP scoring methodology. Finally, we note that the small facility adjustment is applied to the measure performance rate (as opposed to the measure score), with rounding performed at the 6th decimal place. Rounding to the nearest integer already occurs after the small facility adjustment is applied, and this is consistent with the commenters recommendation on this finalized policy. The following summarizes the rounding algorithm that is currently applied to the performance score calculation for facilities with 11–25 eligible patients:

- Calculate the measure performance rate (x_i=(#patient-months numerator/#patient-months denominator)*100), round to 6th decimal place
- Calculate the facility weight (w_i=1-n_i/26), round to 6th decimal place
- Calculate the Standard Error (SE(x_i)), round to 6th decimal place
- Calculate adjusted measure performance rate ($t_i = x_i + w_i * SE(x_i)$), round to nearest integer.

For these reasons, we are finalizing the minimum data policies as proposed, with the exception of the patient minimum policies for the Anemia Management and Mineral Metabolism reporting measures. We are finalizing that a facility must treat at least 11 qualifying patients to receive a score on the Anemia Management and Mineral Metabolism reporting measures.

We proposed to continue our policies that govern when a newly opened facility would be eligible to be scored on measures as follows.

- Facilities with a CCN open date on or after July 1 of the performance period (for PY 2017, this would be July 1, 2015) are not eligible to be scored on any reporting measures except the ICH CAHPS reporting measure.
- Facilities with a CCN open date on or after January 1 of the performance period (for PY 2017, this would be January 1, 2015) are not eligible to receive a score on the ICH CAHPS reporting measure in the PY 2017 program, due to the time it takes to contract with a CMS-approved third-party vendor to administer the survey.
- Facilities are eligible to receive a score on all of the clinical measures except the NHSN Bloodstream Infection clinical measure if they have a CCN open date at any time before the end of the performance period.
- Facilities with a CCN open date after January 1 of the performance period (for PY 2017, this would be January 1, 2015) are not eligible to receive a score on the NHSN Bloodstream Infection clinical measure, due to the need to collect 12 months of data to accurately score the measure.

We also proposed to continue our policy that a facility will not receive a TPS unless it receives a score on at least one clinical measure and at least one reporting measure. We note that as a result, facilities will not be eligible for a payment reduction under the PY 2017 ESRD QIP if they have a CCN open date on or after July 1, 2015.

We sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

Table 24 displays the finalized patient minimum requirements for each of the reporting measures, as well as the CCN open dates after which a facility will not be eligible to receive a score on a reporting measure.

TABLE 24—MINIMUM DATA REQUIREMENTS FOR THE PY 2017 ESRD QIP

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Adult Hemodialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients
Adult Peritoneal Dialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients
Pediatric Hemodialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients
Vascular Access Type: Catheter (Clinical).	11 qualifying patients	N/A	11–25 patients
Vascular Access Type: Fistula (Clinical).	11 qualifying patients	N/A	11–25 patients
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 patients
NHSN Bloodstream Infection (Clinical).	11 qualifying patients	On or before January 1, 2015	11–25 patients
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges
ICH CAHPS (Reporting)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period..	Before January 1, 2015	N/A
Anemia Management (Reporting).	11 qualifying patients	Before July 1, 2015	N/A
Mineral Metabolism (Reporting)	11 qualifying patients	Before July 1, 2015	N/A

8. Payment Reductions for the PY 2017 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. For PY 2017, we proposed that a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if:

- It performed at the performance standard for each clinical measure;
- It received zero points for each clinical measure that does not have a numerical value for the performance standard established through the rulemaking process before the beginning of the PY 2017 performance period; and
- It received 10 points (which is the 50th percentile of facility performance on the PY 2015 reporting measures) for each reporting measure.

We recognize that these conditions are more stringent than the conditions used to establish the minimum TPS in the PY 2016 ESRD QIP, because this proposal increases the number of points a facility would have to receive on each reporting measure from 5 to 10. The PY 2015 program is the most recent year for which we will have calculated final measure scores before the beginning of the performance period for PY 2017 (that is., CY 2015). We note that facility performance on the Anemia Management, Mineral Metabolism, NHSN Dialysis Event, and ICH CAHPS reporting measures in the PY 2015 program is so high that the median score on each of the measures was 10 points. We proposed to increase the number of points a facility would have to achieve for each reporting measure to the 50th percentile of facility performance on the PY 2015 reporting measures (that is, the average of the median scores for each reporting measure), because a score of 5 on each of these reporting measures is indicative of a below-average performance, and we want to incentivize facilities to provide above-average care.

We sought comments on this proposal. We did not receive any comments and are finalizing it as proposed.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2014 ESRD PPS Final Rule (78 FR 72223 through 72224), we finalized a payment reduction scale for PY 2016 and future payment years, such that for every 10 points a facility falls below the minimum TPS, the facility would receive an additional 0.5 percent reduction on its ESRD PPS payments, with a maximum reduction of 2.0 percent. We did not propose any changes to this policy.

Based on the finalized performance standards listed above, we have determined that a facility must meet or exceed a minimum TPS of 60 for PY 2017. For all of the clinical measures except the NHSN Bloodstream Infection clinical measure, these data come from CY 2013. For the NHSN Bloodstream Infection clinical measure, we set the performance standard to zero for purposes of determining this minimum TPS, because we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the PY 2017 performance period. We proposed that facilities failing to meet the minimum TPS, as established in the CY 2015 ESRD PPS Final Rule, will receive payment reductions based on the estimated TPS ranges indicated in Table 25 below.

TABLE 25—PAYMENT REDUCTION SCALE FOR PY 2017 BASED ON THE MOST RECENTLY AVAILABLE DATA FROM CY 2013

Total performance score	Reduction (%)
100–60	0
59–50	0.5
49–40	1.0
39–30	1.5
29–0	2.0

9. Data Validation

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. We began a pilot data-validation program in CY 2013 for the ESRD QIP, and we have procured the services of a data-validation contractor that is tasked with validating a national sample of facilities' records as they report CY 2014 data to CROWNWeb. Our first priority was to develop a methodology for validating data submitted to CROWNWeb under the pilot data-validation program, and this continues to be our goal. Once this methodology has been fully developed, we will propose to adopt it through the rulemaking process. For the PY 2016 ESRD QIP (78 FR 72223 through 72224), we finalized a requirement to sample approximately 10 records from 300 randomly selected facilities; these facilities will have 60 days to comply once they receive requests for records. We proposed to continue this pilot for the PY 2017 ESRD QIP. Under this continued validation study, we will sample the same number of records (approximately 10 per facility) from the same number of facilities (that is, 300) during CY 2015. If a facility is randomly selected to participate in the pilot validation study but does not provide CMS with the requisite medical records within 60 days of receiving a request, then we proposed to deduct 10 points from the facility's TPS. Once we have developed and adopted a methodology for validating the CROWNWeb data, we intend to consider whether payment reductions under the ESRD QIP should be based, in part, on whether a facility has met our standards for data validation.

We also proposed a feasibility study for validating data reported to CDC's NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure. HAIs are relatively rare, and we proposed that the feasibility study would target records with a higher probability of including a dialysis event, because this would enrich the validation sample while reducing the burden on facilities. The methodology for this proposed feasibility study would resemble the methodology used by the Hospital Inpatient Quality Reporting Program to validate the central line-associated bloodstream infection measure, the catheter-associated urinary tract infection measure, and the surgical site infection measure (77 FR 53539 through 535553).

Specifically, we proposed to randomly select nine facilities to participate in the feasibility study. A CMS contractor will send these facilities quarterly requests for lists of all positive blood cultures drawn from its patients during the quarter, including any positive blood cultures that were collected from the facility's patients on the day of, or the day following, their admission to a hospital. Facilities will have 60 days to respond to quarterly requests for lists of positive blood cultures. A CMS contractor will then develop a methodology for determining when a positive blood culture qualifies as a ''candidate dialysis event,'' and is therefore appropriate for further validation. Once the contractor determines a methodology for identifying candidate dialysis events, the contractor will analyze the records of patients who had a positive blood culture in order to determine if the facility reported dialysis events for those patients in accordance with the NHSN Dialysis Event Protocol. If the contractor determines that additional medical records are needed from a facility to validate whether the facility

accurately reported the dialysis events, then the contractor will send a request for additional information to the facility, and the facility will have 60 days from the date of the letter to respond to the request. Overall, we estimate that, on average, quarterly lists will include two positive blood cultures per facility, but we recognize these estimates may vary considerably from facility to facility. If a facility is randomly selected to participate in the feasibility study but does not provide CMS with the requisite lists of positive blood cultures or the requisite medical records within 60 days of receiving a request, then we proposed to deduct 10 points from the facility's TPS.

The goals of the proposed feasibility study will be five-fold: (1) To estimate the burden and associated costs to facilities of validating the NHSN Bloodstream Infection clinical measure; (2) to assess the costs to CMS to validate this measure; (3) to develop a methodology for identifying candidate dialysis events from lists of positive blood cultures; (4) to develop a methodology for determining whether a facility accurately reported dialysis events under the NHSN Bloodstream Infection clinical measure; and (5) to reach some preliminary conclusions about whether facilities are accurately reporting data under the NHSN Bloodstream Infection clinical measure. Based on the results of this study, we will consider the feasibility of proposing in future rulemaking to validate the NHSN Bloodstream Infection clinical measure for all facilities.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Some commenters supported the proposal to validate data submitted for the NHSN Bloodstream Infection measure, and stated that asking facilities to provide blood culture reports on a quarterly basis is appropriate. However, one commenter also recommended that the proposed feasibility study be more robust. In particular, the commenter stated that previous validation studies of NHSN data revealed that facilities were underreporting dialysis events, and that facilities did not understand when to report that an infection was a ''dialysis event.'' The commenter recommended that these findings should be incorporated into the proposed feasibility study. Commenters also recommended expanding the number of facilities undergoing validation beyond 9, because the ''proposed nine-facility feasibility study is not robust enough to evaluate true validation concerns.'' Commenters recommended auditing the NHSN data of 10 percent of facilities, because this would create a strong incentive for facilities to accurately report dialysis events. Another commenter stated that the validation study should be expanded to NHSN data that is used directly used to score the NHSN Bloodstream Infection measure.

Response: We thank the commenters for their support. We initially considered expanding the scope of the feasibility study to include more than nine facilities. We decided not to do so because we thought it was important to demonstrate the study's feasibility, and to further develop the study's methodology, before expanding the study to include more facilities. Expanding the study to include more facilities before demonstrating its feasibility and validity could lead to a waste of agency resources. Furthermore, we are aware of existing studies that call into question the validity of data entered into the NHSN system. The existence of these studies is one of the reasons why we proposed to conduct the feasibility study, and results from previous studies will be taken into account when developing the methodology for the feasibility study. Additionally, we appreciate the recommendation to use a validation study of NHSN data to audit ten percent of facilities, and we agree that such a process could improve the validity of NHSN data overall. We will consider expanding the scope of the study once we have reviewed the results of the feasibility study.

Comment: Some commenters stated that the CROWNWeb validation pilot is actually an audit of facility data, and is not focused on testing a new payment or delivery model. Commenters were concerned that the pilot places facilities at risk for incurring a 2 percent payment reduction and recommended ''intermediate penalties'' as an alternative. Commenters further recommended that CMS ensure that facilities have some means to dispute CMS claims that they reported invalid data.

Response: We agree that one of the purposes of the validation pilot is to identify instances in which facilities reporting invalid data to CROWNWeb. However, we do not believe it is appropriate to designate the validation pilot as an ''audit'' of facility data, because the ultimate objective of the study is to improve the validity of data reported to CROWNWeb, rather than to penalize facilities for reporting invalid data. We further note that we did not propose to penalize facilities for reporting invalid data; if and when we propose to do so in future rulemaking, we will consider implementing an appeal process facilities can use to contest CMS determinations that invalid data was reported to CROWNWeb. Finally, we recognize that facility non-compliance with the requirements of the CROWNWeb validation pilot may result in payment reductions that would not otherwise be imposed. We believe this is warranted, because facility compliance is essential to the success of the validation pilot, and we wish to provide a strong incentive for facilities to transmit the requested medical records needed to validate CROWNWeb data.

Comment: One commenter stated that CROWNWeb should be fully functional before assessing penalties for submitting invalid data.

Response: We agree that is it essential to improve the functionality of CROWNWeb, and we believe that the pilot validation study will assist in identifying systematic issues with CROWNWeb that diminish the system's functionality. We did not propose to impose penalties on facilities for reporting invalid data, and we will consider the functionality of CROWNWeb if we decide to propose to impose such penalties in future rulemaking.

Comment: One commenter recommended that CMS should make the methodology for the proposed NHSN validation feasibility study transparent and seek input from nephrologists and dialysis professionals when developing the methodology.

Response: We agree that it is important to make the methodology of the feasibility study transparent. We will make the methodology publically available on a CMS Web site and notify the public of its availability via a CROWN Memo or similar mode of formal communication. Additionally, we confirm that the CMS contractor conducting the validation feasibility study will consult nephrologists and dialysis professionals when developing the study's methodology.

Comment: Some commenters did not support the proposal to validate data used to calculate the NHSN Bloodstream Infection measure because the commenter stated that the measure should have been validated before it would adopted in the ESRD QIP.

Response: NHSN provides detailed trainings, protocols, and guidance for users to follow to ensure that data are reported in a standardized manner and according to requirements. A small validation study was conducted prior to the adoption of the measure in the ESRD QIP. Information from this study is

described in the measure specifications. We recognize that continuous internal and external evaluation and quality checks of the reported data are important for accuracy and reliability. We further note that one of the purposes of the feasibility study is to improve the validity of data reported to NHSN, and we continue to believe that one of the outcomes of the study will be to improve the validity of the NHSN Bloodstream Infection measure.

Comment: Some commenters did not support the proposal to impose a 10-point reduction on facilities that fail to send medical records to CMS within the 60-day timeframe, because the 60-day time frame is too short, and the penalty discriminates against facilities selected to participate in the validation studies, particularly small facilities. Commenters also stated that the ESRD CfCs already require facilities to comply with such requests. Commenter further stated that CMS has not demonstrated that facilities do not comply with these requests, and therefore did not support a penalty for non-compliance until the problem has been demonstrated. One commenter also questioned whether the Act authorizes CMS to deduct points from a facility's TPS if it does not comply with the requirements of data validation studies.

Response: We disagree that the 60-day time frame is too short for facilities to respond to requests to validate medical records, because facilities should have these records on hand, and sampled facilities will only be required to submit a small number of medical records the CROWNWeb and NHSN Bloodstream Infection studies. We recognize that the ESRD CfCs already require facilities to comply with these requests for medical records, and we are not aware of any evidence suggesting that they are not already doing so. Nevertheless, we continue to believe that assessing penalties on a facility's TPS is the surest way to ensure that facilities provide the medical records needed to complete the studies. This is because facilities are typically not surveyed for compliance with the ESRD CfCs on any given year, so deducting points from a facility's TPS provides a more certain process for penalizing noncompliance with the requirements of the validation studies. Our proposal to deduct points from a facility's TPS is consistent with section 1881(h)(3)(A)(i) of the Act, because it is part of our a methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the measures selected. The main purpose of these studies is to assess whether facilities are reporting accurate data, and we have determined that review of medical records is integral to that determination.

For these reasons, we are finalizing, as proposed, CROWNWeb pilot data-validation program and the feasibility study for validating data reported to CDC's NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure.

10. Monitoring Access to Dialysis Facilities

Public comments on the proposal to adopt the Standardized Hospitalization Ratio measure in the PY 2014 ESRD QIP (76 FR 70267) expressed concerns that ''the measure may lead to 'cherry-picking' of patients based on their risk of hospitalizations, causing access to care issues for patients with more severe illness.'' We share commenters' concerns about the SHR measure, and we believe that these concerns equally apply to other outcome measures proposed for the ESRD QIP. We recognize that, in general, inadequate risk adjustment in outcome measure calculations can create an incentive for facilities to deny services to sicker patients, because these patients' illnesses would not be properly accounted for in the risk-adjustment calculations. We believe that outcome measures proposed and adopted for the ESRD QIP properly risk adjust for patients with severe illnesses, but we remain concerned that misperceptions to the contrary might negatively impact access to dialysis therapy.

Because we proposed to adopt the SRR clinical measure for the PY 2017 program, and also proposed to adopt the STrR clinical measure for the PY 2018 program, we proposed to initiate a monitoring program focused on access to dialysis therapy. This program would compare dialysis data before and after the adoption of an outcome measure, looking for changes in admission and discharge practices, as well as changes in rates and patterns of involuntary discharges. Specifically, this program would assess and analyze the characteristics of beneficiaries admitted to dialysis centers (stratified by location, size, and setting) in order to determine when and if selective admission and discharge practices are coupled with negative patient attributes and trends over time. We believe this program will enable us to identify patterns that are indicative of diminished access to dialysis therapy.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Some commenters supported the proposed access study because monitoring and remediating cases of cherry-picking are important for ensuring that patients receive high quality care.

Response: We thank commenters for their support.

Comment: One commenter requested more information from CMS regarding its proposal to monitor dialysis facility admission and discharge practices, because this proposal may lead to additional reporting (and burden) for facilities.

Response: We are still in the process of finalizing the methodology for the proposed access study. Once we have developed the methodology, we will make it publically available on a CMS Web site and notify the public of its availability via a CROWN Memo or similar mode of formal communication. We clarify, however, that the study will make use of existing data and will not impose any additional burden on facilities.

Comment: One commenter recommended that, instead of performing the proposed monitoring access study, CMS focus its efforts on developing a more comprehensive set of comorbidities for use in adjusting the standardized outcome measures.

Response: We appreciate the recommendation to further develop the risk-adjustment methodologies associated with the SRR and STrR measures, and we will continue to do so as part of our ongoing measure re-evaluation process. However, we disagree that efforts to develop risk-adjustment methodologies should be pursued in lieu of the proposed access study. We believe both activities are important, and we intend to pursue them at the same time.

For these reasons, and because we are finalizing the SRR clinical measure for PY 2017 (as discussed in more detail above), and the STrR measure for PY 2018 (as discussed in more detail below), we are finalizing that we will conduct a study to determine the impact of adopting the SRR and STrR measures on access to care. Further details about the study and its methodology will be made available on a CMS Web site, and facilities will be notified via a CROWN Memo when this information is available.

11. Extraordinary Circumstances Exception

Many comments on the CY 2014 ESRD PPS proposed rule included the recommendation to exempt a facility from all the requirements of the ESRD QIP clinical and reporting measures during the time the facility was forced to close temporarily due to a natural

disaster or other extraordinary circumstances. In response to these comments, we agreed that ''there are times when facilities are unable to submit required quality data due to extraordinary circumstances that are not within their control, and we do not wish to penalize facilities for such circumstances or unduly increase their burden during these times'' (78 FR 72209).

Section 1881(h)(3)(A)(i) of the Act states, ''[T]he Secretary shall develop a methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the measures selected under paragraph (2) for a performance period established under paragraph (4)(D).'' Given the possibility that facilities could be unfairly penalized for circumstances that are beyond their control, we believe the best way to implement an extraordinary circumstances exception is under the authority of this section. We therefore proposed to interpret section 1881(h)(3)(A)(i) of the Act to enable us to configure the methodology for assessing facilities' total performance such that we will not require a facility to submit, nor penalize a facility for failing to submit, data on any ESRD QIP quality measure data from any month in which a facility is granted an extraordinary circumstances exception.

Under this policy, we proposed that, in the event of extraordinary circumstances not within the control of the facility (such as a natural disaster), for the facility to receive consideration for an exception from all ESRD QIP requirements during the period in which the facility was closed, the facility would need to submit a CMS Disaster Extension/Exception Request Form through *www.qualitynet.org* within 90 calendar days of the date of the disaster or extraordinary circumstance. We proposed that the facility would need to provide the following information on the form:

- Facility CCN;
- Facility name;
- CEO name and contact information;
- Additional contact name and contact information;
- Reason for requesting an exception;
- Dates affected;
- Date facility will start submitting data again, with justification for this date; and
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper, and other media articles.

Incomplete forms will be returned to the facility without further review of their content. We will evaluate the request and provide the facility with a response. If we determine that the facility was, in fact, closed for a period of time due to extraordinary circumstances, then we will exempt the facility from the ESRD QIP requirements for any month during which the facility was closed due to the extraordinary circumstances. As such, a facility granted a temporary exception will be scored on each measure only for the months during a performance period not covered by the exception. For example, if a facility is granted an extraordinary circumstances exception for the time period between January 15 and February 15, 2015, then the facility will not be required to report, and will not be penalized for not reporting, data on any ESRD QIP measure data for January and February of CY 2015. The effect of this proposal is that if a facility, because it has been granted an exception, cannot meet the reporting requirements that apply to a measure, the facility will not receive a score on the measure. For example, if a facility is granted an extraordinary circumstances exception for February 2015, then that facility would not be scored on the NHSN Bloodstream Infection clinical measure for the applicable payment year, because this measure requires facilities to submit 12 months of data in order to avoid receiving zero points on the measure.

We stated that this policy would not preclude us from granting exceptions to facilities that have not requested them when we determine that an extraordinary circumstance (for example, a hurricane or other act of nature) affects an entire region or locale. If we made the determination to grant an exception to facilities in a region or locale, then we proposed to communicate this decision through routine communication channels to facilities, vendors, and Networks, including but not limited to issuing memoranda, emails, and notices on a CMS-approved Web site.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Some commenters supported the proposal to add an Extraordinary Circumstances Exception to the ESRD QIP, because facilities should not be required to meet the program's requirements when they are forced to close.

Response: We thank commenters for their support.

Comment: Some commenters supported the proposal to add an Extraordinary Circumstance Exception but sought clarification as to what constitutes an ''extraordinary circumstance.'' Commenters recommended that events such as fires and explosions, which are not typically considered ''natural disasters'' should be considered ''extraordinary circumstances.'' Commenters also recommended granting exceptions for facilities that temporarily close for renovation or relocate.

Response: The Extraordinary Circumstances Exception is intended to address facility closures beyond the control of the facility, and is not limited to natural disasters. We note that eligibility determinations for this exception will be made on a case-by-case basis and based entirely on evidence and documentation that facilities present.

Comment: One commenter recommended that camps and short-term dialysis units should have an opportunity to take advantage of the extraordinary circumstances exception, because they operate under unique circumstances that do not apply to most facilities.

Response: We appreciate that camps and short-term dialysis units operate under unique circumstances. However, these circumstances are categorically different than the types of circumstances covered by the Extraordinary Circumstances Exception, because their closure is within the facility's control and is generally planned in advance. Accordingly, operating for a short period of time will not be grounds for granting an Extraordinary Circumstances Exception.

For these reasons, we are finalizing the proposal to adopt an Extraordinary Circumstance Exception in the ESRD QIP, beginning with the PY 2017 program.

F. Requirements for the PY 2018 ESRD QIP

1. Modification of the Mineral Metabolism Reporting Measure Beginning in PY 2018

In the CY 2013 ESRD QIP, we adopted a reporting measure focused on mineral metabolism, which was based in part on NQF #0255 (77 FR 67487 through 67487). In the CY 2014 ESRD PPS, we finalized two revisions to the Mineral Metabolism reporting measure: (1) To include home peritoneal dialysis patients in the measure; and (2) to remove serum calcium reporting from the measure because of its reporting under the Hypercalcemia clinical measure (78 FR 72197 through 72198). Accordingly, in order to meet the requirements for the Mineral Metabolism reporting measure, facilities currently must report serum phosphorus

values for each qualifying patient treated at the facility on a monthly basis.

Since the publication of the CY 2014 ESRD PPS final rule, members of the renal community requested an ad hoc NQF review of measure #0255, focusing in particular on whether the measure should be updated to allow for the reporting of plasma phosphorus data. The NQF Consensus Standards Approval Committee (CSAC) reviewed the measure and recommended that the phosphorus reporting measure (NQF #0255) be modified to allow for the reporting of plasma phosphorus data as an alternative to serum phosphorus data. Although our TEP reviewed this issue and concluded that measure #0255 should remain unchanged, we concur with the CSAC's recommendation due to the CSAC's ad hoc review of lab data demonstrating the equivalency of plasma and serum measurements of phosphorus, as well as an additional concurrent internal review of the data by CMS and our measure development contractor. We are in agreement with the CSAC that readings of phosphorus using either plasma or serum are appropriate for the measure. As the measure developer for NQF#255, we are also in the process of revising the specifications for that measure and plan to submit the revised measure specifications to the NQF for endorsement. We believe the change to these specifications is non-substantive because plasma readings are an alternative method of reporting on phosphorus data and, as we state above, are roughly equivalent to serum phosphorus readings.

We considered proposing to allow facilities to report plasma phosphorus data for the Mineral Metabolism reporting measure in the PY 2017 program, but we have determined that it is not operationally feasible to configure the relevant data fields in CROWNWeb to accept plasma phosphorus readings prior to January 1, 2015, the beginning of the performance period for that program year. For this reason, we proposed to modify the measure specifications for the Mineral Metabolism reporting measure to allow facilities to report either serum phosphorus data or plasma phosphorus data, beginning with the PY 2018 program. We further clarified that we were not proposing any other changes to the measure specifications for the Mineral Metabolism reporting measure.

We sought comments on this proposal. The comments and responses are set forth below.

Comment: One commenter supported the proposal to allow facilities to report both plasma and serum phosphorous under the Mineral Metabolism reporting measure, beginning in PY 2018.

Response: We thank the commenter for the support.

Comment: Many commenters supported the proposal to modify that Mineral Metabolism reporting measure, but sought clarification as to why it is not feasible to do so starting in PY 2017, and urged CMS to adopt the change for PY 2017.

Response: We thank commenters for their support. We have already begun working to incorporate this modification into the CROWNWeb system. However, we do not expect to be able to fully implement the modification by January 1, 2015 (that is, the beginning of the PY 2017 performance period), so it is not possible to collect plasma phosphorus data for the PY 2017 program.

For these reasons, we are finalizing the proposed modifications to the Mineral Metabolism reporting measure, beginning with the PY 2018 program. The technical specifications for this finalized measure can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

2. New Measures for the PY 2018 ESRD QIP and Future Payment Years

For the PY 2018 ESRD QIP, we proposed to continue to use all of the measures proposed for the PY 2017 ESRD QIP, with the exception of the ICH CAHPS reporting measure, which we proposed to convert to a clinical measure. We also proposed to adopt five new measures. The proposed new measures include one new outcome measure evaluating transfusions in the ESRD population, one measure on pediatric peritoneal dialysis adequacy, one measure on pain assessment, one measure on clinical depression screening, and one measure on healthcare personnel influenza vaccination (see Table 26).

TABLE 26—NEW MEASURES PROPOSED FOR THE PY 2018 ESRD QIP

NQF#	Measure title
N/A	Pediatric Peritoneal Dialysis Adequacy, a clinical measure. Percentage of pediatric peritoneal dialysis patient-months with spKt/V greater than or equal to 1.8 (dialytic + residual).
0258	In-Center Hemodialysis Consumer Assessment of Providers and Systems Survey,[1] a clinical measure. Proportion of responses to rating items grouped into three composite measures and three global ratings.
N/A	Standardized Transfusion Ratio, a clinical measure. Risk-adjusted standardized transfusion ratio for dialysis facility patients.
N/A[2]	Pain Assessment and Follow-Up, a reporting measure. Percentage of adult patients with documentation of pain assessment through discussion with the patient including the use of a standardized tool(s) on each visit and documentation of a follow-up place when pain is present.
N/A[3]	Depression Screening and Follow-Up, a reporting measure. Percentage of adult patients screened for clinical depression using a standardized tool and follow-up plan is documented.
N/A[4]	NHSN Healthcare Personnel Influenza Vaccination, a reporting measure.

[1] The proposed dimensions of the ICH CAHPS survey for use in the PY 2018 ESRD QIP are: Nephrologists' Communication and Caring, Quality of Dialysis Center Care and Operations, Providing Information to Patients, Overall Rating of the Nephrologists, Overall Rating of the Dialysis Center Staff, and Overall Rating of the Dialysis Facility.

[2] We note that the NQF has previously endorsed a pain measure (NQF #0420) upon which this measure is based.

[3] We note that the NQF has previously endorsed a depression measure (NQF #0418) upon which this measure is based.

[4] We note that the NQF has previously endorsed a vaccination measure (NQF #0431) upon which this measure is based.

a. Standardized Transfusion Ratio (STrR) Clinical Measure

Background

We are concerned that the inclusion of erythropoiesis-stimulating agents (ESAs) in the ESRD PPS and the removal of the Hemoglobin Less than 10 g/dL clinical measure from the ESRD QIP measure set could result in the underutilization of ESAs to manage anemia in ESRD patients, with the result that these patients have lower achieved hemoglobin levels and more frequently need red-blood-cell transfusions.

In addition, patients with ESRD who are eligible to receive a kidney transplant and are transfused risk becoming sensitized to the donor pool, thereby making it less likely that a transplant will be successful. Blood transfusions also carry a small risk of transmitting blood-borne infections to the patient, and the patient could additionally develop a transfusion reaction. Furthermore, using infusion centers or hospitals to transfuse patients is expensive, inconvenient, and could compromise future vascular access.

Overview of Measure

The Standardized Transfusion Ratio (STrR) for all adult Medicare ESRD patients is a ratio of the number of observed eligible blood transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected from a predictive model that accounts for patient characteristics within each facility. Eligible transfusions are those that do not have any claims pertaining to the comorbidities identified for exclusion in the 12 months immediately prior to the transfusion date.

We plan to submit the STrR measure to NQF for review at the next available call for measures. Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iv) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (which is currently NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, 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, so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We have given due consideration to endorsed measures, as well as those adopted by a consensus organization, and we proposed this measure under the authority of 1881(h)(2)(B)(ii) of the Act. NQF has not endorsed and a consensus organization has not adopted a measure on transfusions. Because the proposed STrR measure has the potential to decrease transfusions resulting from underutilization of anemia medications, we believe it is appropriate to adopt the STrR in the PY 2018 ESRD QIP. We considered proposing to adopt the measure for the PY 2017, but we recognized that this is a new measure, and wanted to give facilities more time to familiarize themselves with it. The Measure Application Partnership, in its February 1, 2013 Pre-Rulemaking Report, supported the direction of the measure, stating that it ''addresses an important concept, but the establishment of guidelines for hemoglobin range is needed.'' We have received public comments and input from a TEP that we convened on a prototype STrR measure, and finalized development of the proposed STrR measure in September 2013. The resulting measure specifications did not include hemoglobin thresholds, as no input from the TEP or public comments supported moving forward with thresholds included in the measure. We therefore believe these efforts meet the requirements for further development of the STrR prior to implementation in the ESRD QIP.

In the process of preparing to submit the measure for NQF review, we conducted analyses on the reliability of the STrR measure. The full analysis is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* The STrR is not a simple average; instead, we estimate the IUR using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by ''random noise,'' indicating the measure would not be a reliable characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities. We have determined that the average IUR for the STrR measure is 0.54, meaning that about half of the variation in the measure can be attributed to between-facility differences, and about half to within-facility variation. This value of IUR indicates a moderate degree of reliability and is consistent with the reliability of other outcome measures in CMS quality reporting and VBP programs. We therefore believe that facilities can be reliably scored on the proposed STrR measure.

Data Sources

Data for the measure come from various CMS-maintained data sources for ESRD patients including Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the CROWNWeb database, the CMS Annual Facility Survey (Form CMS–2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS–2728), transplant data from the OPTN, the Death Notification Form (Form CMS–2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. These data sources include all Medicare patients. Information on transfusions is obtained from Medicare Inpatient and Outpatient Claims SAFs.

Outcome

The outcome of interest for the STrR is blood transfusion events (defined as the transfer of one or more units of blood or blood products into the recipient's blood stream) among Medicare ESRD patients dialyzing at the facility during the inclusion time periods.

Cohort

The cohort for the STrR includes all adult Medicare ESRD dialysis patients who have been documented as having had ESRD for at least 90 days.

Inclusion and Exclusion Criteria

Patients will not be included in the STrR during the first 90 days of ESRD dialysis treatment. Starting with day 91 after onset of ESRD, a patient is attributed to a facility once he or she has been receiving dialysis there for 60 days. When a patient transfers from one facility to another, we are proposing that the patient would continue to be attributed to the original facility for 60 days from the date of the transfer. Starting on day 61, the patient would be attributed to the transferee facility. Patients would be excluded from the measure for three days prior to the date they receive a transplant to avoid including transfusions associated with the transplant hospitalization.

We also proposed to require that patients reach a certain level of Medicare-paid dialysis bills to be included in the STrR, or that patients

have Medicare-paid inpatient claims during the period. This requirement was intended to assure completeness of transfusion information for all patients included in the measure calculation by excluding non-Medicare patients and patients for whom Medicare is a secondary payer, because they are not expected to have complete information on transfusion available in the claims data. For each patient, a month is included as a month at risk for transfusion if that month in the period is considered ''eligible.'' A month is considered eligible if it is within two months of a month in which a patient has $900 of Medicare-paid claims or at least one Medicare-paid inpatient claim. The $900 amount represents approximately the tenth percentile of monthly dialysis claims per patient.

In addition, a transfusion event is eligible for inclusion in the STrR measure if the patient did not present with certain comorbid conditions during the 12 month period immediately prior to the date of the transfusion event. We proposed to exclude these transfusion events because the identified comorbid conditions are associated with a higher risk of transfusion and require different anemia management practices that the measure is not intended to address. Specifically, we proposed that a transfusion event will be excluded from the measure if the patient, during the 12 month look back period, had a Medicare claim for: Hemolytic and aplastic anemia; solid organ cancer (breast, prostate, lung, digestive tract and others); lymphoma; carcinoma in situ; coagulation disorders; multiple myeloma; myelodysplastic syndrome and myelofibrosis; leukemia; head and neck cancer; other cancers (connective tissue, skin, and others); metastatic cancer; or sickle cell anemia. The specific diagnoses used to identify each of these conditions are listed in the proposed measure specifications, which are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

Risk Adjustment

The denominator of the STrR uses expected transfusions calculated from a Cox model that is extended to handle repeated events. For computational purposes, the proposed STrR measure adopts a model with piecewise-constant baseline rates. A stage 1 model is fitted to the national data with piecewise-constant baseline rates across facilities. Transfusion rates are adjusted for: Patient age; diabetes as a cause of ESRD; duration of ESRD; nursing home status; BMI at incidence; comorbidity index at incidence; and calendar year. This model allows baseline transfusion rates to vary between facilities, and applies the regression coefficients for the risk-adjustment model to each facility identically. This approach is robust to possible differences between facilities in the patient mix being treated. The second stage uses the risk-adjustment factor from the first stage as an offset. The stage 2 model then calculates the national baseline transfusion rate.

The STrR measure includes the following risk adjustors, which are obtained from the following data sources:

Risk adjustor	Data source
Age	REMIS database.
Diabetes as cause of ESRD	CMS Form 2728.
BMI at incidence of ESRD	CMS Form 2728.
Comorbidity index	CMS Form 2728.
Nursing home status	Nursing Home Minimum Dataset.
Duration of ESRD	CMS Form 2728.

More details on the risk-adjustment calculations, and the rationale for selecting these risk adjustors and not others, can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

As indicated in the table above, the proposed STrR measure risk adjusts predominantly on the basis of patient characteristics collected on CMS Form 2728, and we believe that this risk-adjustment methodology is reliable and valid.

NQF evaluates measures on the basis of four criteria: Importance, scientific acceptability, feasibility, and usability. The validity and reliability of a measure's risk-adjustment calculations fall under the ''scientific acceptability'' criterion, and Measure Evaluation Criterion 2b4 specifies NQF's preferred approach for risk adjusting outcome measures (*http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx#scientific*). This criterion states that patient comorbidities should only be included in risk-adjustment calculations if they are (1) present at the start of care and (2) not indicative of disparities or deficiencies in the quality of care provided. As indicated in the ''Inclusion and Exclusion Criteria'' subsection above, the proposed STrR clinical measure includes Medicare patients who have been documented as having had ESRD for at least 90 days and are not excluded for other reasons. Accordingly, we believe that NQF Measure Evaluation Criterion 2b4 supports risk-adjusting the proposed STrR measure on the basis of incident patient comorbidity data collected on CMS Form 2728, because these comorbidities are likely present at the start of care. Moreover, comorbidities that develop after the 90th day of chronic dialysis treatment, and are statistically associated with transfusions, can be reflective of the quality of care provided by the facility. Therefore, we do not believe that NQF Measure Evaluation Criterion 2b4 supports risk adjusting the proposed STrR measure on the basis of updated comorbidity data, because doing so may mask disparities or deficiencies in the quality of care provided, thereby obscuring assessments of facility performance. For these reasons, we believe that the risk-adjustment methodology for the proposed STrR measure is consistent with NQF guidelines for measure developers. Testing that we have undertaken has confirmed the validity and reliability of the proposed STrR measure using these data. We anticipate submitting the measure to the NQF for endorsement in CY 2015.

Full documentation of the STrR risk-adjustment methodology is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

Calculating the STrR Measure

The STrR measure is calculated as the ratio of the number of observed transfusions to the number of expected transfusions. The ratio is greater than one for facilities that have more

transfusions than would be expected for an average facility with similar cases, and less than one if the facility has fewer transfusions than would be expected for an average facility with similar cases. This ratio is calculated in terms of patient-years at risk. ''Patient-year at risk'' means that the denominator of the rate calculation is obtained by adding exposure times of all patients until a censoring event (that is, death, transplant, or end of the time period) because each patient's time at risk varies based on these censoring events. Time at risk is the time period in which each patient is eligible to have the transfusion event occur for the purposes of the measure calculation, exclusive of all days that have claims pertaining to the exclusionary comorbidities identified within the previous 12 months.

The predicted value from stage 1 of the model and the baseline rate from stage 2 of the model, as described above, are then used to calculate the expected number of transfusion events for each patient over the period during which the patient is seen to be at risk for a transfusion event.

The STrR is a point estimate—the best estimate of a facility's transfusion rate based on the facility's case mix. For more detailed information on the calculation methodology, please refer to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on this proposal to adopt the proposed STrR clinical measure. The comments and our responses are set forth below.

Comment: Some commenters supported the proposal to adopt the Standardized Transfusion Ratio clinical measure because the measure ''assesses the poor outcomes related to anemia in the ESRD QIP.''

Response: We thank commenters for their support.

Comment: Many commenters did not support the proposal to adopt the STrR measure because it is not a fair way to evaluate facility performance. Specifically, commenters stated that transfusion events are beyond the control of facilities, that physicians outside of the facility may order a transfusion (which would unduly detriment the facility's score on the measure) or fail to continue a patient's ESA doses during the patient's hospitalization, and that hospital physicians' misunderstanding about hemoglobin levels is often the source of unnecessary transfusions. One commenter recommended stratifying the STrR measure according to patient comorbidities to capture only blood transfusions that could be prevented by the dialysis facility. Commenters further stated that the measure does not reliably differentiate facility performance because a transfusion event could be attributed to a chronic condition or an acute problem during hospitalization, as opposed to poor anemia management on the part of facilities.

Response: We recognize that most transfusions occur outside the dialysis facility. We further recognize that blood transfusions are often ordered in response to acute events, such as gastrointestinal bleeding or other trauma, that happen during the hospitalization. However, peer-reviewed research identifies a strong association between achieved hemoglobin and subsequent transfusion events.[7] Our analysis of patient and facility level risk-adjusted models supports the literature. These observational analyses are consistent with the findings of an earlier randomized controlled trial that identified marked differences in rates of transfusion related to targeted hemoglobin.[8] Because dialysis facilities have a direct role in determining achieved hemoglobin as a result of their anemia management practices, we believe there is a shared responsibility in subsequent transfusion events. The attribution of responsibility to the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) as measured by the STrR is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication. These exclusion co-morbidities are obtained from Medicare Claims, based on recommendations of the Anemia Technical Expert Panel convened in 2012, as well as recent peer reviewed publications evaluating transfusions.[9] We believe that the salient quality issue is not that a clinical decision to order a transfusion was made, but that the management of a patient's anemia resulted in circumstances that necessitated such a transfusion.

We also believe that the discontinuation of a patient's ESA dose during an acute hospitalization is very unlikely to affect the patient's hemoglobin levels unless the hospitalization is of very long duration, given the several weeks long half-life of red blood cells in the patient's circulation after being release from the bone marrow. Therefore, ESA dosing and achieved hemoglobin present on admission, which are the responsibility of the dialysis facility, are much stronger drivers of the need for transfusion than whether or not an ESA is given during an average length hospitalization for any given admission diagnosis.

Further, we are not aware of peer-reviewed evidence that would support a concern that hospital-based physicians do not understand the significance of hemoglobin levels and, therefore, order unnecessary transfusions. Although transfusion decisions are individualized based on a patient's clinical condition, many acute care hospitals use national guidelines to determine when a blood transfusion is appropriate. The guidelines that we are aware of do not differentiate between chronic dialysis patients and the general population. Additionally, if this type of misunderstanding does exist, we believe that proper communication and coordination of care between the dialysis facility and hospital physicians could help reduce the possibility that an unnecessary transfusion is ordered.

Comment: Many commenters expressed a number of technical concerns with the specifications for the STrR measure. Specifically, commenters stated that using the 2728 form as the data source for determining patient comorbidities is inappropriate because the form is not used to track comorbidities that develop after the initiation of ESRD, the form is often filled out incorrectly, and the form systematically underestimates the number of patient comorbidities. Commenter therefore recommends obtaining a reliable data source (such as the Common Working File) for comorbidities before adopting the measure. Commenters further stated that facilities do not have ready access to transfusion data, which they could use

[7] Collins et al., ''Effect of Facility-Level Hemoglobin Concentration on Dialysis Patient Risk of Transfusion'', Am J Kidney Dis. 2014;63(6):997–1006; Hirth RA, Turenne T, Wheeler JRC et al., (November 2012) ''Did the dialysis Prospective Payment System result in more patients receiving transfusions?'' Poster presentation at ASN Renal Week in San Diego, CA; Sibbel S, Bond C, Wilfehrt H et al. (2013 April) ''Decreased Population Hemoglobin (HB) Levels and Increased Transfusion (TFN) Rates Under New ESA Guidelines in Patients (PTS) with ESRD at a Large Dialysis Organization (LDO). Poster to be presented at the National Kidney Foundation (NKF) Spring Clinical Meeting in Orlando, FL. Abstract retrieved from *http://ww3.aievolution.com/nkf1301/index.cfm?do=abs.pubSearchAbstracts;* Hirth, et al. 2014.

[8] (Foley 2008).

[9] Ibrahim HN, Ishani A, Foley RN et al. ''Temporal Trends in red blood transfusion among US dialysis patients, 1992–2005''. American Journal of Kidney Disease. 2008; 52: 1115.

to design quality improvement programs.

Response: The STrR uses both Form 2728-derived incident comorbidities and patient demographics as well as Medicare Claims derived prevalent comorbidities for its risk-adjustment and exclusions. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication, and may develop after initiation of dialysis. It is important, however, that we be circumspect in risk-adjusting for conditions that appear after the initiation of dialysis, to avoid adjusting for conditions that resulted from the care decisions made by the provider. These exclusion co-morbidities are obtained from Medicare Claims, based on recommendations of the Anemia Technical Expert Panel convened in 2012, as well as recent peer reviewed publications evaluating transfusions.[10]

Comment: Some commenters were concerned about validity of claims data used to identify qualifying transfusion events, because hospital coding for transfusions is inconsistent, and sometimes codes do not distinguish between preparing for a transfusion and the transfusion itself. Commenters also stated that the claims data used to score the measure is incapable of differentiating among the various reasons for a blood transfusion. As such, the measure does not accurately predict or identify when a patient actually receives a transfusion.

Response: Prior research has supported the validity of billing codes for identifying red blood cell transfusions.[11] Additionally, other recent articles accepted and published in peer reviewed journals support the review and acceptance of this method of identification of transfusions from administrative data.[12] Specifically, we used multiple sources (procedure codes, revenue center codes, and value codes) to improve the ability to detect actual transfusion events during a hospitalization. Red blood cell transfusions are identified by in-patient records with revenue center codes in (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) or value code = 37 or procedure code in (9903, 9904) and with out-patient records with revenue center codes in (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) and HCPCS code in (P9010, P9011, P9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9056, P9058, 36430). The measure does not attempt to address the particular reason for a transfusion event, only that one occurred. One ''transfusion event'' is counted per inpatient claim if one or more transfusion-related revenue center or value codes are present. This is the way most inpatient transfusion events are reported on claims (that is, using revenue center or value codes, not procedure codes). We only count a single transfusion event for an inpatient claim regardless of the number of transfusion revenue center and value codes reported so that the number of discrete events counted is the same whether the claim indicates 1 unit of blood or multiple units of blood.

Comment: Some commenters did not support the proposed STrR measure because it has not been endorsed by NQF, and one commenter was concerned about the measure's validity and reliability. Commenter recommended delaying the adoption of the measure until it has been endorsed by NQF.

Response: The STrR measure has undergone rigorous review by a TEP and the CMS measure development contractor, and for the reasons detailed in the proposed rule and this final rule, we believe that the measure reliably assesses facility performance. Because unexpected transfusions in the ESRD population are responsible for considerable and unnecessary morbidities and healthcare costs, and because no NQF-endorsed measures of anemia management are currently available for use in the ESRD QIP, we believe that the benefits of adopting the measure for the PY 2018 ESRD QIP outweigh the costs of waiting to adopt the measure until it has been endorsed by NQF.

Comment: One commenter recommended that CMS develop a hemoglobin-adjusted STrR rather than the STrR proposed in the proposed rule. Commenter stated that facilities should only be held responsible for transfusions related to chronically low hemoglobin levels, and that this adjustment would better differentiate between patients with chronically and acutely low hemoglobin levels.

Response: We thank commenters for the recommendation. We agree that achieved hemoglobin is a significant facility-associated component of transfusion risk. Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, there is a shared responsibility in subsequent transfusion events. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication. Applying a hemoglobin target would not be consistent with the FDA label, which does not support hemoglobin targets.

Comment: One commenter recommended that CMS use calendar year (CY) 2010 to set permanent performance standards for the STrR measure. Because transfusion rates have increased since CY 2010, commenter stated that the proposed performance standard would set an inappropriately low threshold for expected transfusion events.

Response: We do not believe it would be appropriate to use CY 2010 to set permanent performance standards for the STrR measure. The measure was designed to assess relative rates of transfusion, not to hold facilities accountable to a historical rate of transfusion. Furthermore, setting the performance standard at CY 2010 rates would not allow us to respond to fluctuations in transfusion rates in the future, and we believe it is appropriate to do so, particularly in the event that future national transfusion rates fall below levels achieved in CY 2010.

Comment: Some commenters stated that the risk-adjustment methodology for the proposed STrR measure should not be based on the risk-adjustment methodology for the Standardized Hospitalization measure, because hospitalizations and transfusions involve different types of risk factors. Commenters stated that adjusting for risks that are more proximately associated with transfusions would require the use of claims data for determining patient comorbidities.

Response: We agree with commenters' assertion that more proximate claims-based risk factors are appropriate for use in the risk adjustment strategy for STrR. We also believe that this has already been accomplished using our measure methodology. The responsibility of the

[10] Ibrahim HN, Ishani A, Foley RN et al. ''Temporal Trends in red blood transfusion among US dialysis patients, 1992–2005''. American Journal of Kidney Disease. 2008; 52: 1115.

[11] Segal JB1, Ness PM, Powe NR. Validating billing data for RBC transfusions: A brief report. Transfusion. 2001 Apr;41(4):530–3.

[12] Collins et al., ''Effect of Facility-Level Hemoglobin Concentration on Dialysis Patient Risk of Transfusion,'' Am J Kidney Dis. 2014;63(6):997–1006; and Hirth et al, Blood Transfusion Practices in Dialysis Patients in a Dynamic Regulatory Environment, Am J Kidney Dis. 2014 (in-press).

dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication. By excluding transfusions not associated with anemia management, we are able to assess the rate of transfusions most subject to influence by the quality of care provided by dialysis facilities. Exclusion comorbidities must have occurred within the last year, and have a similar, but stronger impact for the measure, than risk-adjustment. As a consequence, transfusions that are occurring are not attributable to these non-anemia management-based causes. These exclusion co-morbidities are obtained from Medicare Claims, based on recommendations of the Anemia TEP convened in 2012, as well as recent peer reviewed publications evaluating transfusions.[13]

Comment: One commenter recommended that CMS limit the number of transfusion events that a single patient can contribute to this measure, because very frequent transfusions may be required due to conditions that the dialysis facility cannot control, such as chemotherapy treatment, presence of bone marrow malignancies, or sickle cell anemia, which may not be captured in the past year on Medicare claims.

Response: We thank commenters for the recommendation. Because of the way transfusion information is reported in claims, there are different rules for counting transfusion events depending on whether or not they occur in inpatient or (less commonly) in outpatient settings.

For the STrR, transfusion events are counted differently depending on whether they are identified based on a procedure code, a revenue center code, or a value code. The transfusion procedure may only be billed only once per day per visit. For the STrR, unique ''transfusion events'' are counted for each transfusion procedure code listed on an inpatient claim, with one event counted for any of those codes on a given day. Additionally, one ''transfusion event'' is counted per inpatient claim if one or more transfusion-related revenue center or value code is present. The vast majority of inpatient claims we identify as having evidence of a transfusion (92 percent) do not include a transfusion related procedure code. Therefore, most inpatient transfusion events are identified based on revenue center or value codes. As noted above, we count a single transfusion event for the inpatient claim regardless of the number of transfusion revenue center and value codes reported on the claim, resulting in a very conservative estimate of blood transfusions from inpatient claims. In all cases, the number of events counted is the same whether the claim indicates 1 unit of blood or multiple units of blood, again favoring a conservative estimate of number of transfusion events from inpatient claims.

Transfusion events are not common in outpatient settings, but similar rules apply. Multiple HCPCS codes reported for the same Revenue Center Date are counted as a single transfusion event regardless of the number of units of blood recorded. In other words, three pints of blood reported with the same Revenue Center Date would be counted as a single transfusion event.

Therefore, the algorithm for identifying blood transfusion events described here results in a very conservative estimate of transfusion rates, limiting the impact of individual patients who receive multiple units of blood or multiple transfusions during any one episode of care. We agree that there are many conditions, including acute malignancy diagnoses and hereditary anemias (for example, sickle cell anemia) that influence transfusion risk. The STrR uses Form 2728-derived incident comorbidities and patient demographics as well as Medicare Claims derived prevalent comorbidities in the risk-adjustment strategy for STrR. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions described in the technical report at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html* for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication. These exclusion co-morbidities are obtained from Medicare Claims, based on recommendations of the Anemia Technical Expert Panel convened in 2012, as well as recent peer reviewed publications evaluating transfusions.[14] The list of comorbid exclusions includes acute cancer diagnoses and Sickle Cell Anemia, as well as other conditions that are associated with increased transfusion risk beyond the dialysis facilities' control.

Comment: Some commenters stated that transfusions related to ''non-actionable conditions,'' such as chronic gastrointestinal bleeding, motor vehicle accidents, and transfusions related to surgical procedures, should be excluded from the measure. Accordingly, commenters recommended that CMS should develop a comprehensive list of exclusions before adopting the measure.

Response: The STrR incorporates a list of exclusions based on patient conditions identified through claims data. These exclusions help to ensure that transfusions for which the facility may not reasonably be held accountable are not incorporated in the measure numerator. A full list of exclusions may be read at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* However, for any given admission diagnosis such as a motor vehicle accident, or a hospital event such as a surgical procedure, the achieved hemoglobin present on admission, which is a function of ESA dosing and the responsibility of the dialysis facility, is a strong predictor of a transfusion event during the hospitalization.

Comment: One commenter sought clarification on how transfusions will be attributed to facilities, particularly when a patient receives a transfusion and temporarily relocates to a new facility before returning to their home facility.

Response: The STrR Methodology Report, which was published concomitantly with the CY 2015 ESRD PPS Proposed Rule, provides the detailed algorithm used by the STrR measure to attribute patients to a facility. Briefly, if a patient undergoes a transfusion event, the facility to which this patient is assigned at the time is responsible for it irrespective of where the event takes place or whether the patient is temporarily receiving dialysis at another facility.

Comment: One commenter did not support the STrR measure as proposed, because it is not sufficient on its own right to discourage under-treatment of anemia. Commenter also recommended that the measure should be stratified to capture only those transfusions that could have been prevented by the dialysis facility.

[13] Ibrahim HN, Ishani A, Foley RN et al. ''Temporal Trends in red blood transfusion among U.S. dialysis patients, 1992–2005,'' American Journal of Kidney Disease. 2008; 52: 1115.

[14] Ibrahim HN, Ishani A, Foley RN et al. ''Temporal Trends in red blood transfusion among U.S. dialysis patients, 1992–2005.'' American Journal of Kidney Disease. 2008; 52: 1115.

Response: The STrR is intended to monitor facility-level, risk-adjusted blood transfusion use, which is one important consequence of under-treatment of anemia in chronic dialysis patients, and it is the most appropriate measure of which we are aware that is available for this purpose.

Comment: One commenter stated that facilities will experience difficulty in explaining facility scores on the STrR clinical measure to patients, and that doing so may be ''politically challenging'' when the dialysis facility is affiliated with the admitting hospital system.

Response: We have produced a technical report that describes the measure methodology and provided a Web link in the proposed rule (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*). A transfusion ratio of greater than 1.0 reflects that a facility's patients are at higher risk for transfusions than they would be at an average facility. A score below 1.0 reflects that a facility's patients are at lower risk for transfusions than they would be at an average facility. A lower ratio is preferable because it indicates that a facility is doing a better job of managing patient anemia, as assessed through the occurrence of transfusions.

For these reasons, we are finalizing the STrR measure as proposed for the PY 2018 program and future payment years. The technical specifications for this finalized measure can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

b. Adoption of the Pediatric Peritoneal Dialysis Adequacy Clinical Measure in the Dialysis Adequacy Measure Topic

Section 1881(h)(2)(A)(i) states that the ESRD QIP must evaluate facilities based on measures of dialysis adequacy. Beginning with the PY 2018 ESRD QIP, we proposed to add a new measure of pediatric peritoneal dialysis adequacy to the Dialysis Adequacy measure topic. We stated that if this proposal is finalized, then the modified Dialysis Adequacy measure topic would include four clinical measures on dialysis adequacy—(1) Adult Hemodialysis Adequacy; (2) Adult Peritoneal Dialysis Adequacy; and (3) Pediatric Hemodialysis Adequacy; and (4) Pediatric Peritoneal Dialysis Adequacy.

Approximately 900 pediatric patients in the United States receive peritoneal dialysis.[15] Although recent studies suggest improvement in mortality rates among pediatric patients receiving maintenance dialysis over time, mortality in this patient population remains high.[16] Despite a lack of long-term outcome studies on pediatric peritoneal dialysis patients, outcome studies performed in the adult ESRD population have shown an association between the dose of peritoneal dialysis and clinical outcomes,[17] which could suggest that improved quality of dialysis care in the fragile pediatric patient population may further improve survival in those patients.

Section 1881(h)(2)(A)(iv) gives the Secretary authority to adopt measures for the ESRD QIP that cover a wide variety of topics. Section 1881(h)(2)(B)(ii) of the Act states that ''In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of Act [in this case NQF], the Secretary may specify a measure that is not so endorsed so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.'' We have given due consideration to endorsed measures, as well as those adopted by a consensus organization. Because no NQF-endorsed measures or measures adopted by a consensus organization on pediatric peritoneal dialysis adequacy currently exist, we proposed to adopt the Pediatric Peritoneal Dialysis Adequacy clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

The Measure Application Partnership expressed conditional support for measure XCBMM, ''Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V'' in its January 2014 Pre-Rulemaking Report, noting it would ''consider this measure for inclusion in the program once it has been reviewed for endorsement.'' However, we believe the measure is ready for adoption in the ESRD QIP because it has been fully tested for reliability and has received consensus support from the TEP that was tasked with developing it. We intend to submit this measure to the NQF for endorsement in late 2014 or early 2015.

For PY 2018 and future payment years, we proposed to adopt the Pediatric Peritoneal Dialysis Adequacy clinical measure, which assesses the percentage of eligible pediatric peritoneal dialysis patient-months in which a Kt/V of greater than or equal to 1.8 was achieved during the performance period. Qualifying patient-months are defined as months in which a peritoneal dialysis patient is under the age of 18 and has been receiving peritoneal dialysis treatment for 90 days or longer. Performance on this measure will be expressed as a proportion of patient-months meeting the measure threshold of 1.8, and the measure will be scored based on Kt/V data entered on Medicare 72x claims. The measure is a complement to the existing Kt/V dialysis adequacy measures previously adopted in the ESRD QIP. Technical specifications for the proposed pediatric peritoneal dialysis adequacy clinical measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on this proposal to adopt the Pediatric Peritoneal Dialysis Adequacy measure. The comments and our responses are set forth below.

Comment: Many commenters supported the adoption of the Pediatric Peritoneal Dialysis Adequacy measure, because it is important to ensure that this patient population is adequately dialyzed.

Response: We thank the commenters for their support.

Comment: One commenter supported adoption of the Pediatric Peritoneal Dialysis Adequacy clinical measure, but recommended CMS change the Kt/V target to a range, because it is harder to reach the proposed threshold for a pediatric patient than it is to reach the threshold for adult patients.

Response: The proposed minimum target of Kt/V–1.8 is consistent with clinical guidelines and also the recommendations of a TEP which we convened for this purpose. The TEP recommended using a target of 1.8 while recognizing that although limited

[15] U.S. Renal Data System, USRDS 2012 Annual Data report: Atlas of Chronic Kidney Disease and End-stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2012.

[16] U.S. Renal Data System, USRDS 2012 Annual Data report: Atlas of Chronic Kidney Disease and End-stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2012.

[17] Paniagua R, Amato D, Vonesh E, et al. ''Effects of increased peritoneal clearance on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial.'' *Journal of the American Society of Nephrology: JASN* (2002) 13:1307–1320. PMID: 11961019; *See also* Lo WK, Lui SL, Chan TM, et al. ''Minimal and optimal peritoneal Kt/V targets: Results of anuric peritoneal dialysis patient's survival analysis.'' *Kidney international* (2005) 67:2032–2038. PMID: 15840054.

evidence in the pediatric population exists, clinical practice guidelines and clinical opinion support the recommendation that target clearance in pediatric patients should meet or exceed adult standards. Studies of adult peritoneal dialysis patients identified better survival at Kt/V 1.8/week, and not 1.7 (Paniagua 2002, JASN 2002, Lo, KI 2005). We also believe that a target range could have the effect of substituting the current target with the lower boundary of any specified range.

Comment: One commenter did not support the adoption of the Pediatric Peritoneal Dialysis Adequacy clinical measure because it exposes pediatric patients to unnecessary risk. Commenter stated that ''residual'' Kt/V requires 24-hour urine collection, and that young children who are not toilet trained would need to be hospitalized and have a Foley catheter placed, which would put them at risk for infections and illness.

Response: We appreciate commenters' concerns for the safety of pediatric patients, and for the opportunity to clarify this point. The commenters statement about the potential difficulties inherent in collecting a 24 hour urine on young children on peritoneal dialysis have been previously addressed in both the KDOQI recommendations as well as the recommendations of the TEP. Both KDOQI and the TEP members recommend addition of 24 hour urine if available. They acknowledge that the 24 hour urine is usually not available for use in the Kt/V calculation for very young PD patients. In that case, they recommend that the Kt/V collection be based solely on the dialysate collection. The commenter's concern that patients would have to be hospitalized to complete a 24 hour collection in order to perform the calculation is not consistent with the clinical guidelines upon which the measure was based.

For these reasons, we are finalizing the Pediatric Peritoneal Dialysis Adequacy measure as proposed for the PY 2018 program and future payment years and adding this measure to the Dialysis Adequacy Measure Topic. The technical specifications for this finalized measure can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

c. ICH CAHPS Clinical Measure

Section 1881(h)(2)(A)(ii) of the Act states that the Secretary shall specify, to the extent feasible, measures of patient satisfaction. Patients with ESRD are an extremely vulnerable population: They are completely reliant on ESRD facilities for life-saving care, and they are often reluctant to express concerns about the care they receive from an array of staff, both professional and non-professional. Patient-centered experience is an important measure of the quality of patient care, and it is a component of the 2013 NQS, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care.

Following a rigorous process, the ICH CAHPS Survey was developed to capture the experience of in-center hemodialysis patients. The NQF endorsed and the Measures Application Partnership supported this quality measure (NQF #0258: CAHPS In-Center Hemodialysis Survey). The ICH CAHPS Survey captures the experience of in-center hemodialysis patients on three dimensions: ''Nephrologists' communication and caring;'' ''quality of dialysis center care and operations;'' and ''providing information to patients.'' Three global ratings are also part of the standardized ICH CAHPS Survey: Rating of the nephrologist; rating of the staff; and rating of the facility.

We believe that this measure enables patients to rate their experience of in-center dialysis treatment without fear of retribution. Public reporting of results from the ICH CAHPS survey, once enough data are available, will satisfy requests to provide consumers (patients and family members alike) with desired information on viewpoints from patients. In addition, collecting and reporting ICH CAHPS survey results assists facilities with their internal quality improvement efforts and external benchmarking with other facilities, and it provides CMS with information that can be used to monitor the experience of patients with ESRD.

Starting with the PY 2014 program, we have taken steps to develop the baseline data necessary to propose and implement NQF #0258 as a clinical measure in PY 2018. In the PY 2014 and PY 2015 programs, we adopted a reporting measure related to the ICH CAHPS survey, which required that facilities attest they had administered the survey according to the specifications set by the Agency for Healthcare Research and Quality (AHRQ). In the CY 2014 ESRD PPS final rule, we: (1) Expanded the ICH CAHPS reporting measure to require facilities to submit (via CMS-approved vendors) their survey results to CMS; (2) increased the patient minimum for the measure from 11 to 30 survey-eligible patients; (3) required that facilities (via CMS-approved vendors) administer the survey according to specifications set by CMS; and (4) required facilities (via CMS-approved vendors) to administer the survey twice during each performance period, and to report both sets of survey results by the date specified on *http://ichcahps.org,* starting in PY 2017 (78 FR 72193 through 72196).

By CY 2016 (the proposed performance period for the PY 2018 ESRD QIP), we will have worked with dialysis facilities for four years to help them become familiar with the ICH CAHPS survey. By that time, we believe that facilities will be sufficiently versed in the survey administration process to be reliably evaluated on the NQF-endorsed ICH CAHPS measure (NQF #0258). Because facilities (and CMS-approved vendors) will be familiar enough with the ICH CAHPS survey instrument to be reliably scored on the basis of their survey results, we believe it is reasonable to expand the ICH CAHPS reporting measure into a clinical measure for the PY 2018 ESRD QIP.

For these reasons, and because a clinical measure would have a greater impact on clinical practice by holding facilities accountable for their actual performance, we proposed to replace the ICH CAHPS reporting measure that we adopted in the CY 2014 ESRD PPS Final Rule with a new clinical measure for PY 2018 and future payment years. This proposed ICH CAHPS clinical measure is NQF #0258: CAHPS In-Center Hemodialysis Survey. We did not propose to change the semiannual survey administration and reporting requirements. The proposed scoring methodology for the ICH CAHPS clinical measure is discussed below in section III.G.4.c. Technical specifications for the ICH CAHPS clinical measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Some commenters supported the proposal to convert the ICH CAHPS reporting measure into a clinical measure, because a clinical measure would hold facilities responsible for their ability to provide patients with a positive experience of care, adopting the clinical measure would strengthen the significance of patient input in the ESRD QIP, and facilities have had sufficient experience with the survey instrument for them to be reliably scored on the measure. One commenter stated that, in the hospital setting, scoring CAHPS survey results

has led to positive changes in the treatment environment.

Response: We thank commenters for their support.

Comment: One commenter did not support the adoption of an ICH CAHPS clinical measure because the measure would be based on patient perceptions (as opposed to clinical data). Commenter further stated that the ICH CAHPS clinical measure unfairly penalizes facilities, because providers have to contend with a number of obstacles (including reductions in payments under the ESRD PPS) and clinical variables, of which patients may not be aware. Commenter also stated that the ''efficacy of the survey administration'' may impact results, so the proposed clinical measure would evaluate facilities, in part, based on the competencies of survey vendors.

Response: We understand commenters' concerns about the ICH CAHPS measure and its patient-centered assessment of care. We further understand that patients may not be aware of the multiple influences on facilities, such as the ESRD PPS bundle and other clinical variables. However, we believe that patients are qualified to assess their perceptions of their individual care, because the quality of care provided to patients should not be impacted by reimbursement rates or the severity of a patient's illness. The ICH CAHPS survey provides patients with an opportunity to assess the care they receive as in-center hemodialysis patients, and the results from this survey will give facilities the opportunity to develop plans for quality improvement on this aspect of care. All ICH CAHPS survey vendors must be approved by CMS to ensure that the survey is administered consistently across facilities, and vendors are required to undergo annual training sessions and submit a Quality Assurance Plan to us. Furthermore, the ICH CAHPS Coordination Team intends to carry out oversight activities, including site cities and data reviews for anomalies, to ensure that the survey is being administered according to the ICH CAHPS survey protocol. We note that, ultimately, the choice of survey vendor is within the control of the facility. If a facility believes its vendor is not properly administering the survey, then the facility should report to this to CMS and seek the services of another qualified survey vendor.

Comment: Some commenters did not support the proposal to convert the ICH CAHPS reporting measure into a clinical measure, because the clinical measure includes questions pertaining to nephrologists' care in the ICH CAHPS survey. Commenters stated that most dialysis facilities have little to no control over the nephrologists who are working in facilities, as well as over physicians seen outside the facility, and that both types of physicians are implicated in the survey question used to determine facility scores on the global rating for Nephrologists' Communication and Caring. Commenter further stated that this limits the facility's opportunity improve patient experience in this area.

Response: We disagree that facilities should not be held accountable for the quality of care provided by nephrologists treating patients at their facility. Dialysis facilities are required under our regulations (42 CFR 494.150(c)(2)(i)), to oversee the provision of care by a multi-disciplinary team, including the nephrologist treating the patient. Oversight of individual staff nephrologist care, ensuring adherence to facility policies and Medicare regulations, is primarily the responsibility of the site Medical Director, a paid employee of the dialysis facility, and, additionally, the responsibility of the facility governing body. We understand and agree that facilities should not make or unduly influence treatment decisions made by a patient and his or her nephrologist. However, the facility can ensure that the treatment environment is one in which patients feel empowered and informed enough to participate in their care by enacting policies regarding patient engagement, and selecting medical professionals whose behavior aligns with these principles. As a result, we believe facilities are capable of improving patients' experiences with their nephrologists and may share information received with physicians outside of the facility.

Comment: Some commenters did not support the adoption of the proposed ICH CAHPS clinical measure because patients typically dialyze at the same facility for long periods of time, and it is difficult for facilities and nephrologists to always meet patients' expectations. As an alternative to basing measure scores on ''top-box'' responses, one commenter recommended that facilities should receive credit for responses that indicate satisfactory (as opposed to exemplary) experience.

Response: While we understand commenters' concerns about being able to consistently meet patients' expectations regarding their care, we believe that patient satisfaction and involvement in their treatment is a key element of successful ESRD treatment. The scoring methodology does not require facilities to get 100 percent on a particular measure, but it evaluates overall how the facility does.

Comment: Some commenters did not support the proposal to convert the ICH CAHPS reporting measure into a clinical measure. Commenters stated that the ICH CAHPS survey was originally developed for hospitals, and that transitioning the survey to the dialysis facility setting may encourage facilities to provide substandard care (for example, inappropriately shortening the length of dialysis sessions) in order to please patients. Commenters further stated that it is often impossible for facilities to meet patient expectations when treating a chronic condition such as ESRD, and that patients might inappropriately direct their frustrations towards facilities and their staff.

Response: We understand that facilities are concerned about a potential conflict between ''pleasing patients'' and providing clinically adequate care. The ICH CAHPS survey was developed through literature reviews; focus groups of in-center hemodialysis patients and their families, nephrologists and facility staff; a review of existing surveys for ESRD patients; and a Technical Expert Panel. We therefore believe the survey adequately accounts for many perspectives of dialysis care and will allow patients to provide their opinions of the care they receive without fear of retribution. At this point, we lack any evidence to substantiate concerns that facilities will provide substandard care ''in order to please patients'' or that ''it is often impossible for facilities to meet patient expectations when treating a chronic condition''; should such evidence arise, we will reevaluate the use of the ICH CAHPS survey in the ESRD QIP for future payment years.

Comment: One commenter stated that the ICH CAHPS survey instrument is unreliable, because only 53 percent of patients with ESRD are able to complete forms for patient-reported outcomes, and basing facility scores on responses from the remaining patients cannot be generalized to reflect the true experience of all patients at a facility.

Response: We acknowledge commenter's concern regarding the overall response rate, but note that a 53 percent response rate is considered better than average, particularly for a vulnerable, chronically ill patient population. However, response rates are not a measure of reliability because response rates are subject to a variety of factors. As part of the process of submitting NQF #0258 to NQF for re-endorsement, we conducted reliability testing for the measure. Specifically, we found that the item total correlations for Kidney Doctor Communication were all

above 0.40. Nineteen of the 22 item-total correlations for Dialysis Facility Care and Operations were above 0.40. Six of 11 item-total correlations for Patient Empowerment were above 0.40. Internal consistency reliabilities for the three scales ranged from 0.75 to 0.93. We believe the measure is reliable because the item total correlations for the measure's three composite measures all exceeded 0.40, which indicates a moderate level of reliability.

Comment: Some commenters did not support the expansion of the ICH CAHPS reporting measure into a clinical measure, because published research demonstrates that several items on the survey are unreliable.

Response: We are aware of some studies that have questioned the reliability of the ICH CAHPS survey questions. However, a recent study in which we have been involved found that psychometric analyses strongly support the internal consistency, reliability, and validity of the ICH CAHPS survey scales.[18] This study further showed that these scales can be used to discriminate variation in quality of care among dialysis facilities, and that scale scores were strongly related to patients' global ratings of nephrologists, dialysis center, and dialysis center staff. We therefore believe that the survey questions are reliable.

For reasons, we are finalizing the ICH CAHPS clinical measure as proposed for the PY 2018 program and future payment years. Technical specifications for the ICH CAHPS clinical measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

d. Screening for Clinical Depression and Follow-Up Reporting Measure

Depression is the most common psychological disorder in patients with ESRD. Depression causes suffering, a decrease in quality of life, and impairment in social and occupational functions; it is also associated with increased health care costs. Current estimates put the depression prevalence rate as high as 20 percent to 25 percent in patients with ESRD.[19] Studies have also shown that depression and anxiety are the most common comorbid illnesses in patients with ESRD.[20] Moreover, depressive affect and decreased perception of social support have been associated with higher rates of mortality in the ESRD population, and some studies suggest that this association is as strong as that between medical risk factors and mortality.[21] Nevertheless, depression and anxiety remain under-recognized and under-treated, despite the availability of reliable screening instruments.[22] Therefore, a measure that assesses whether facilities screen patients for depression, and develop follow-up plans when appropriate, offers an opportunity to improve the health of patients with ESRD.

We proposed to adopt a depression measure that is based on an NQF-endorsed measure (NQF #0418: Screening for Clinical Depression). NQF #0418 assesses the percentage of patients screened for clinical depression using an age-appropriate standardized tool and documentation of a follow-up plan where necessary. The Measures Application Partnership supported the use of NQF #0418 in the ESRD QIP in its January 2014 Pre-Rulemaking Report, because the measure ''addresses a National Quality Strategy [NQS] aim not adequately addressed in the program measure set'' and promotes person- and family-centered care. We proposed to adopt a reporting measure based on this NQF-endorsed measure so that we can collect data that we can use in the future to calculate both achievement and improvement scores, should we propose to adopt the clinical version of this measure in future rulemaking. Although we recognize that we recently adopted the NHSN Bloodstream Infection clinical measure despite a lack of baseline data to calculate achievement and improvement scores, we believe that measure warranted special treatment in light of the fact that it addresses patient safety. Because the proposed screening for clinical depression measure addresses quality of life and patient well-being, and not patient safety, we think it is appropriate to adopt it as a reporting measure until such time that we can collect the baseline data needed to score it as a clinical measure.

Section 1881(h)(2)(B)(ii) of the Act states that ''In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [in this case NQF], 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.'' Because we have given due consideration to endorsed measures as well as those adopted by a consensus organization and determined it is not practical or feasible to adopt NQF #0418 as a clinical measure in the ESRD QIP at this time, we proposed to adopt the Screening for Clinical Depression and Follow-Up Plan reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

For PY 2018 and future payment years, we proposed that facilities must report one of the following conditions in CROWNWeb, at least once per performance period, for each qualifying patient (defined below):

1. Screening for clinical depression is documented as being positive, and a follow-up plan is documented
2. Screening for clinical depression documented as positive, and a follow-up plan not documented, and the facility possess documentation stating the patient is not eligible
3. Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given
4. Screening for clinical depression is documented as negative, and a follow-up plan is not required
5. Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible
6. Clinical depression screening not documented, and no reason is given

For this proposed measure, qualifying patients are defined as patients 12 years or older who have been treated at the facility for 90 days or longer. This proposed measure will collect the same data described in NQF #0418, but we are proposing to score facilities based on whether they successfully report the data, and not the measure results. More specifically, facilities will be scored on

[18] Weidmer BA, Cleary PD, Keller S, Evensen C, Hurtado MP, Kosiak B, Gallagher PM, Levine R, Hays RD (2014). Development and Evaluation of the CAHPS (Consumer Assessment of Healthcare Providers and Systems) Survey for In-Center Hemodialysis Patients. *Am J Kidney Diseases.* [Epub ahead of print].

[19] Kimmel PL, Cuckor D, Cohen SD, Peterson RA. Depression in end-stage renal disease patients: a critical review. Advances in Chronic Kidney Disease. 2007:14(4):328–34.

[20] Feroze, U., Martin, D., Reina-Patton, A., Kalantar-Zadeh, K., & Kopple, J. D. (2010). Mental health, depression, and anxiety in patients on maintenance dialysis. *Iranian Journal of Kidney Diseases,* 4(3), 173–80.

[21] Cukor, D., Cohen, S. D., Peterson, R. A., & Kimmel, P. L. (2007). Psychosocial aspects of chronic disease: ESRD as a paradigmatic illness. *Journal of the American Society of Nephrology,* 18(12), 3042–3055; and Kimmel, P. L., Peterson, R. A., Weihs, K. L., Simmens, S. J., Alleyne, S., Cruz, I., & Veis, J. H. (2000). Multiple measurements of depression predict mortality in a longitudinal study of chronic hemodialysis outpatients. *Kidney International,* 57(5), 2093–2098.

[22] Preljevic, V. T., Østhus, T. B. H., Sandvik, L., Opjordsmoen, S., Nordhus, I. H., Os, I., & Dammen, T. (2012). Screening for anxiety and depression in dialysis patients: Comparison of the Hospital Anxiety and Depression Scale and the Beck Depression Inventory. *Journal of Psychosomatic Research,* 73(2), 139–144.

whether they report one of the above conditions for each qualifying patient once before February 1 of the year directly following the performance period. Technical specifications for the Screening for Clinical Depression and Follow-Up reporting measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: Some commenters supported the Screening for Clinical Depression and Follow-Up reporting measure, and recommended that CMS either require facilities to use the same screening for depression, or require facilities to report the methodology used. Commenters also recommended that CMS require facilities to provide documentation of referral for treatment of depression beyond the abilities of the renal social worker.

Response: We appreciate commenters' support, and will consider incorporating these recommendations in future rulemaking.

Comment: Many commenters did not support adoption of the Screening for Clinical Depression and Follow-Up reporting measure. Commenters stated that the Screening for Clinical Depression and Follow-Up reporting measure is outside the dialysis facility's scope of practice, and that staff social workers are not qualified to provide treatment for depression. Commenters also stated that a measure on depression screening and follow-up is not covered within the statutory authorities of the ESRD QIP, since Section 1881 (h)(1)(A) of the Act limits the program to ''renal dialysis services.'' Commenters also stated that while facilities can do depression screenings, they are not equipped to provide psychotherapy services, and that requiring facilities to conduct the assessment is a disservice to patients, who would be better served by pyschotherapists. Comments further stated that depression unrelated to dialysis should not fall under the purview of the dialysis facility, and that conducting the annual assessment is unduly burdensome (particularly with respect to hiring staff to provide the assessment and training staff to enter data correctly). Commenters further stated that a future clinical version of this measure would require dialysis facilities to provide these services. Commenter stated that the measure would be more appropriate for the Comprehensive ESRD Care Initiative, because that initiative includes physicians as well as dialysis facilities.

Response: We appreciate commenters' input on this measure. First, we disagree that screening patients for clinical depression is outside the scope of practice for dialysis facilities. Patient assessments, including screenings for clinical depression, are a critical aspect of renal dialysis services, because they enable facilities to assess whether a patient needs additional care. We further note that the ESRD CfCs requires that facilities perform a ''comprehensive assessment [for each patient that] must include, but is not limited to . . . [an] evaluation of psychosocial needs by a social worker'' (42 CFR 494.80(a)(7)). We maintain that performing depression assessments is covered by this section (and, by extension, fall within the scope of work for dialysis facilities), because screening for clinical depression is an evaluation of the patient's psychosocial needs. We further disagree that requiring facilities to report whether they screen patients for clinical depression is unduly burdensome because depression screening is a type of a psychosocial evaluation, which, as stated above, facilities are already required to perform as a condition for coverage under the Medicare program. We also note that this measure does not, and will not, require facilities to provide psychotherapy services to patients. We believe that this measure will incentivize facilities to perform a clinical depression screening for each qualifying patient and develop a follow-up plan in order to ensure that the patient receives appropriate treatment. Although we agree that facilities are not equipped to actually treat the depression, we believe that the screenings can be performed by the individuals already in the multidisciplinary care team, such as a staff social worker. We appreciate that the Comprehensive ESRD Care model seeks to directly address coordination of care issues in the dialysis facility setting, but do not believe this precludes us from adopting a measure on this issue for the ESRD QIP, and we believe that information gained as a result of this measure can be used to better inform policy decisions in both the ESRD QIP and the CEC model.

Comment: Some commenters did not support the proposal to adopt the Screening for Clinical Depression and Follow-Up reporting measure because facilities are already performing these screenings, and because screening for depression overlaps with the Medicare Conditions for Coverage for ESRD facilities. One commenter recommended CMS instead consider using a measure such as the Standardized Hospitalization Ratio to capture the effective management of the dialysis patient.

Response: We appreciate that some facilities may already be performing these screenings. However, we do not believe that all facilities are doing so, and we believe that the Screening for Clinical Depression and Follow-Up reporting measure will incentivize all facilities to conduct depression screening and initiate follow-up plans when necessary. We also recognize that some facilities that are already screening patients for depression in order to meet the requirements of the ESRD CfCs will experience significant additional burdens associated with reporting data for the reporting measure. Nevertheless, depression is a highly prevalent condition in patients with ESRD, which impacts many aspects of a patient's life and is associated with higher rates of mortality in the ESRD population. We therefore believe the benefits of incentivizing facilities that are not already doing so to regularly screen their patients for depression outweigh the data reporting burdens for facilities that are already conducting these screening to meet the requirements of the ESRD CfCs.

Comment: Some commenters sought clarification as to what characteristics a screening instrument must have to qualify as an ''age appropriate tool'' and what constitutes a ''follow-up plan'' in the context of the proposed Clinical Depression and Follow-Up reporting measure. The commenters also sought clarification as to whether facilities are required to screen all patients for depression, or whether only patients ''identified as potentially having a problem'' should be screened. Commenters sought clarification as to whether the facility would be required to perform the screening, or whether another provider would be required to do so.

Response: The measure does not require facilities to select any particular screening tool because we believe that each facility should be able to select the tool that is most appropriate for each of their patients. However, examples of screening tools that we would consider to be age-appropriate include, but are not limited to:

Adolescent Screening Tools (12–17 years): Patient Health Questionnaire for Adolescents (PHQ–A), Beck Depression Inventory-Primary Care Version (BDI–PC), Mood Feeling Questionnaire (MFQ), Center for Epidemiologic Studies Depression Scale (CES–D), and PRIME MD–PHQ2

Adult Screening Tools (18 years and older): Patient Health Questionnaire

(PHQ–9), Beck Depression Inventory (BDI or BDI–II), Center for Epidemiologic Studies Depression Scale (CES–D), Depression Scale (DEPS), Duke Anxiety-Depression Scale (DADS), Geriatric Depression Scale (GDS), Cornell Scale Screening, and PRIME MD–PHQ2

We further note that we would consider an appropriate follow-up plan to be one that outlines a proposed course of action, including at least one of the following: (1) Additional evaluation for depression; (2) suicide risk assessment; (3) referral to a practitioner who is qualified to diagnose and treat depression; (4) pharmacological interventions; and/or (4) other interventions or follow-up for the diagnosis or treatment of depression.

Under this measure, facilities are required to report whether they screened qualifying patients for depression, and whether they developed a follow-up plan.

Comment: One commenter recommended increasing the minimum age for qualifying patients from 12 to 18, because pediatric patients present unique challenges for depression assessment.

Response: Although we recognize that patients between the ages of 12 and 17 present unique challenges for depression assessment, we believe it is critically important to include these patients because adolescent-onset depression is associated with multiple negative health outcomes, including an increased sick of death by suicide, suicide attempts, and recurrence of depression in young adulthood. In addition, the measure specifications for NQF #0418, the measure upon which this reporting measure is based, provides that the measure is appropriate for patients ages 12 to 17, and we agree with NQF's assessment because there are age-appropriate screening tools for this population, and requiring facilities to report data on whether these depression screenings were provided could prevent the negative outcomes listed above.

Comment: Some commenters did not support the proposal to adopt the Depression Screening and Follow-Up reporting measure, because the measure upon which it is based (NQF #0418) is specified for physicians, not dialysis facilities. Because the follow-up component of the measure requires a physician referral, commenter stated that the measure is not appropriate for dialysis facilities.

Response: We recognize that the NQF-endorsed version of this measure is specified for physicians, but we continue to believe that it is an appropriate measure for the dialysis facility setting. Dialysis facilities see patients with ESRD far more frequently than nephrologists and primary care physicians. Accordingly, dialysis facilities are in a better position to detect when their patients are in need of treatment for depression. Furthermore, under the ESRD CfCs, the nephrologist is considered part of the multidisciplinary team that provides dialysis treatment. As a result, we believe nephrologists should be capable of referring patients in need of further treatment.

Comment: Some commenters did not support the adoption of the Depression Screening and Follow-Up reporting measure because it is a ''check-box'' measure (that is, facilities receive credit on the basis of attestations), there is no depression screening tool specific to patients with ESRD, and there is limited data on the effectiveness of pharmacotherapies for depression in ESRD patients. One commenter was concerned that adopting the measure could lead to increased utilization of pharmacotherapies without a concomitant decline in rates of depression, because this effect has been seen in studies of the general population. One commenter also recommended that CMS develop alternative measures on depression that would be more valid for the dialysis setting.

Response: We recognize that scores on this measure are based on whether the facility reported one of six conditions for each qualifying patient. Depression is a significant concern for patients with ESRD, but it remains underdiagnosed and undertreated. We believe that facilities will more vigilantly monitor and screen for depression because the measure requires facilities to report whether they performed the screening. Additionally, we appreciate commenters' concerns that this measure could lead to an overutilization of pharmacotherapies for depression in patients with ESRD. However, we are not aware of any evidence indicating pharmacotherapies are overused in the ESRD population; absent such evidence, we do not believe that this concern is sufficient to delay adoption of this measure. Finally, we appreciate commenters' recommendation that we develop a measure specific to depression in the dialysis setting. We will continue to evaluate the measure's specifications, and if we conclude that modifications are needed, we intend to propose to adopt them in the future.

Comment: One commenter did not support the adoption of the Screening for Depression and Follow-Up reporting measure because patients risk being denied transplants if they are diagnosed with depression. Commenter was also concerned that adopting the measure may result in an over-reliance on pharmacotherapies without encouraging the types of emotional and social support that are needed to treat patients suffering from depression and ESRD.

Response: We appreciate commenters' concerns regarding the impact of depression on transplant eligibility and the possibility that this measure may result in increased use of pharmacotherapies the treatment of depression. However, absent evidence of transplant denials resulting from depression treatment or overuse of pharmacotherapies to treat patients' depression, we do not believe these concerns are sufficient to support delaying adoption of the Clinical Depression Screening and Follow-Up reporting measure. We believe that a patient's psychosocial wellbeing is a critical aspect of an ESRD patient's overall health and quality of life.

Comment: One commenter did not support the Depression Screening and Follow-Up measure because a patient's status can change considerably during the year, and the commenter recommended requiring more frequent assessments.

Response: We agree that patients' depression status may change over the course of a year, and we encourage facilities to conduct more frequent screenings. Nevertheless, because PY 2018 will be the first time this measure will be included in the ESRD QIP, we think it is appropriate to ask facilities to report whether they performed the screening at least once per performance period. We may consider revising this requirement in future years as we learn more information, based on the data we receive.

Comment: One commenter did not support the Depression Screening and Follow-Up measure because it does not require facilities to assess the underlying psychosocial causes of depression, and because the measure does not require facilities to ensure that patients are engaged in their care, including the setting of patient-centric goals for treatment.

Response: This measure is intended to ensure ESRD patients who may be experiencing depression are identified and referred, if necessary, for follow-up treatment. It does not require the dialysis facility to diagnose the nature and causes of depression because these tasks are not suitable for a dialysis facility. Rather, we recognize that treatment for clinical depression should be furnished by appropriately trained

practitioners and other mental health professionals, and it is our hope that these professionals will evaluate psychosocial causes and engage patients in the selection of treatment goals.

Comment: Some commenters did not support the Screening for Clinical Depression and Follow-Up reporting measure, because there is a lack of concrete information about the causes of depression and optimal screening methods and referral practices in the ESRD population. One commenter also stated that applying the principles underlying this measure to both adult and pediatric patients is not valid, because adult and pediatric present the different symptoms of depression and require different types of follow-up treatment.

Response: The measure specifications for NQF #0418 (the measure upon which this reporting measure is based) provide guidance about what constitutes screening and follow-up within the context of the measure. Furthermore, the NQF-endorsed specifications do not include an exclusion for patients with ESRD, and we are not aware of any studies demonstrating that the particular causes of depression for patients with ESRD invalidate the measure's prescriptions for screening and follow-up. We therefore believe that the Screening for Clinical Depression and Follow-Up reporting measure is appropriate for patients with ESRD. Finally, as stated above, we note that NQF #0418 was specified for patients aged 12 and older, and we agree with NQF that it is appropriate to include pediatric patients who are 12 years or older.

Comment: Some commenters did not support the proposal to adopt the Depression Screening and Follow-Up measure, because meeting the requirements of the measure will create costs for the facility that will not be covered by comparable increases in payments under the ESRD PPS. Another commenter stated that Medicare fee-for-service does not allow or reimburse facilities for taking actions to address depression.

Response: We recognize that depression screenings are not specifically reimbursed under the ESRD PPS. However, psychosocial evaluations are included in the ESRD CfCs and are required for Medicare participation, and depression screening is a type of psychosocial evaluation. Although we understand facilities may incur additional costs for complying with the measure's requirements (because facilities cannot bill Medicare separately for these assessments and referrals), on balance we believe that these costs are outweighed by potential improvements for patients' well-being.

For these reasons, we are finalizing the Clinical Depression Screening and Follow-Up reporting measure as proposed. Technical specifications for the measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html*

e. Pain Assessment and Follow-Up Reporting Measure

Pain is one of the most common symptoms in patients with ESRD.[23] Studies have shown that pain is a significant problem for more than 50 percent of patients with ESRD, and up to 82 percent of those patients report moderate to severe chronic pain.[24] Pain is commonly associated with quality of life in early- and late-stage chronic kidney disease patients, but it is not effectively managed in the ESRD patient population and chronic pain often goes untreated.[25] Observational studies suggest that under-managed pain has the potential to induce or exacerbate comorbid conditions in ESRD, which may in turn adversely affect dialysis treatment.[26] Patients with ESRD frequently experience pain that has a debilitating impact on their daily lives, and research has shown a lack of effective pain management strategies currently in place in dialysis facilities.[27] Therefore, a measure that assesses whether facilities regularly assess their patients' pain, and develop follow-up plans as necessary, offers the possibility of improving the health and well-being of patients with ESRD.

We proposed to adopt a pain measure that is based on an NQF-endorsed measure (NQF #0420: Pain Assessment and Follow-Up). NQF #0420 assesses the percentage of patients with documentation of a pain assessment using a standardized tool, and documentation of a follow-up plan when pain is present. The Measures Application Partnership supported the use of NQF #0420 in the ESRD QIP in its January 2014 Pre-Rulemaking Report, because the measure ''addresses a National Quality Strategy [NQS] aim not adequately addressed in the program measure set'' and promotes person- and family-centered care. We proposed to adopt a reporting measure based on this NQF-endorsed measure so that we can collect data that we can use in the future to calculate both achievement and improvement scores, should we propose to adopt the clinical version of this measure in future rulemaking. Although we recognize that we recently adopted the NHSN Bloodstream Infection clinical measure despite a lack of baseline data to calculate achievement and improvement scores, we believe that measure warranted special treatment in light of the fact that it addresses patient safety. Because the proposed screening for pain measure addresses quality of life and patient well-being, and not patient safety, we think it is appropriate to adopt it as a reporting measure until such time that we can collect the baseline data needed to score it as a clinical measure.

Section 1881(h)(2)(B)(ii) of the Act states that ''In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act [in this case NQF], the Secretary may specify a measure that is not so endorsed so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.'' Because we have given due consideration to endorsed measures, as well as those adopted by a consensus organization, and determined it is not practical or feasible to adopt those measures in the ESRD QIP, we proposed to adopt the Pain Assessment and Follow-Up reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

For PY 2018 and future payment years, we proposed that facilities must report one of the following conditions in CROWNWeb, once every six months per performance period, for each qualifying patient (defined below):

1. Pain assessment using a standardized tool is documented as

[23] Cohen, S. D., Patel, S. S., Khetpal, P., Peterson, R. A., & Kimmel, P. L. (2007). Pain, sleep disturbance, and quality of life in patients with chronic kidney disease. *Clinical Journal of the American Society of Nephrology,* 2(5), 919–925.

[24] Davison SN. Pain in hemodialysis patients: prevalence, cause, severity, and management. *American Journal of Kidney Disease.* 2003; 42:1239–1247

[25] Davison, S. N. (2007). The prevalence and management of chronic pain in end-stage renal disease. *Journal of Palliative Medicine,* 10(6), 1277–1287.

[26] De Castro C. (2013). Pain assessment and management in hemodialysis patients. *CANNT Journal;* 23(3):29–32; Weisbord SD, Fried LF, Arnold RM, Fine MJ, Levenson DJ, et al. Prevalence, severity, and importance of physical and emotional symptoms in chronic hemodialysis patients. (2005) *Journal of the American Society of Nephrology;* 16(8):2487–2494.

[27] De Castro C. (2013). Pain assessment and management in hemodialysis patients. *CANNT Journal;* 23(3):29–32; Wyne A, Rai R, Cuerden M, Clark WF, Suri RS. (2011). Opioid and benzodiazepine use in end-stage renal disease: a systematic review. *Clinical Journal of the American Society of Nephrology.* 6(2):326–333.

positive, and a follow-up plan is documented

2. Pain assessment documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible

3. Pain assessment documented as positive using a standardized tool, a follow-up plan is not documented, and no reason is given

4. Pain assessment using a standardized tool is documented as negative, and no follow-up plan required

5. No documentation of pain assessment, and the facility possesses documentation the patient is not eligible for a pain assessment using a standardized tool

6. No documentation of pain assessment, and no reason is given

For this measure, a qualifying patient is defined as a patient age 18 years or older who has been treated at the facility for 90 days or longer. This proposed measure will collect the same data described in NQF #0420, but we are proposing a few modifications to the NQF-endorsed version. First, we proposed that facilities must report data for each patient once every six months, whereas NQF #0420 requires facilities to report the data based on each visit. We proposed this modification because we agree with public comments reflected on the Measures Application Partnership's January 2014 Pre-Rulemaking Report, which stated that conducting a pain assessment every time a patient receives dialysis would be unduly burdensome for facilities. Second, we proposed that conditions covering the first 6 months of the performance period must be reported in CROWNWeb before August 1 of the performance period, and that conditions covering the second 6 months of the performance period must be reported in CROWNWeb before February 1 of the year directly following the performance period. We believe this reporting schedule will ensure regular monitoring and follow-up of patients' pain without imposing an undue burden on facilities. Third, we proposed to score facilities based on whether they successfully report the data, and not based on the measure results. Technical specifications for the Pain Assessment and Follow-Up reporting measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: One commenter supported adoption of the Pain Assessment and Follow-Up reporting measure because the measure can help reduce the pain associated with dialysis needles, and also encourage facility staff to undergo training in pain management and cannulation techniques. Commenters also supported the measure because pain is an underdiagnosed and undertreated condition in patients with ESRD that can inhibit individual function and change the ability of patients to fulfill their desired and required roles in life.

Response: We thank the commenters for the support.

Comment: Some commenters supported adopting the proposed Pain Assessment and Follow-Up reporting measure, because pain is an important concern among the ESRD population. Commenters recommended that CMS also require facilities to use the same screening tool, or collect information from facilities about the validated pain assessment tool used.

Response: We thank commenters for their support. We did not propose to collect information about the pain assessment tool used or to require facilities to use the same tool. However, we will take these recommendations into consideration as we reevaluate the measure for future payment years.

Comment: Many commenters did not support adoption of the Pain Assessment and Follow-Up reporting measure. Commenters stated that the Pain Assessment and Follow-Up reporting measure is outside the dialysis facility's scope of practice. Commenters also noted that while facilities can do pain screenings, they are not equipped to provide pain treatment services, and that requiring facilities to conduct the assessment is a disservice for patients, who would be better served by pain centers. Comments further stated that pain unrelated to dialysis should not fall under the purview of the dialysis facility, and that conducting the semiannual assessment is unduly burdensome. Commenters further stated that a future clinical version of this measure would require dialysis facilities to provide these services. Commenter stated that the measure would be more appropriate for the Coordinated ESRD Care model, because that initiative includes physicians as well as dialysis facilities.

Response: We appreciate commenters' input on this measure. First, we disagree that screening patients for pain is outside the scope of work for dialysis facilities. Patient assessments are a critical aspect of renal dialysis services because they enable facilities to provide care that is directly responsive to patient needs. The ESRD CfCs require that facilities perform a ''comprehensive assessment [for each patient that] must include, but is not limited to . . . [an] evaluation of current health status and medical condition, including co-morbid conditions'' (42 CFR 494.80(a)(7)). Because screening for pain is an assessment of patients' current health status, this screening falls within the ESRD CfCs and, by extension, the scope of work for dialysis facilities. We further disagree that the requirement for twice annual pain assessments is unduly burdensome because facilities are already required to perform an assessment of their patients' current health status, and pain assessments are an example of such as assessment. We also note that this measure does not, and will not, require facilities to provide chronic pain treatment services to patients. This measure requires facilities to report whether or not they performed a pain assessment for each qualifying patient, including whether or not they documented a follow-up plan. Although we agree that facilities are not the appropriate parties to actually treat pain, we do think the assessment can be performed by members of the multidisciplinary care team, such as a staff nurse. We recognize that the Coordinated ESRD Care model seeks to directly address coordination of care issues in the dialysis facility setting, but do not believe this precludes us from adopting a measure on the same issue for the ESRD QIP, and we believe that information collected as a result of this measure can be used to better inform policy decisions in the ESRD QIP and the CEC model.

Comment: Some commenters did not support adoption of the Pain Assessment and Follow-Up reporting measure because facilities are already performing these screenings, screening for pain overlaps with the Medicare Conditions for Coverage for ESRD facilities, and the ICH CAHPS survey already asks patients about the presence of pain. One commenter recommended CMS instead consider using a measure such as the Standardized Hospitalization Ratio to capture the effective management of the dialysis patient. Another commenter also stated that uremia is typically responsible for pain in patients with ESRD, and recommended delaying the adoption of the measure until research identifies an effective way to relieve pain associated with uremia.

Response: We appreciate that some facilities may already be performing these screenings. However, we do not believe that all facilities are doing so,

and we believe that the Pain Assessment and Follow-Up reporting measure will incentivize all facilities to conduct pain assessments and initiate follow-up plans when necessary. Additionally, one of the reasons we believe this measure is appropriate for dialysis facilities is that the actions required to comply with the reporting requirements are covered, as discussed above, by the ESRD CfCs.

Comment: One commenter recommended increasing the number of pain assessments patients receive each year beyond two and notes that the Joint Commission recommends assessing pain on an on-going basis.

Response: We agree that patients' pain status may change over the course of a year, and we encourage facilities to conduct more frequent assessments. Nevertheless, because PY 2018 will be the first time this measure is adopted in the ESRD QIP, we think it is appropriate to require facilities to report whether or not they performed a pain assessment once every six months. We may consider asking facilities to report more frequently in future years, after we have had an opportunity to evaluate the data that facilities report on this measure.

Comment: One commenter sought clarification as to whether facilities are required to screen all patients for pain, or whether only patients ''identified as potentially having a problem'' should be screened.

Response: Under this measure, facilities are required to report whether they performed pain assessments for qualifying patients, and whether they developed a follow-up plan based on that assessment. As stated in the CY 2015 ESRD PPS Proposed Rule, qualifying patients for this measure are patients aged 18 years or older who have been treated at the facility for 90 days or longer (79 FR 40261).

Comment: Commenter did not support the proposal to adopt the Pain Assessment and Follow-Up reporting measure, because the measure upon which it is based (NQF #0420) is specified for physicians, not dialysis facilities. Because the follow-up component of the measure requires a physician referral, commenter stated that the measure is not appropriate for dialysis facilities.

Response: We recognize that the NQF-endorsed version of this measure is specified for physicians, but we continue to believe that it is an appropriate measure for the dialysis facility setting. Dialysis facilities see patients with ESRD far more frequently than nephrologists and primary care physicians. Accordingly, dialysis facilities are in a better position to detect when their patients are in need of treatment for pain. Furthermore, under the ESRD CfCs, the nephrologist is considered part of the multidisciplinary team that provides dialysis treatment. We therefore believe that nephrologists should be capable of referring patients for follow-up care following an initial pain assessment, if necessary.

Comment: One commenter did not support the adoption of the Pain Assessment and Follow-Up reporting measure because it focuses on chronic, not acute, pain, and chronic pain is best managed by physicians, not dialysis facilities. Commenter also stated that the measure is not appropriate because significant pain is not typically associated with dialysis, and facilities are already addressing acute pain associated with dialysis, when it occurs.

Response: The purpose of this measure is to incentivize facilities to assess both chronic and acute pain. Although some facilities may already have in place robust processes to address acute pain, we believe there is still considerable room for improvement in the assessment and management of acute pain. Although chronic pain is best treated by a qualified physician, dialysis facilities see patients far more frequently than nephrologists or other physicians, so dialysis facilities are in the best position to conduct regular assessments and refer patients to appropriate practitioners as needed. We further note that the reporting measure does not require facilities to treat chronic pain, or to report whether they have done so.

Comment: One commenter did not support adoption of the Pain Assessment and Follow-Up reporting measure, because it is unclear whether the measure seeks to assess acute or chronic pain, and the commenter does not understand how this measure will improve patient care. For example, a pain assessment performed at one point in time may not be relevant to the patient's experience of pain at a different time.

Response: As stated above, this measure is intended to assess overall pain—both acute and chronic. We further believe that this measure will improve patients' quality of life because it will increase the likelihood that patients who suffer from pain will be identified and referred to an appropriate practitioner. Finally, as stated above, we agree that patients' pain status may change over the course of a year, and we encourage facilities to conduct more frequent assessments.

Comment: Some commenters did not support the adoption of the Pain Assessment and Follow-Up reporting measure because it is a ''check-box'' measure (that is, facilities receive credit on the basis of attestations), and because there is no pain assessment tool specific for patients with ESRD.

Response: We recognize that scores on this measure are based on whether a facility reports one of six conditions for each qualifying patient once every six months. However, we disagree that the measure will not make an impact on patients' quality of life. Pain—both chronic and acute—is a significant concern for patients with ESRD, but it remains underdiagnosed and undertreated. We believe this measure will incentivize facilities to more vigilantly monitor and address patients' pain, and that as a result patients with pain issues will be identified more quickly and receive the follow-up care necessary to improve and maintain their quality of life.

We understand that there is no firm consensus on what pain assessment tool is best for patients with ESRD; however, there are a number of standardized tools available. We believe that facilities are in the best position to choose an appropriate screening tool for use with their patients. Examples of standardized assessment tools that we believe would be appropriate include but are not limited to the following: the Brief Pain Inventory (BPI); Faces Pain Scale (FPS); McGill Pain Questionnaire (MPQ); Multidimensional Pain Inventory (MPI); Neuropathic Pain Scale (NPS); Numeric Rating Scale (NRS); Oswestry Disability Index (ODI); Roland Morris Disability Questionnaire (RMDQ); Verbal Descriptor Scale (VDS); Verbal Numeric Rating Scale (VNRS); and Visual Analog Scale (VAS).

Comment: One commenter did not support the proposal to adopt the Pain Assessment and Follow-Up measure because the commenter is concerned that facilities will simply conduct a straightforward assessment (for example, a numerical pain scale) and prescribe analgesics. Commenter stated that it would be preferable to identify the underlying causes of chronic and acute pain, and to develop care plans that address these causes.

Response: As stated above, we believe that facilities have many options when selecting an appropriate pain assessment tool, and we believe that facilities should be able to select the tool that is most appropriate for their patients. We further believe that decisions to prescribe analgesics are best left to the prescribing clinician, though it is our hope that clinicians will take into account the underlying causes of pain, as well as patients' treatment goals, when prescribing therapies.

Comment: One commenter did not support the proposal to adopt the Pain Assessment and Follow-Up measure, because meeting the requirements of the measure will create costs for the facility that will not be covered by comparable increases in payments under the ESRD PPS. Another commenter stated that Medicare fee-for-service does not allow or reimburse facilities for taking actions to address pain management.

Response: We recognize that pain assessments are not covered under the ESRD PPS. However, evaluations of current health status and medical condition are included in the ESRD CfCs and required for participation in the Medicare program, and pain assessment is an example of such an evaluation. Although we understand that facilities may incur additional costs for complying with the measure's requirements, on balance we believe that these costs are outweighed by potential improvements in patients' quality of life.

Comment: One commenter did not support the proposed Pain Assessment and Follow-Up reporting measure, because adopting the measure may lead to prescription of narcotics and other pain medications, which can cause iatrogenic effects.

Response: We understand the commenter's concern that a measure assessing pain may lead to prescription of narcotics and other pain medications, which can carry the risk of negative side effects when used or prescribed inappropriately. However, absent evidence indicating that pain medication utilization rates among ESRD patients are unnecessarily high, we do not believe this concern is sufficient to delay adoption of the Pain Assessment and Follow-Up reporting measure because of the prevalence and severity of pain-related health issues in the ESRD population.

For these reasons, we are finalizing the Pain Assessment and Follow-Up reporting measure as proposed. Technical specifications for the measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*

f. NHSN Healthcare Personnel Influenza Vaccination Reporting Measure

Infection is the second most common cause of death in patients with ESRD, following cardiovascular causes,[28] and influenza accounts for significant morbidity and mortality in patients receiving hemodialysis.[29] Healthcare personnel (HCP) can acquire influenza from patients and transmit influenza to patients and other HCP; decreasing transmission of influenza from HCP to persons at high risk likely reduces influenza-related deaths among persons at high risk for complications from influenza, including patients with ESRD.[30] Vaccination is an effective preventive measure against influenza that can prevent many illnesses, deaths, and losses in productivity.[31] In addition, HCP are considered high priorities for vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients, and to reduce disease burden and healthcare costs. Results of studies in post-acute care settings similar to the ESRD facility setting indicate that higher vaccination coverage among HCP is associated with lower all-cause mortality.[32] We therefore proposed to adopt an NHSN HCP Influenza Vaccination reporting measure for PY 2018 and future payment years.

We proposed to use a measure that is based on an NQF-endorsed measure (NQF #0431: Influenza Vaccination Coverage Among Healthcare Personnel) of the percentage of qualifying HCP who: (a) Received an influenza vaccination; (b) were determined to have a medical contraindication; (c) declined influenza vaccination; or (d) were of an unknown vaccination status. A ''qualifying HCP'' is defined as an employee, licensed independent practitioner, or adult student/trainee/volunteer who works in a facility for at least one day between October 1 and March 31. The Measures Application Partnership supported the use of NQF #0431 in the ESRD QIP in its January 2014 Pre-Rulemaking Report because the measure is NQF-endorsed for use in the dialysis facility care setting. We proposed to adopt a reporting measure based on this NQF-endorsed measure so that we can collect data that we can use in the future to calculate both achievement and improvement scores, should we propose to adopt the clinical version of this measure in future rulemaking. Although we recognize that we recently adopted the NHSN Bloodstream Infection clinical measure despite a lack of baseline data to calculate achievement and improvement scores, we believe that measure warranted special treatment in light of the fact that it addresses patient safety. Because the proposed NHSN HCP Influenza Vaccination reporting measure addresses population health, and not patient safety, we think it is appropriate to adopt it as a reporting measure until such time that we can collect the baseline data needed to score it as a clinical measure.

Section 1881(h)(2)(B)(ii) of the Act states that ''In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [in this case, NQF], 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.'' Because we have given due consideration to endorsed measures as well as those adopted by a consensus organization, and determined it is not practical or feasible to adopt this measure in the ESRD QIP, we proposed to adopt the NHSN Healthcare Personnel Influenza Vaccination reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

For PY 2018 and future payment years, we proposed that facilities must submit, on an annual basis, an HCP Influenza Vaccination Summary Form to CDC's NHSN system, according to the specifications available in the NHSN Healthcare Personnel Safety Component Protocol (*http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf*). This proposed measure differs from NQF #0431 in that we are proposing to collect the same data but will score facilities on the basis of whether they submit this data, rather than on the percentage of HCP vaccinated. We proposed that the deadline for reporting this information to NHSN be May 15th of each year. This date is consistent with the reporting deadline established by CMS for other provider types reporting HCP vaccination data to NHSN. Because the

[28] Soni R, Horowitz B, Unruh M. Immunization in end-stage renal disease: opportunity to improve outcomes. Semin, Dial. 2013 Jul–Aug;26(4):416–26.

[29] Fiore AE, Shay DK, Haber P, et al. Prevention and control of influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2007;56:1–54.

[30] Pearson ML, Bridges CM, Harper SA. Influenza vaccination of health-care personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). MMWR. 2006:55:1–16.

[31] Talbot TR, Bradley SE., Cosgrove SE., et al. Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infect Control Hosp Epidemiol. 2005;26(11):882–90.

[32] Carman WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomized controlled trial. Lancet. 2000;355(9198):93–7; *see also* Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. J infect Dis. 1997;175(1):1–6.

flu season typically spans from October to April, NHSN protocols submitted by May 15 would document vaccinations received during the preceding flu season. For example, NHSN HCP Influenza Vaccination Summary Forms submitted by May 15, 2016, would contain data from October 1, 2015 to March 31, 2016, and would be used for the PY 2018 ESRD QIP; NHSN protocols submitted by May 15, 2017, would contain data from October 1, 2016 to March 31, 2017, and would be used for the PY 2019 ESRD QIP, and so on. Technical specifications for this measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.*

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Some commenters supported the proposal to adopt the NHSN HCP Influenza Vaccination reporting measure because HCP can expose patients to influenza if they have not been vaccinated, and because the measure will help improve patient safety.

Response: We thank the commenters for their support.

Comment: One commenter did not support the adoption of the NHSN HCP Influenza Vaccination reporting measure, because its definition of HCP is overly inclusive and reporting vaccination status for short-term HCP is overly burdensome. Commenter was concerned about facilities' ability to comply with the requirement to provide written documentation of each HCP's vaccination during the influenza season, and that if this measure is expanded to a clinical measure in the future it may limit access to temporary workers (including students and volunteers) due to the requirement that HCPs are included in the measure even if they only work at the facility for a single day.

Response: We disagree that the definition of ''qualified healthcare personnel'' is overly inclusive. The NHSN HCP Influenza vaccination measure was pilot-tested at over 300 healthcare facilities in the United States; based on the results of this pilot test, CDC restricted the types of non-employee healthcare personnel included in the measure in order to balance inclusiveness and feasibility of reporting for healthcare facilities. It is important to measure influenza vaccination among non-employee healthcare personnel as many of these personnel provide care to or interact directly with patients and employee healthcare personnel, placing them at risk of acquiring or transmitting influenza. We therefore believe the inclusion of non-employee healthcare personnel in this measure is appropriate. We also note that this measure does not require facilities to report documentation regarding HCP immunization status when vaccinations are obtained within their own healthcare facility. Under the NHSN HCP Influenza Vaccination reporting measure and associated NHSN module, facilities should obtain written documentation of influenza vaccinations obtained outside of the healthcare facility, but need only report the total number of those vaccinations received outside of the healthcare facility.

Comment: One commenter supported CMS's effort to ensure HCPs are vaccinated, but was concerned about the administrative aspects of the proposed NHSN HCP Influenza Vaccination reporting measure. The commenter specifically sought clarification as to whether written documentation would be required to establish an HCP's vaccination status, and whether vaccinations received before October 1 would qualify under this proposed measure.

Response: Written documentation of an HCP's vaccination status is only required for HCP receiving the influenza vaccination outside of the healthcare facility. Acceptable forms of documentation of influenza vaccination received outside of the healthcare facility include a signed statement or form, or an electronic form or email from the healthcare worker indicating when and where he/she has received the influenza vaccine, or a note, receipt, vaccination card, or similar form of documentation from the outside vaccinating entity stating that the healthcare worker received the influenza vaccine at that location. Facilities should maintain this documentation for their own record; however, only summary count of number reported within this category should be reported.

Under the NHSN HCP Influenza Vaccination reporting measure, the performance period for the denominator (the number of healthcare personnel working in a facility) is from October 1 through March 31. However, the numerator measurement (vaccination status) includes vaccines obtained ''as soon as vaccine is available.'' As a result, an HCP working at the facility as of October 1 who was vaccinated in September would be considered vaccinated for the performance period under this measure.

Comment: One commenter supported the NHSN HCP Influenza reporting measure, but stated that the NQF-endorsed measure ''only includes personnel working at a facility for 30 days or more.'' Commenter recommended that CMS exclude HCP working at a facility for less than 30 days from this measure.

Response: The NHSN HCP Influenza Vaccination module's requirement to include only healthcare personnel working in the healthcare facility for 30 days or more was in place during the 2012–2013 influenza season. Beginning with the 2013–2014 influenza season, facilities are required to report healthcare personnel working in the facility for one day or more from October 1 through March 31, because this more accurately captures healthcare personnel in the facility at risk of acquiring or transmitting influenza virus. The National Quality Forum (NQF) accepted CDC's proposal to make the change to one day or more in May 2013, and the current NQF-endorsed measure available at *http://www.qualityforum.org/QPS/0431* reflects this revised specification.

Comment: Some commenters did not support the proposal to adopt the NHSN HCP Influenza Vaccination reporting measure because influenza vaccination is already a requirement for employment in dialysis facilities, and that adopting this measure will dilute the scores of other measures in the ESRD QIP.

Response: Although influenza vaccinations for healthcare professionals may be a condition of employment for some facilities, this is not a condition for all facilities, and some facilities do not require volunteers or short-term employees to have current influenza vaccinations. Accordingly, we believe that potential improvements to patients' health warrant the adoption of the measure. We further clarify that adopting this measure in the ESRD QIP will not dilute the weights of the clinical measures in the program. The scoring methodology we are adopting for PY 2018 weights the reporting measure scores equally to comprise 10 percent of a facility's TPS. Although this methodology reduces the significance of the other reporting measures it does not impact weight of the clinical measures, and it allows us to collect the baseline data needed to expand the NHSN HCP measure into a clinical measure in the future. We therefore believe that the benefits of adopting this measure outweigh the drawbacks of diluting the weight of the other reporting measures in the ESRD QIP measure set.

Comment: Some commenters did not support the proposal to adopt the NHSN HCP Influenza Vaccination measure, because meeting the requirements of the measure will create costs for the facility that will not be covered by comparable increases in payments under the ESRD PPS.

Response: We understand that this measure may result in additional cost to dialysis facilities from having to compile and report the vaccination status of their health care professionals; however, we believe that these costs are outweighed by improvements in community health resulting from an immunized workforce.

Comment: Some commenters stated that reporting data to NHSN HCP Influenza Module for dialysis facilities within a hospital will result in duplicative reporting because these entities are already included in the hospital's reporting. One commenter recommended that facilities receive full credit on the measure if they indicate their hospital submitted the data on their behalf.

Response: Dialysis facility reporting will be completely separate from acute care reporting regardless of whether a dialysis facility is affiliated with acute care. It is important that all eligible healthcare personnel be counted by each facility where they work so that each facility's reporting to NHSN under this measure presents an accurate picture of the vaccination coverage among healthcare personnel at that specific facility or location. The concerns regarding duplicative reporting are unfounded, because reporting for the same individual's vaccination status will only occur in instances where that individual worked in both facilities during the reporting period. In these cases, it is appropriate to include the HCP in both facilities' counts because they meet the eligibility criteria for both facilities' reporting.

Comment: One commenter recommended that CMS consider collecting data for the NHSN HCP Influenza Vaccination reporting measure as actual numbers of HCPs vaccinated rather than percentages, because small facilities may appear to be noncompliant based on a small number of HCP not receiving a vaccination. The commenter further recommended that this information be reported annually rather than monthly, because this is consistent with the way data is entered into CROWNWeb.

Response: Under the proposed NHSN HCP Influenza Vaccination reporting measure, facilities are required to report the number of HCP working in the facility (denominator data) and the number of those individuals with a certain vaccination status (numerator data). Accordingly, in the process of calculating the percentage of HCPs who receive an influenza vaccination, the measure collects data on the actual number of HCPs vaccinated. We also note that for the PY 2018 program NHSN HCP Influenza Vaccination is a reporting measure, meaning that facilities will receive a score on this measure based on the successful reporting of data, not on the values actually reported. In addition, monthly reporting is not required of facilities under this measure. Instead, facilities are required to submit a single summary report of final HCP influenza vaccination data for the specified influenza season by the annual reporting deadline.

For these reasons, we are finalizing the NHSN HCP Influenza Vaccination measure as proposed. Technical specifications for the measure can be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

Figure 2: Summary of Finalized PY 2018 Measures

★ New measure for PY 2018

Clinical Measures

1. Vascular Access Type Measure Topic – AVF
2. Vascular Access Type Measure Topic – Catheter ≥ 90 days
3. Kt/V Dialysis Adequacy Measure Topic – Adult Hemodialysis
4. Kt/V Dialysis Adequacy Measure Topic – Adult Peritoneal Dialysis
5. Kt/V Dialysis Adequacy Measure Topic – Pediatric Hemodialysis
6. ★ Kt/V Dialysis Adequacy Measure Topic – Pediatric Peritoneal Dialysis
7. Hypercalcemia
8. NHSN Bloodstream Infection in Hemodialysis Outpatients
9. Standardized Readmission Ratio
10. ★ Standardized Transfusion Ratio
11. ★ ICH CAHPS Patient Experience of Care Survey

Reporting Measures

1. Mineral Metabolism
2. Anemia Management
3. ★ Clinical Depression Screening and Follow-Up
4. ★ Pain Assessment and Follow-Up
5. ★ NHSN Healthcare Personnel Influenza Vaccination

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2. Performance Period for the PY 2018 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish the performance period with respect to a year, and that the performance period occur prior to the beginning of such year. In accordance with our proposal to adopt CY 2015 as the performance period for the PY 2017 ESRD QIP, as well as our policy goal to collect 12 months of data on each measure when feasible, we proposed to adopt CY 2016 as the performance period for the PY 2018 ESRD QIP. With respect to the NHSN Healthcare Personnel Influenza Vaccination Reporting measure, we proposed that the performance period will be from October 1, 2015 through March 31, 2016, which is consistent with the length of the 2015–2016 influenza season.

We sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

3. Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2018 ESRD QIP

a. Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures in the PY 2018 ESRD QIP

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we proposed for PY 2018 to set the performance standards, achievement thresholds, and benchmarks based on the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2014 for all the clinical measures except for the proposed ICH CAHPS clinical measure. As finalized in the CY 2014 ESRD PPS Final Rule (78 FR 72213), facilities are not required to administer the ICH CAHPS survey (via a CMS-approved third-party vendor) on a semiannual basis until CY 2015, the proposed performance period for the PY 2017 ESRD QIP. We believe that ICH CAHPS data collected during CY 2014 will not be reliable enough to use for the purposes of establishing performance standards, achievement thresholds, and benchmarks, because facilities are only required to administer the survey once in CY 2014. Therefore, we proposed to set the performance standards, achievement thresholds, and benchmarks based on the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2015 for the proposed ICH CAHPS clinical measure.

We sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

b. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures for the PY 2018 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the performance standards for the clinical measures, because we do not yet have data from CY 2014 or the first portion of CY 2015. We will publish values for the clinical measures, using data from CY 2014 and the first portion of CY 2015, in the CY 2016 ESRD PPS Final Rule.

c. Performance Standards for the PY 2018 Reporting Measures

In the CY 2014 ESRD PPS Final Rule, we finalized performance standards for the Anemia Management and Mineral Metabolism reporting measures (78 FR 72213). We did not propose any changes to this policy beyond the proposal to modify the reporting requirements for the Mineral Metabolism reporting measure, which appears above in Section III.G.1.

For the Screening for Clinical Depression and Follow-Up reporting measure, we proposed to set the performance standard as successfully reporting one of the above-listed clinical depression and follow-up screening conditions for each qualifying patient in CROWNWeb before the February 1st directly following the performance period.

For the Pain Assessment and Follow-Up reporting measure, we proposed to set the performance standard as successfully reporting one of the above-listed pain assessment and follow-up conditions for each qualifying patient in CROWNWeb twice annually: once before August 1st for the first 6 months of the performance period, and once before the February 1st directly following the performance period for the last six months of the performance period.

For the NHSN Healthcare Provider Influenza Vaccination reporting measure, we proposed to set the performance standard as successfully submitting the HCP Influenza Vaccination Summary Form to CDC's NHSN system by May 15, 2017.

We sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

4. Scoring the PY 2018 ESRD QIP Measures

a. Scoring Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). In determining a facility's achievement score for each measure under the PY 2018 ESRD QIP, we proposed to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. Under this methodology, facilities receive points along an achievement range based on their performance during the proposed performance period for each measure, which we define as a scale between the achievement threshold and the benchmark.

We sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

b. Scoring Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). In determining a facility's improvement score for each measure under the PY 2018 ESRD QIP, we proposed to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. Under this methodology, facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We proposed to define the improvement threshold as the facility's performance on the measure during CY 2015. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2016 (the proposed performance period) to its performance rate on the measure during CY 2015.

We sought comments on these proposals. We did not receive any comments and are finalizing them as proposed.

c. Scoring the ICH CAHPS Clinical Measure

For PY 2018 and future payment years, we proposed the following scoring methodology for the ICH CAHPS clinical measure. We proposed to score the measure on the basis of three composite measures and three global ratings.

Composite Measures:

• Nephrologists' Communication and Caring;

• Quality of Dialysis Center Care and Operations; and

• Providing Information to Patients.

Global Ratings:

• Overall rating of the nephrologists (Question 8)

• Overall rating of the dialysis center staff (Question 32)

• Overall rating of the dialysis facility (Question 35)

The composite measures are groupings of questions that measure the same dimension of healthcare. (Groupings of questions and composite measures can be found at *https://ichcahps.org/Portals/0/ICH_Composites_English.pdf.*) Global ratings questions employ a scale of 0 to 10, worst to best; each of the questions within a composite measure use either ''Yes'' or ''No'' responses, or response categories ranging from ''Never'' to ''Always,'' to assess the patient's experience of care at a facility. Facility performance on each composite measure will be determined by the percent of patients who choose ''top-box'' responses (that is, most positive or ''Always'') to the ICH CAHPS survey questions in each domain. Examples of questions and top-box responses are displayed below:

Q11: In the last 3 months, how often did the dialysis center staff explain things in a way that was easy for you to understand?

Top-box response: ''Always''

Q19: The dialysis center staff can connect you to the dialysis machine through a graft, fistula, or catheter.

Do you know how to take care of your graft, fistula or catheter?

Top-box response: ''Yes''

We proposed that a facility will receive an achievement score and an improvement score for each of the composite measures and global ratings in the ICH CAHPS survey instrument. For purposes of calculating achievement scores for the ICH CAHPS clinical measure, we proposed to base the score on where a facility's performance rate falls relative to the achievement threshold and the benchmark for that measure. We proposed that facilities will earn between 0 to 10 points for achievement based on where its performance for the measure falls relative to the achievement threshold. If a facility's performance rate during the performance period is:

• Equal to or greater than the benchmark, then the facility would receive 10 points for achievement;

• Less than the achievement threshold, then the facility would receive 0 points for achievement; or

• Equal to or greater than the achievement threshold, but below the benchmark, then the following formula would be used to derive the achievement score:

[9 * ((Facility's performance period rate − achievement threshold)/(benchmark − achievement threshold))] + .5, with all scores rounded to the nearest integer, with half rounded up.

For the purposes of calculating improvement scores for the ICH CAHPS clinical measure, we proposed that the improvement threshold will be defined as facility performance in CY 2015, and further proposed to base the score on where a facility's performance rate falls relative to the improvement threshold and the benchmark for that measure. We proposed that a facility can earn between 0 to 9 points based on how much its performance on the measure during the performance period improves from its performance on the measure during the baseline period. If a facility's performance rate during the performance period is:

• Less than the improvement threshold, then the facility would receive 0 points for improvement; or

• Equal to or greater than the improvement threshold, but below the benchmark, then the following formula would be used to derive the improvement score:

[10 * ((Facility performance period rate − Improvement threshold)/(Benchmark − Improvement threshold))] − .5, with all scores rounded to the nearest integer, with half rounded up.

We further proposed that a facility's ICH CAHPS score will be based on the higher of the facility's achievement or improvement score for each of the composite measures and global ratings. Additionally, we proposed that achievement and/or improvement scores on the three composite measures and the three global ratings will be averaged together to yield an overall score on the ICH CAHPS clinical measure.

The timing and frequency of administering the ICH CAHPS survey is critical to obtaining reliable results. For example, if a facility did not conduct two semiannual surveys during a given performance period, then patient experiences during the 6-month period(s) covered by the missed survey(s) would not be captured. Additionally, if facilities (via CMS-approved vendors) do not report their ICH CAHPS survey results to CMS, then these results cannot be taken into account when establishing national performance standards for the measure, thereby diminishing the measure's reliability. Because timely survey administration and data reporting is critical to reliably scoring ICH CAHPS as a clinical measure in the ESRD QIP, we proposed that a facility will receive a score of 0 on the measure if it does not meet the survey administration and reporting requirements finalized in the CY 2014 ESRD PPS Final Rule (78 FR 72193 through 72196).

We sought comments on these proposals to score the ICH CAHPS clinical measure. The comment and our response are set forth below.

Comment: One commenter sought clarification as to how multiple administrations of the ICH CAHPS survey in a single performance period will factor into facilities' ICH CAHPS clinical measure scores if the ICH CAHPS clinical measure proposal is finalized.

Response: We clarify that survey responses from the two survey administrations will be compiled together into a single dataset, which will then be used to calculate facility scores on the ICH CAHPS clinical measure. In other words, responses to the first and second survey administrations will be combined to produce a facility's ICH CAHPS score. Each of the three composite measures consists of six or more questions from the survey that are reported as one composite score. Scores are created by first determining the proportion of answers to each response option for all questions in the composite. The final composite score averages the proportion of those responding to each answer choice in all questions. Only questions that are answered by survey respondents will be included in the calculation of composite scores.

For these reasons, we are finalizing the scoring methodology for the ICH CAHPS clinical measure as proposed for the PY 2018 program and future payment years.

d. Calculating Facility Performance on Reporting Measures

In the CY 2014 ESRD PPS Final Rule, we finalized policies for scoring performance on the Anemia Management and Mineral Metabolism reporting measures in the ESRD QIP (78 FR 72216). We did not propose any changes to these policies beyond the proposals that were made beginning with the PY 2017 program, which appear in section III.F.7 above.

With respect to the Screening for Clinical Depression and Follow-up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures, we proposed that facilities will receive a score of 10 on the measures if they meet

the proposed performance standards for the measures, and a score of 0 on the measure if they do not. We proposed to score these reporting measures differently than the Anemia Management and Mineral Metabolism reporting measures because they require annual or semiannual reporting, and therefore scoring based on monthly reporting rates is not feasible.

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: One commenter did not support the proposal to allocate zero points on the proposed Pain Assessment and Follow-Up measure if a facility does not report one of the six specified conditions for each patient. Commenter recommended using a scoring system that awards partial points for partial compliance.

Response: We agree with the commenter that an all-or-nothing methodology will not incentivize facilities to provide pain assessments and follow-ups if they are unable meet the requirements of the Pain Assessment and Follow-Up measure for a single qualifying patient. We also believe that this same concern applies equally to the Screening for Clinical Depression and Follow-Up reporting measure, because the proposed scoring methodology for both reporting measures is identical. In order to respond to the commenter's recommendation to award partial points, we finalize that the two measures will be scored as follows:

Pain Assessment and Follow-Up:

$$\left\{\frac{\text{Number of patients for whom facility reports one of six conditions during the first six months}}{\text{Number of eligible patients in the first six months}} + \frac{\text{Number of patients for whom facility reports one of six conditions during the second six months}}{\text{Number of eligible patients in the second six months}}\right\} \div 2$$

Screening for Clinical Depression and Follow-Up:

$$\frac{\text{Number of patients for whom facility reports one of six conditions during the performance period}}{\text{Number of eligible patients during the performance period}}$$

We selected the above scoring methodology for the Screening for Clinical Depression and Follow-Up reporting measure because it evaluates the percentage of eligible patients for whom a facility reports the data required for the measure. In contrast to the proposed scoring methodology, which would have assigned zero points on the measure if a facility failed to report data for a single patient, this methodology allows facilities to receive a high score on the measure even if they fail to report data for a small number of patients. We selected the above scoring methodology for the Pain Assessment and Follow-Up measure for the same reasons. However, in this case we calculated separate percentages for first and second six months and averaged the two percentages together. We did this because the Pain Assessment and Follow-Up measure requires facilities to report data on a semiannual basis, and we believe that taking the average of the two percentages provides a fair way to evaluate facilities' overall performance during the performance period.

For these reasons, we are finalizing that we will calculate facility performance on the Screening for Clinical Depression and Follow-Up, Pain Assessment and Follow-Up, and NHSN HCP Influenza Vaccination reporting measures as described above.

5. Minimum Data for Scoring Measures for the PY 2018 ESRD QIP

With the following exceptions discussed below, we did not propose to change the minimum data policies for the PY 2018 ESRD QIP from those proposed above for the PY 2017 ESRD QIP. We also proposed that the 30 survey-eligible patient minimum during the eligibility period and 30 survey complete minimum during the performance period that we proposed to adopt for the ICH CAHPS reporting measure will also apply to the ICH CAHPS clinical measure. We have determined that the ICH CAHPS survey is satisfactorily reliable when a facility obtains a total of at least 30 completed surveys during the performance period. Therefore, even if a facility meets the 30 survey-eligible patient minimum during the eligibility period and the survey administration and reporting requirements, if the facility is only able to obtain 29 or fewer survey completes during the performance period, the facility will not be eligible to receive a score on the ICH CAHPS clinical measure.

We further proposed that facilities with fewer than 10 patient-years at risk will not be eligible to receive a score on the proposed STrR clinical measure. We considered adopting the 11-patient minimum requirement that we use for the other clinical measures. We decided, however, to base facilities' eligibility for the measure in terms of the number of patient-years at risk, because facility performance rates are based on the number of patient-years at risk, not the number of patients. Additionally, we decided to set the minimum data requirements at 10 patient-years at risk because, based on national average event rates, this is the time required to achieve an average of 5 transfusion events. The 5 expected transfusion events requirement translates to a standard deviation of approximately

0.45 if the facility has rates exactly corresponding to the national average. In addition, 10 patient-years at risk is the threshold used in the Dialysis Facility Compare program, and we believe that public-reporting and VBP programs for ESRD should adopt consistent measure specifications where feasible.

For the proposed STrR measure, we proposed to apply the small-facility adjuster to facilities with 21 or fewer patient-years at risk. We decided to base the threshold for applying the small-facility adjuster on the number of patient-years at risk, because facility performance rates are based on the number of patient-years at risk, not the number of patients. We proposed to set the threshold at 21 patient-years at risk, because we determined that this was the minimum number of patient-years at risk needed to achieve an IUR of 0.4 (that is, moderate reliability) for the proposed STrR measure. Because the small-facility adjuster gives facilities the benefit of the doubt when measure scores can be unduly influenced by a few outlier patients, we believe that setting the threshold at 21 qualifying patient-years at risk will not unduly penalize facilities that treat small numbers of patients on the proposed STrR clinical measure.

With these exceptions, we did not propose to change the policy, finalized most recently in the CY 2014 ESRD PPS Final Rule (78 FR 72220 through 72221), that facilities must have at least 11 qualifying patients for the entire performance period in order to be scored on a clinical measure.

We currently have a policy, most recently finalized in the CY 2014 ESRD PPS final rule (78 FR 72197 through 72198 and 72220 through 72221), to score facilities on reporting measures only if they have a minimum number of qualifying patients during the performance period. As discussed in Section III.F.7 above, we proposed to modify the case minimum requirements for the Anemia Management and Mineral Metabolism reporting measures beginning with the PY 2017 ESRD QIP. We did not propose any additional changes in the patient minimum requirements for the Anemia Management and Mineral Metabolism reporting measures in the PY 2018 program.

For the Screening for Clinical Depression and Follow-Up and the Pain Assessment and Follow-Up reporting measures, we proposed a case minimum of one qualifying patient. We believe this patient minimum requirement will enable us to gather a sufficient amount of data to calculate future performance standards, benchmarks, and achievement thresholds, should we propose to adopt clinical versions of these measures in the future.

As discussed in Section III.G.2.f, we did not propose that a facility will have to meet a patient minimum in order to receive a score on the NHSN Healthcare Provider Influenza Vaccination reporting measure. We believe it is standard practice for all HCP to receive influenza vaccinations and, as discussed above, HCP vaccination is likely to reduce influenza-related deaths and complications among the ESRD population. Accordingly, we proposed that all facilities, regardless of patient population size, will be scored on the influenza vaccination measure.

We sought comments on this proposal. The comments and our responses are set forth below:

Comment: Some commenters supported the proposal to determine facility eligibility for scoring on the ICH CAHPS reporting measure based on the number of patients treated in the eligibility period, because it will allow providers to better anticipate their eligibility in a given year.

Response: We thank commenters for their support.

Comment: Many commenters did not support the proposed data minimum requirements for the reporting measures because the commenters stated that the requirements unfairly penalize facilities that may not be able to legitimately report data for a few patients. As an alternative, the commenters recommended applying a consistent case minimum of 26 for all measures in the ESRD QIP.

Response: We agree with commenters that setting the patient minimum for the Screening for Clinical Depression and Follow-Up, and Pain Assessment and Follow-Up reporting measures at one qualifying patient may unfairly penalize small facilities, because a failing to report data for two or more patients will have a greater impact on small facility than on larger facilities. However, we disagree that it is appropriate to set the case minimum at 26 for these reporting measures, because doing so would not allow CMS to collect baseline data for a large percentage of patients. We believe that setting the case minimum at 11 for the Screening for Depression and Follow-Up and Pain Assessment and Follow-Up reporting measures strikes the appropriate balance between the need to maximize data collection and the need to not unduly penalize small facilities that are unable, for legitimate reasons, to report data on all but one patient. We further believe that setting the case minimum at 11 is appropriate, because this would align with the case minimum policy for the clinical measures in the ESRD QIP. Therefore, we are finalizing a case minimum policy of 11 for the Screening for Clinical Depression and Follow-Up and Pain Assessment and Follow-Up reporting measures.

Under our current policy, we begin counting the number of months for which a facility is open on the first day of the month after the facility's CCN open date. Only facilities with a CCN open date before July 1, 2016, are eligible to be scored on the Anemia Management and Mineral Metabolism reporting measures in the PY 2018 program. We proposed to apply this finalized policy to the Screening for Clinical Depression and Follow-Up and the Pain Assessment and Follow-Up reporting measures. We further proposed that facilities with a CCN open date after January 1, 2016, will not be eligible to receive a score on the NHSN Healthcare Personnel Influenza Vaccination reporting measure in the PY 2018 program. Due to the time it takes for facilities to register with NHSN and become familiar with the NHSN Healthcare Personnel Safety Component Protocol, we do not believe it is reasonable to expect facilities with CCN open dates after January 1, 2016, to submit an HCP Influenza Vaccination Summary Form to CDC's NHSN system before the May 15, 2016, deadline.

As finalized in the CY 2014 ESRD PPS Final Rule (78 FR 72220), facilities are generally eligible to receive a score on the clinical measures if their CCN open date occurs before the end of the performance period. However, facilities with a CCN open date after January 1 of the performance period are not eligible to receive a score on the NHSN Bloodstream Infection clinical measure, due to the need to collect 12 months of data to accurately score the measure. We proposed that facilities with a CCN open date after January 1, 2016, will also not be eligible to receive a score on the ICH CAHPS clinical measure in the PY 2018 program. Due to the additional time needed to arrange to contract with CMS-approved third-party vendors, and for vendors to administer the survey twice and report the results to CMS, we do not believe facilities with CCN open dates after January 1, 2016, can reasonably be expected to meet the requirements associated with the proposed ICH CAHPS clinical measure for that performance period.

As discussed in Section III.G.7 below, we are continuing our policy that a facility will not receive a TPS unless it receives a score on at least one clinical measure and at least one reporting

measure. We note that finalizing the above proposals would result in facilities not being eligible for a payment reduction for the PY 2018 ESRD QIP if they have a CCN open date on or after July 1, 2016.

We sought comments on these proposals but did not receive any comments.

For these reasons, we are finalizing the minimum data policies for the PY 2018 program as proposed, with the exception of the patient minimum policies for the Screening for Clinical Depression and Follow-Up and Pain Assessment and Follow-Up reporting measures. For the reasons discussed above, we are finalizing the policy that a facility must treat at least 11 qualifying patients during the performance period to receive a score on the Screening for Clinical Depression and Follow-Up and Pain Assessment and Follow-Up reporting measures.

Table 27 displays the finalized patient minimum requirements for each of the measures, as well as the CCN open dates after which a facility will not be eligible to receive a score on a reporting measure.

TABLE 27—MINIMUM DATA REQUIREMENTS FOR THE PY 2018 ESRD QIP

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Adult Hemodialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Adult Peritoneal Dialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Pediatric Hemodialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Pediatric Peritoneal Dialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 patients.
Vascular Access Type: Catheter (Clinical).	11 qualifying patients	N/A	11–25 patients.
Vascular Access Type: Fistula (Clinical).	11 qualifying patients	N/A	11–25 patients.
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 patients.
NHSN Bloodstream Infection (Clinical).	11 qualifying patients	Before January 1, 2016	11–25 patients.
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
STrR (Clinical)	10 patient-years at risk	N/A	10–21 patient-years at risk.
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period..	Before January 1, 2016	N/A.
Anemia Management (Reporting)	11 qualifying patients	Before July 1, 2016	N/A.
Mineral Metabolism (Reporting)	11 qualifying patients	Before July 1, 2016	N/A.
Depression Screening and Follow-Up (Reporting).	11 qualifying patients	Before July 1, 2016	N/A.
Pain Assessment and Follow-Up (Reporting).	11 qualifying patients	Before July 1, 2016	N/A.
NHSN HCP Influenza Vaccination (Reporting).	N/A	Before January 1, 2016	N/A.

6. Calculating the Clinical Measure Domain Score

As the ESRD QIP evolves and we continue to adopt new clinical measures that track the goals of the NQS, we do not believe that the current scoring methodology provides the program with enough flexibility to strengthen incentives for quality improvement in areas where quality gaps continue to exist. Therefore, under the authority of Section 1881(h)(3)(A)(i) of the Act, we proposed to revise the scoring methodology beginning with the PY 2018 ESRD QIP so that we assign measure scores on the basis of two domains: A Clinical Measure Domain and a Reporting Measure Domain.

First, we proposed to establish a Clinical Measure Domain, which we define as an aggregated metric of facility performance on the clinical measures and measure topics in the ESRD QIP. Under this proposed approach, we would score individual clinical measures and measure topics using the methodology we finalize for that measure or measure topic. Clinical measures and measure topics would then be grouped into subdomains within the Clinical Measure Domain, according to quality categories. Within these subdomains, measure scores would be multiplied by a weighting coefficient, weighted measure scores would be summed together to determine subdomain scores, and then subdomain scores would be summed together to determine a facility's Clinical Measure Domain score. This scoring methodology provides more flexibility to focus on quality improvement efforts, because it makes it possible to group measures according to quality categories and to weight each category according to opportunities for quality improvement.

We further proposed to divide the clinical measure domain into three subdomains for the purposes of calculating the Clinical Measure Domain score:

- Safety
- Patient and Family Engagement/Care Coordination
- Clinical Care

We took several considerations into account when selecting these particular

subdomains. First, safety, patient engagement, care coordination, and clinical care are all NQS goals for which the ESRD QIP has proposed and/or finalized measures. We are attempting to align all CMS quality improvement efforts with the NQS because its patient-centered approach prioritizes measures across our quality reporting and pay-for-performance programs to ensure that the measurement approaches in these programs, as a whole, can make meaningful improvements in the quality of care furnished in a variety of settings. We also believe that adopting an NQS-based subdomain structure for the clinical measures in the ESRD QIP is responsive to stakeholder requests that we align our measurement approaches across HHS programs.

Second, we proposed to combine the NQS goals of Care Coordination and Patient- and Caregiver-Centered Experience of Care into one subdomain because we believe the two goals complement each other. ''Care Coordination'' refers to the NQS goal of promoting effective communication and coordination of care. ''Patient- and Caregiver- Centered Experience of Care'' refers to the NQS goal of ensuring that each patient and family is engaged as a partner in care. In order to engage patients and families as partners, we believe that effective communication and coordination of care must coexist, and that patient and family engagement cannot occur independently of effective communication and care coordination. We therefore believe that it is appropriate to combine measures of care coordination with those of patient and family engagement for the purposes of calculating a facility's clinical measure domain score.

For PY 2018 and future payment years, we proposed to include the following measures in the following subdomains of the proposed clinical measure domain (see Table 28):

TABLE 28—PROPOSED SUBDOMAINS IN THE CLINICAL MEASURE DOMAIN

Subdomain	Measures and measure topics
Safety Subdomain	NHSN Bloodstream Infection measure.
Patient and Family Engagement/Care Coordination Subdomain	ICH CAHPS measure. SRR measure.
Clinical Care Subdomain	STrR measure. Dialysis Adequacy measure topic. Vascular Access Type measure topic. Hypercalcemia measure.

We sought comments on these proposals to adopt a Clinical Measure Domain that includes three subdomains (safety, patient and family engagement/care coordination, and clinical care) for the purpose of calculating a facility's clinical measure domain score for PY 2018.

In deciding how to weight the proposed subdomains that comprise the clinical measure domain score, we took the following considerations into account: (1) The number of measures and measure topics in a proposed subdomain; (2) how much experience facilities have had with the measures and measure topics in a proposed subdomain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD. Because the proposed Clinical Care subdomain contains the largest number of measures, and facilities have the most experience with the measures in this subdomain, we proposed to weight the Clinical Care subdomain significantly higher than the other subdomains. Facilities have more experience with the NHSN Bloodstream Infection measure in the proposed Safety subdomain than they do with the SRR measure in the proposed Patient and Family Engagement/Care Coordination subdomain, but we proposed to include a larger number of measures in the Patient and Family Engagement/Care Coordination subdomain. We proposed to give the Patient and Family Engagement/Care Coordination subdomain slightly more weight than the Safety subdomain, because it includes two measures, whereas only one measure appears in the proposed Safety subdomain. In future rulemaking, we will consider revising these weights based on facility experience with the measures contained within these proposed subdomains.

For these reasons, we proposed the following weights for the three subdomains in the clinical measure domain score for PY 2018:

Subdomain	Weight in the clinical measure domain percent score
Safety	20
Patient and Family Engagement/Care Coordination	30
Clinical Care	50

In deciding how to weight measures and measure topics within a proposed subdomain, we took into account the same considerations we considered when deciding how to weight the proposed subdomains. Because the NHSN Bloodstream Infection clinical measure is the only measure in the proposed Safety subdomain, we proposed to assign the entire subdomain weight to that measure. We additionally noted that improving patient safety and reducing bloodstream infections in patients with ESRD are two of our highest priorities for quality improvement, so we believe it is appropriate to weight the NHSN Bloodstream Infection clinical measure at 20 percent of a facility's Clinical Measure Domain Score. Because facilities have substantially more experience with the ICH CAHPS clinical measure, as compared with the SRR clinical measure, we proposed to give the proposed ICH CAHPS measure twice as much weight as the proposed SRR measure. Additionally, we noted that improving patients' experience of care is as high a priority for CMS quality improvement efforts as improving patient safety, so we believe it is appropriate to assign the ICH CAHPS clinical measure the same weight as the NHSN Bloodstream Infection clinical measure. We proposed to give the Dialysis Adequacy and Vascular Access Type measure topics the most weight in the Clinical Care subdomain because facilities have substantially more experience with these measure topics, as compared to the other measures in the Clinical Care subdomain. We proposed to assign equal weights to the STrR and Hypercalcemia measures because PY 2018 would be the first program year in which facilities are measured on the STrR measure, and because the clinical significance of the Hypercalcemia measure is diminished in the absence of other information about mineral metabolism (for example,

a patient's phosphorus and plasma parathyroid hormone levels), which would provide a more comprehensive assessment of mineral metabolism (78 FR 72217). For these reasons, we proposed to use the following weighting system for calculating a facility's Clinical Measure domain score:

Measures/measure topics by subdomain	Measure weight in the clinical measure domain score (percent)
Safety Subdomain	20
NHSN Bloodstream Infection measure	20
Patient and Family Engagement/Care Coordination Subdomain	30
ICH CAHPS measure	20
SRR measure	10
Clinical Care Subdomain	50
STrR measure	7
Dialysis Adequacy measure topic	18
Vascular Access Type measure topic	18
Hypercalcemia measure	7

We sought comments on this proposal for weighting individual measures within the Clinical Measure Domain. The comments and our responses are set forth below.

Comment: One commenter supported the proposal to create a Clinical Measure Domain, and the weightings applied therein, because the proposed domain appropriately prioritizes outcome measures, and compared to process measures, outcome measures provide a better indication of quality care.

Response: We thank the commenter for the support.

Comment: One commenter supported ICH CAHPS clinical measure's proposed weight in the Clinical Measure Domain and recommended that CMS consider giving the measure greater weight in the future, because CAHPS is weighted slightly higher in other value-based purchasing programs.

Response: We thank the commenter for the support and we will consider increasing the weight of the ICH CAHPS clinical measure in future payment years.

Comment: Commenter supported placing the NHSN Bloodstream Infection measure alone in the Safety subdomain because reducing bloodstream infections is one of the highest priorities for patients with ESRD.

Response: We thank the commenter for the support.

Comment: One commenter did not support the proposed weighting for the subdomains within the clinical measure domain. Commenter stated that the proposed weighting places too much emphasis on the Patient and Family Engagement/Care Coordination subdomain which contains clinical measures over which the facility has the least control, and places too little emphasis on safety. Commenter recommended that CMS revise the weights of the subdomains to weight the Safety and Clinical Care subdomains equally, and assign less weight to the Patient and Family Engagement/Care Coordination subdomain.

Response: We disagree with the commenter that the proposed subdomain weighting places too much emphasis on Patient and Family Engagement/Care Coordination, as compared to the Safety subdomain. As discussed in the CY 2015 ESRD PPS Proposed Rule (79 FR 40267), we proposed to assign the Patient and Family Engagement/Care Coordination subdomain slightly more weight than the Safety subdomain, because the former subdomain includes two measures and the latter subdomain only includes one measure. We continue to believe that these weights are appropriate for the PY 2018 ESRD QIP measure set, but we will reconsider the weighting system in its entirety, in light of the three criteria listed above (that is., the number of measures and measure topics in a proposed subdomain; how much experience facilities have had with the measures and measure topics in a proposed subdomain; and how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD) in future rulemaking.

Comment: One commenter recommended reducing the weight of the ICH CAHPS clinical measure in the Clinical Measure Domain ''to avoid penalizing dialysis units that provide safe, high quality care'' but do not score as highly on the ICH CAHPS measure.

Response: We agree that safety is a paramount concern in dialysis treatment, but also believe that patient experience is a crucial element of the overall care provided by the dialysis facility. As stated in the CY 2015 ESRD PPS Proposed Rule, we based decisions about subdomain and measure weighting on three criteria, and we continue to believe that the weight of the ICH CAHPS clinical measure is consistent with these criteria. We further note that it is possible for a facility that does not perform well on the ICH CAHPS clinical measure to avoid a payment reduction if it performs well on the other clinical measures.

Comment: One commenter did not support weighting the ICH CAHPS clinical measure at 20 percent of a facility's TPS, because small facilities will have trouble meeting the eligibility requirements for this measure, which will result in a 20 percent reduction in their TPS.

Response: If a facility does not meet the eligibility requirements for the ICH CAHPS clinical measure, the facility will not be scored on the measure and the corresponding measure weight will be reallocated equally across the clinical measures for which the facility received a score.

Comment: Some commenters recommended lowering the weight of the ICH CAHPS clinical measure, because no studies have demonstrated a positive association between scores on the measure and positive patient outcomes.

Response: While it is premature to know for certain in this provider setting, measuring patient experience can lead to quality improvement. In other settings, better patient experience can lead to better outcomes. Patient experience and clinical measures may be related, but they are distinct measures of quality. ICH CAHPS supports the National Quality Forum's strategy priorities of Effective Communication and Care Coordination and Person and Family-centered Care as well as the Institute of Medicine's six specific aims for improvement.

Comment: One commenter did not support the proposed weighting for the Safety subdomain because there is only one measure in the domain. Commenter recommended that CMS not include subdomains with only one measure, or in the alternative, reduce that subdomain's weight so that the one measure is weighted similar to measures in the other subdomains.

Response: As stated in the proposed rule, we decided how to weight the Clinical Measure Domain subdomains and individual measures using three criteria: ''(1) The number of measures and measure topics in a proposed subdomain; (2) how much experience facilities have had with the measures and measure topics in a proposed subdomain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD'' (79 FR 40267). We further stated that facilities have more experience with the NHSN Bloodstream Infection clinical measure than they do with the measures in the Patient and Family Engagement/Care Coordination subdomain, and that ''improving patient safety and reducing bloodstream infections in patients with ESRD is one

of our highest priorities for quality improvement, so we believe it is appropriate to weight the NHSN Bloodstream Infection clinical measure at 20 percent of a facility's Clinical Measure Domain score'' (79 FR 40268). We continue to believe that the weight assigned to the Safety subdomain and the NHSN Bloodstream Infection clinical measure is appropriate for these reasons.

Comment: Some commenters recommended lowering the weight of the NHSN Bloodstream Infection measure, because facilities do not reliably report the data used to calculate performance rates on the measure.

Response: NHSN provides detailed trainings, protocols, and guidance for users to follow to ensure that data are reported in a standardized manner and according to requirements. We recognize that continuous internal and external evaluation and quality checks of the reported data are important for accuracy and reliability. We further note that one of the purposes of the feasibility study is to improve the validity of data reported to NHSN, and we continue to believe that one of the outcomes of the study will be to improve the validity and reliability of the NHSN Bloodstream Infection measure. For this reason, and the reasons stated in the CY 2015 ESRD PPS Proposed Rule, we continue to believe that the NHSN Bloodstream Infection measure is weighted appropriately.

Comment: Some commenters recommended increasing the weight of the Vascular Access Type measure topic, because high scores on the measure topic are strongly associated with positive patient outcomes.

Response: We agree that the Vascular Access Type measures are strongly associated with positive patient outcomes. For this reason, and for the reasons described in the CY 2015 ESRD PPS Proposed Rule, the Vascular Access Type received the second highest weighting (that is, 18 percent) in the Clinical Measure Domain, lower only than the ICH CAHPS clinical measure (20 percent) and the NHSN Bloodstream Infection measure (20 percent). Accordingly, we believe that the Vascular Access Type measure topic is weighted appropriately.

Comment: One commenter supported CMS's inclusion of a Patient and Family Engagement/Care Coordination subdomain, but feels the measures within this domain are not meaningful to patients because the ICH CAHPS clinical measure excludes home dialysis patients, and the Standardized Readmission Ratio does not assess patients' quality of life.

Response: We disagree that the measures in the Patient and Family Engagement/Care Coordination subdomain are not meaningful to patients. We are continuing to investigate the possibility of expanding the ICH CAHPS survey to include a greater proportion of the ESRD population. Nevertheless, the measure as it is currently specified assesses the experience of care for the majority of patients with ESRD. In addition, we believe the Standardized Readmission Ratio does assess patients' quality of life because preventing unplanned hospital readmissions significantly improves patients' quality of life.

Comment: One commenter did not think facilities' experience with a clinical measure should affect the weight assigned to the measure. For example, the proposed weight for the STrR clinical measure was reduced because facilities have not had a large amount of experience with this measure.

Response: We consider facility experience with a clinical measure in how we weight that measure in order to give facilities time to become familiar with the reporting requirements and put into place the necessary tools to maximize their potential to score highly. We therefore believe it is appropriate to increase a measure's weight as facilities gain familiarity with the measure.

Comment: Some commenters supported the proposed criteria for assigning weights to measures and subdomains, but commenters recommended adding three additional criteria when assigning weights. Specifically, the commenters recommended the following three criteria: 1) Strength of evidence; 2) Opportunity for improvement; and 3) Clinical significance.

Response: We agree with commenters that these criteria encompass important considerations for evaluating measures. We clarify that these are criteria that are taken into account when making decisions about whether to adopt a measure in the ESRD QIP, because it would be inappropriate to adopt a measure that did not meet these criteria. For this reason, we do not believe it would be appropriate to also factor these criteria into decisions about how much weight to give measures in a facility's Clinical Domain score.

Comment: One commenter stated that the Clinical Domain scoring methodology does not provide more flexibility than the current scoring methodology because the current scoring methodology makes it possible to redistribute weights between clinical and reporting measures, and to distribute weights for individual measures within the two categories.

Response: We recognize that under the current scoring methodology it is possible to assign weights to individual measures without grouping them in subdomains, as proposed for the new scoring methodology. We nevertheless believe that assigning weights to subdomains (as opposed to just the measures contained therein) simplifies the process of prioritizing quality improvement goals as the program evolves, and in light of the NQS. We further believe that assigning weights to subdomains provides for greater transparency, because it directly communicates CMS's priorities for measure areas. For these reasons, we believe that the merits of grouping measures into subdomains, and explicitly articulating weights for the various subdomains, outweighs the merits of continuing to weight measures individually.

Comment: One commenter was concerned that some measures span multiple subdomains. For example, SRR could be attributed to Patient and Family Engagement/Care Coordination subdomain as well as the Clinical Care subdomain.

Response: We recognize that some measures could reasonably be placed in multiple subdomains. In such cases, we need to make a judgment regarding which subdomain we think will be most appropriate. In the case of SRR, we believe that it is appropriate to place the measure in the Patient and Family Engagement/Care Coordination subdomain because the measure is primarily intended to evaluate care coordination, not the quality of clinical care provided by facilities.

For these reasons, we are finalizing that we will calculate facilities' Clinical Measure Domain scores beginning in PY 2018 as proposed.

7. Calculating the Reporting Measure Domain Score and the TPS for the PY 2018 ESRD QIP

Starting with the PY 2014 program, the ESRD QIP has used a scoring methodology in which the clinical measures receive substantially more weight than the reporting measures in the TPS, and the weighting coefficients for the two types of measures total 100 percent of the TPS. We continue to believe it is appropriate to incorporate reporting measure scores in the TPS calculations because ''reporting is an important component in quality improvement'' (76 FR 70274); we also continue to believe that clinical measures should carry substantially more weight than reporting measures

because clinical measures ''score providers/facilities based upon actual outcomes'' (76 FR 70275). These statements reflect the fact that clinical and reporting measures serve different functions in the ESRD QIP. Clinical measures provide a direct assessment of the quality of care a facility provides, relative to either the facility's past performance or standards of care nationwide. Reporting measures create an incentive for facilities to monitor significant indicators of health and illness, and they help facilities become familiar with CMS data systems. In addition, they allow the ESRD QIP to collect the robust clinical data needed to establish performance standards for clinical measures.

As we continue to add reporting measures to the ESRD QIP measure set, it becomes increasingly challenging to not weight them so heavily that they dilute the significance of the clinical measures, while still ensuring that we do not weight the reporting measures so lightly that facilities are not incentivized to meet the reporting measure requirements.

Although we considered the possibility of abandoning the use of reporting measures, we determined that this is not feasible because doing so would make it impossible to calculate performance standards for many clinical measures that promise to promote high-quality care. We also considered the possibility of weighting the reporting measures such that each reporting measure comprised a smaller percentage of the TPS. We believe, however, that doing so would result in the reporting measures not carrying enough weight to provide facilities with an incentive to meet the reporting requirements, particularly if additional reporting measures were added to the program. For example, if 5 reporting measures were adopted in the ESRD QIP, and the reporting measures collectively were weighted at 5 percent of a facility's TPS (in order to preserve the significance of the clinical measures), then each reporting measure would only comprise 1 percent of a facility's TPS. Under such conditions, we believe that facilities may choose not to meet the reporting measure requirements, because not doing so would have a negligible impact on their overall TPS. If enough facilities reached this determination, then we would not be able to establish reliable baselines, should we propose to adopt clinical measure versions of the reporting measures. For these reasons, we proposed the following scoring methodology for determining the impact of reporting measure scores on a facility's payment reductions.

For PY 2018 and future payment years, we proposed to establish a new Reporting Measure Domain. We further proposed that a facility's reporting measure domain score will be the sum of all the reporting measure scores that the facility receives. We strive to expand reporting measures into clinical measures in the ESRD QIP as quickly as measure development and administrative processes permit. Therefore, unlike the case with clinical measures in the Clinical Domain Score, we do not intend to continue to use any particular reporting measure in the ESRD QIP for an indefinite period of time. For this reason, we believe that it would be unnecessarily opaque and confusing to group reporting measures into subdomains, as we are proposing for the clinical measures in the Clinical Measure Domain.

Additionally, we proposed to establish a Reporting Measure Adjuster (RMA), which will provide the ESRD QIP with an index of facility performance on reporting measures within the Reporting Measure Domain. We proposed to use the following general formula to determine a facility's RMA, based on its reporting measure domain score:

$$\left[\begin{array}{c}\text{(available Reporting Measure points)} - \\ \text{(Reporting Measure Domain score)}\end{array}\right] \times \text{(coefficient } C\text{)}$$

This formula is constructed such that a high RMA is indicative of low performance on the reporting measures, and a low RMA is indicative of high performance. A facility's Reporting Measure Domain score (that is, the sum of its scores on the reporting measures) is subtracted from the total number of points a facility could earn on the reporting measures for which it was eligible. This result is then multiplied by ''C,'' which is a coefficient used to translate reporting measure points into TPS points. As C increases, so too does the TPS ''value'' of a reporting measure point. For example, if C is set to 2, then 1 reporting measure point is worth 2 TPS points. If C is set to 0.5, then 1 reporting measure point is worth one-half of a TPS point. The value of C is in not tied to the number of reporting measures in the ESRD QIP; rather, it represents how much value we place on the reporting measures' contribution to the quality goals of the ESRD QIP. We will use the rulemaking process to set the value for C for each program year.

For the PY 2018 ESRD QIP, we proposed to use the following formula to determine a facility's RMA:

$$\left[\text{(eligible Reporting Measure points)} - \text{(Reporting Measure Domain score)}\right] \times 5/6$$

We set coefficient C at five-sixths for the PY 2018 program because each reporting measure point in the PY 2016 program, and the proposed PY 2017 program, is equivalent to five-sixths of a TPS point (that is, 30 points for three reporting measures comprised 25 TPS points). We believe it is important to maintain as much consistency as possible in the transition to the proposed scoring methodology. Therefore, we proposed that the ''value'' of a reporting measure point in the TPS, as finalized in the PY 2016 program and proposed for the PY 2017 program, will remain constant in PY 2018.

For the reasons described above, we continue to believe that the clinical measures are considerably more important than the reporting measures in the ESRD QIP. We therefore believe that a facility's TPS should be predominantly determined by its Clinical Measure Domain score, and that

a facility's TPS should be downwardly adjusted in the case of noncompliance with the reporting measure requirements. The RMA, as described above, is constructed such that a high RMA value indicates low reporting measure scores and a low RMA value indicate high reporting measure scores. As a result, a facility's TPS would be entirely determined by its Clinical Measure Domain score if it receives full credit on the reporting measures; the TPS would be slightly decreased if the facility received high (but not perfect) scores on the reporting measures; and the TPS would be significantly decreased if it performed poorly on the reporting measures. For these reasons, we proposed to calculate a facility's TPS by subtracting the facility's RMA from its Clinical Measure Domain score. Additionally, we proposed to continue our policy to require a facility to be eligible for a score on at least one reporting and one clinical measure in order to receive a TPS (78 FR 72217).

In an effort to estimate the impact of this proposed change for the ESRD QIP's scoring methodology, we conducted an analysis of how the proposed scoring methodology affected payment reduction distributions, based on data from CY 2012 and CY 2013. This analysis compared the scoring methodology proposed in this section and the previous section to the scoring methodology finalized for the PY 2016 program. In order to ensure that the analysis reliably estimated the impact on facilities' payment reductions, the proposed scoring methodology and the methodology finalized for the PY 2016 program were each applied to the PY 2016 measure set. The full analysis is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.* The results of this analysis are presented below in Table 29.

TABLE 29—EXPECTED IMPACT OF PROPOSED SCORING METHODOLOGY ON THE DISTRIBUTION OF PAYMENT REDUCTIONS, USING MEASURES AND MEASURE WEIGHTS FINALIZED FOR THE PY 2016 ESRD QIP AND DATA FROM CY 2012 AND CY 2013

Payment reduction (percent)	Finalized scoring methodology for PY 2016, applied to measures and measure weights finalized in the PY 2016 program		Proposed scoring methodology for PY 2018, applied to measures and measure weights finalized in the PY 2016 program	
	Number of facilities	Percent	Number of facilities	Percent
0	4,828	79.4	4,606	75.7
0.5	884	14.5	739	12.2
1.0	242	4.0	306	5.0
1.5	69	1.1	108	1.8
2.0	59	1.0	323	5.3

As illustrated in Table 29, we expect that 4.3 percent more facilities (222 overall) would receive a two percent payment reduction under the proposed methodology for PY 2018, as compared with the scoring methodology that we will use for the PY 2016 program. We therefore believe that adopting the scoring methodology proposed in this section and the previous section will not appreciably change the distribution of facility payment reductions, as is our intention.

We sought comments on these proposals for calculating a facility's reporting measure domain score, to calculate the RMA, and to determine the TPS.

Although we believe advantages are afforded by adopting the scoring methodology proposed in this section and the previous section, we also recognize that there may be advantages associated with maintaining consistency with previous years' scoring methodology. Accordingly, as an alternative to the scoring methodology proposed in this section and the previous section, we also sought public comments on whether we should continue to use the same methodology we currently use to weight measures in the ESRD QIP and calculate a facility's TPS, with the exception that the clinical and reporting measures would be weighted at 90 percent and 10 percent, respectively, of a facility's TPS.

We sought public comments on these proposals. The comments and our responses are set forth below.

Comment: One commenter supported the proposed scoring methodology for PY 2018, because it appropriately balances the importance of reporting and clinical measures in a facility's TPS. Another commenter recommended that CMS consider reallocating measure weights within the domains if a facility does not meet minimum data requirements for a measure.

Response: We thank the commenters for their support and recommendations.

Comment: Some commenters did not support the proposed RMA methodology for the ESRD QIP, because it is too complex and likely difficult to explain to patients. Commenters stated that the ESRD QIP should maintain a consistent scoring methodology from year to year. Commenters also stated that using more complicated scoring formulas makes the ESRD QIP less transparent, and limits facilities' ability to participate. Commenters recommended that CMS delay finalizing any change in scoring methodology to allow for more time to analyze the proposed changes and how facilities would perform under the new scoring system. Commenters recommended that CMS continue to use the current weighting system, because it assigns greater weight to the clinical measures, as compared to the reporting measures. Another commenter stated that the weight of the clinical measures should be increased in the ESRD QIP, and expressed concerns that the proposed scoring methodology will result in less weight for the clinical measures. Specifically, commenters recommended adopting the alternative scoring methodology, in which clinical measures and reporting measures are weighted at 90 percent and 10 percent, respectively.

Response: We appreciate the numerous comments we received on the RMA methodology. As a result of the significant concerns expressed about the RMA methodology, we have decided not to finalize the methodology at this time. We will further review the RMA methodology, and we may decide to propose to adopt it in future rulemaking. In its stead, we will retain

the current scoring methodology used in the ESRD QIP to weight measures and, as proposed, increase the weight assigned to clinical measures. Under this methodology, clinical measures will be weighted as finalized for the Clinical Domain score, and the Clinical Domain Score will comprise 90 percent of a facility's TPS. Reporting measures will be weighted equally to form 10 percent of the facility's TPS.

For these reasons we are not finalizing the RMA scoring methodology as proposed. Instead, we are finalizing the alternative scoring methodology, under which clinical measures will we weighted as finalized for the Clinical Domain score, and the Clinical Domain score will comprise 90 percent of a facility's TPS, with the reporting measures weighted equally to form the remaining 10 percent of a facility's TPS.

8. Example of the PY 2018 ESRD QIP Scoring Methodology

In this section, we provide an example to illustrate the scoring methodology for PY 2018 and future payment years. Figures 3—7 illustrate how to calculate the clinical measure domain score, the reporting measure domain score, the RMA, and the TPS. Note that for this example, Facility A, a hypothetical facility, has performed very well. Figure 3 illustrates the general methodology used to calculate domain scores for the clinical measure domain, as well as the example calculations for Facility A.

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Figure 3

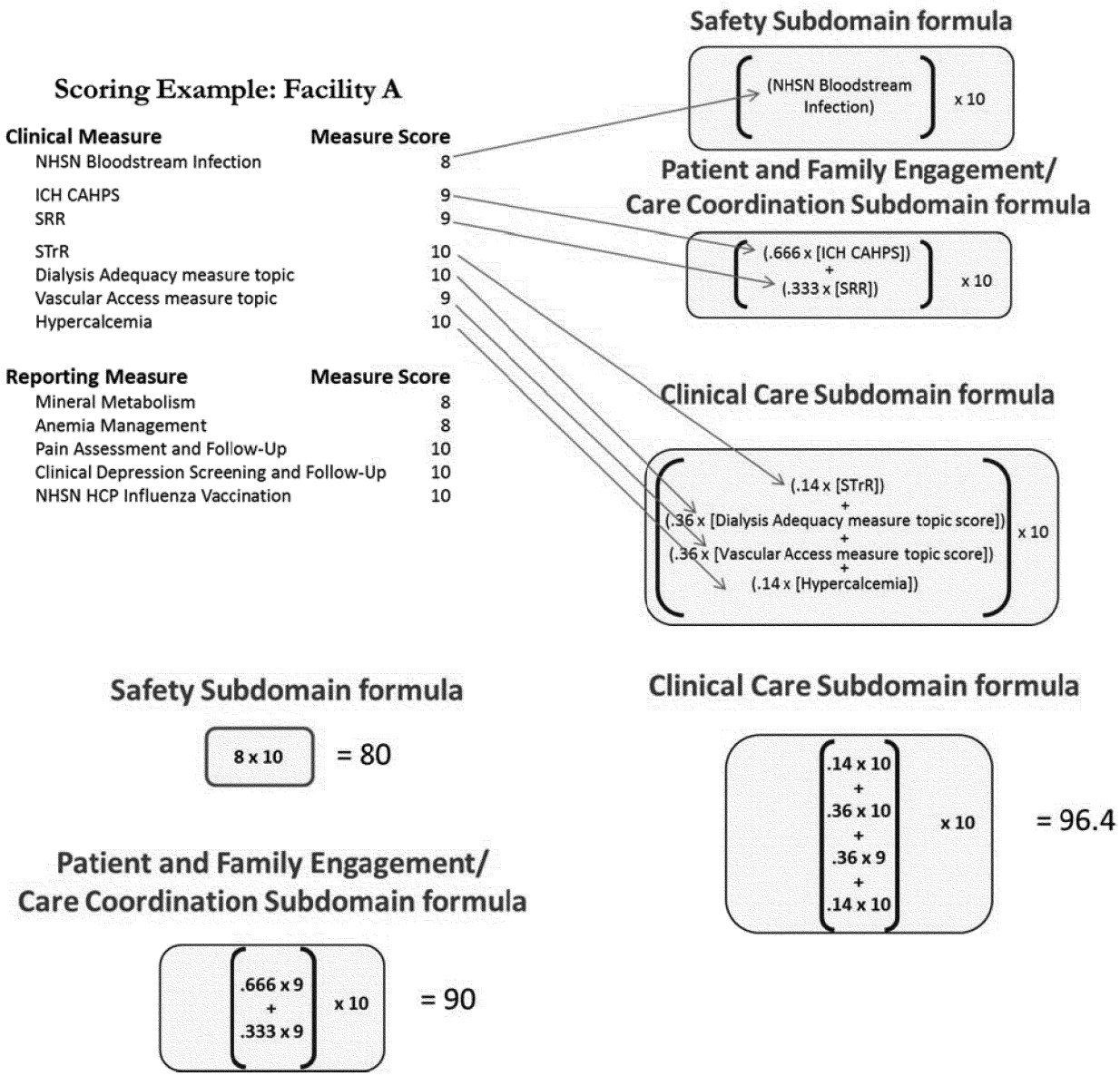
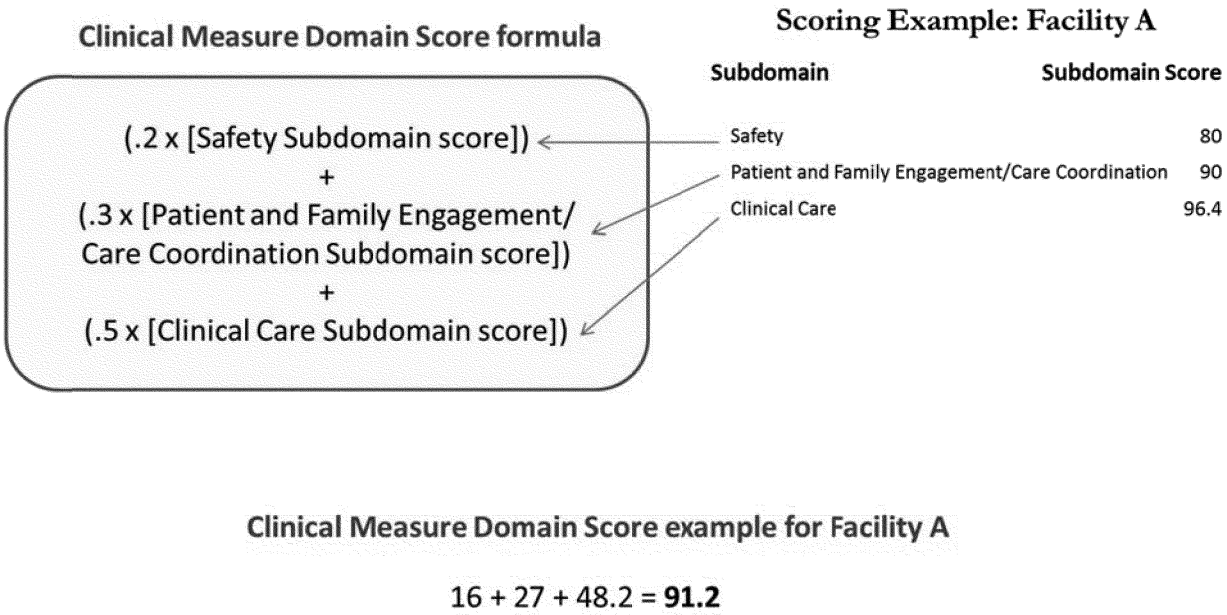


Figure 4 illustrates the general methodology for weighting subdomains in the clinical measure domain, as well as the example calculations for Facility A's clinical measure domain score.

Figure 4



Figures 5 and 6 illustrate the general methodology for calculating a facility's reporting measure domain score and TPS, as well as the example calculations for Facility A.

Figure 5

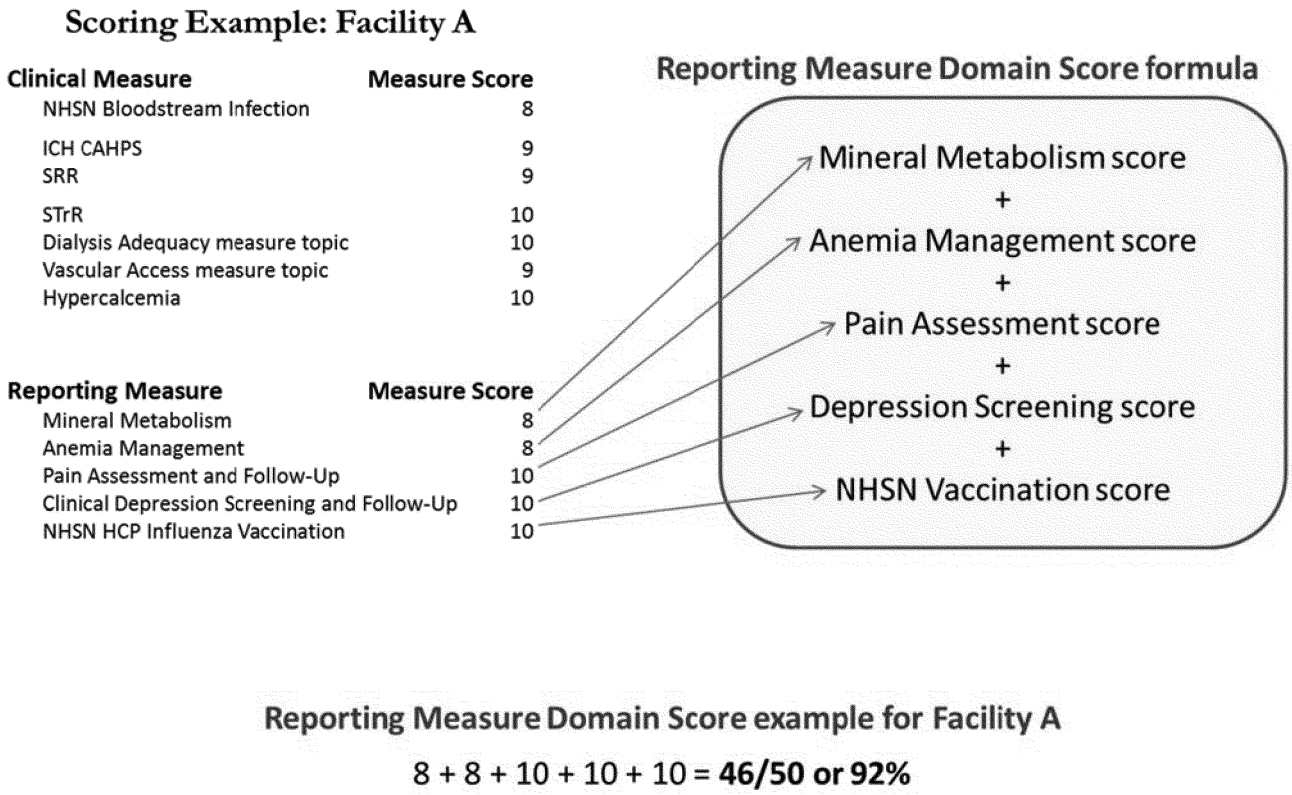
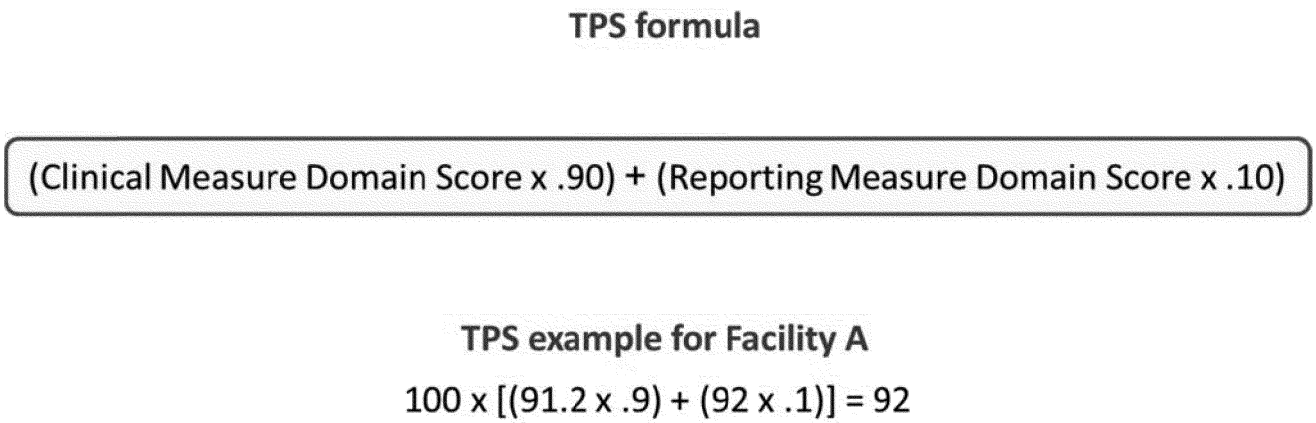


Figure 6



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9. Payment Reductions for the PY 2018 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. For the same reasons described in Section III.F.8 above, we proposed that a facility would not receive a payment reduction for PY 2018 if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if:

- It performed at the performance standard for each clinical measure;
- It received the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2016 reporting measures.

The PY 2016 program is the most recent year for which we will have calculated final measure scores before the beginning of the proposed performance period for PY 2018 (that is,

CY 2016). Because we have not yet calculated final measure scores, we are unable to determine the 50th percentile of facility performance on the PY 2016 reporting measures. We will publish that value in the CY 2016 ESRD PPS final rule once we have calculated final measure scores for the PY 2016 program.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2014 ESRD PPS Final Rule (78 FR 72223 through 72224), we finalized a payment reduction scale for PY 2016 and future payment years: For every 10 points a facility falls below the minimum TPS, the facility would receive an additional 0.5 percent reduction on its ESRD PPS payments for PY 2016 and future payment years, with a maximum reduction of 2.0 percent. We did not propose any changes to this policy.

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate a minimum TPS at this time. We will publish the minimum TPS, based on data from CY 2014 and the first part of CY 2015, in the CY 2016 ESRD PPS Final Rule.

We sought comments on this proposal. We did not receive any comments and are finalizing it as proposed.

H. Future Considerations for Stratifying ESRD QIP Measures for Dual-Eligible Beneficiaries

CMS recognizes that individuals with both Medicare and Medicaid (also known as ''dual-eligible beneficiaries''), comprise a relatively large proportion of Medicare enrollees with ESRD. Because ESRD programs have a long history of performance measurement linked with public reporting, and because there are a large number of dual-eligible beneficiaries receiving ESRD care, we are considering stratifying ESRD QIP measures for Medicare-Medicaid enrollees.

Measure reporting under the ESRD QIP does not currently allow us to separately review results for dual-eligible beneficiaries or compare those results with results achieved by other patients with ESRD, so it is not currently known if their experiences are better, worse, or the same as other patients. Even the basic demographics of dual-eligible beneficiaries receiving ESRD care are not well understood. After discussion of the pros and cons that included input from the ESRD provider community, the Measures Application Partnership's dual-eligible workgroup recommended that CMS take the first step in exploring the feasibility of requiring facilities to separately report ESRD QIP measures for Medicare-Medicaid enrollees by analyzing the composition of the dual-eligible beneficiary population receiving ESRD care and determining potential ways in which stratified reporting may further quality improvement efforts. Furthermore, the Measures Application Partnership recommended, in the context of measure development, that CMS explore whether other risk factors unique to the dual-eligible population receiving ESRD care would present significant hurdles to measure stratification along these lines. We therefore sought comments on whether it would be feasible to stratify ESRD QIP measures based on whether the beneficiary is a dual eligible. We were interested in whether stakeholders recommend stratification and, if so, for what specific measures stakeholders would find stratification most compelling.

We were particularly interested in public comments on whether Medicare-Medicaid stratified quality measures under the ESRD QIP should be reported publicly, and how we should factor those measures into our scoring methodology. We sought comments on the meaningfulness of stratifying measures, and the feasibility and burden associated with reporting stratified measures.

The comments and our responses are set forth below.

Comment: Some commenters did not support stratifying ESRD QIP measures based on whether the beneficiary is dually eligible for Medicare and Medicaid, because the commenter feels this constitutes risk adjusting for patients' socioeconomic status, which may obscure differences in facilities' risk-adjusted quality scores and mask potential disparities in care. One commenter recommended that CMS instead consider evaluating facilities in relation to their peers by comparing facilities serving similar shares of dual-eligible beneficiaries, because ''such an approach adjusts for socioeconomic status without masking differences in quality.'' The commenter further recommended that CMS compare facilities using only ESRD QIP measures that are claims-based, in order to minimize administrative burden to facilities and the agency resulting from the comparison. Another commenter stated that stratifying ESRD QIP scores on the basis of dual-eligibles is an ''interesting idea,'' but one that is complex and would require considerable collaboration with the ESRD community. Some commenters did not support stratifying ESRD QIP measures based on whether the beneficiary is dually eligible. Commenters stated it is not operationally feasible for facilities to separately report ESRD QIP measures for dual eligible beneficiaries, because dual eligibility status can change on a monthly basis. Another commenter also stated its belief that this stratification would include dual eligible patients in the facility's Medicare patient population and the dual eligible population, raising the possibility that a facility could be penalized twice for the same patient. Another commenter recommended stratifying ESRD QIP measures solely for investigative purposes, and not using these scores to determine payment reductions. Another commenter expressed reservations about the effects of stratifying for dual eligible patients, but recommended that CMS place greater emphasis on the role of socioeconomic status and demographic factors when assessing facility performance under the ESRD QIP.

Response: We appreciate commenters' input and we will take it into consideration as we continue to evaluate how to account for dual-eligibles in the ESRD QIP and other CMS ESRD quality initiatives.

IV. Technical Corrections for 42 Part 405

A. Background

In the April 15, 2008, final rule ''Conditions for Coverage for End-Stage Renal Disease Facilities,'' (73 FR 20370) we revised the health and safety standards for Medicare-participating End-Stage Renal Disease (ESRD) facilities. This rule made the first comprehensive revisions to the ESRD Conditions for Coverage (CfCs) since they were adopted in 1976. The original ESRD CfCs at 42 CFR Part 405 Subpart U were deleted and new conditions were issued at 42 CFR Part 494. Subpart U now only addresses certain requirements for ESRD networks.

As a part of these revisions, we intended to delete most of the terms and definitions set out in Part 405 Subpart U, and create new definitions in Part 494. This is discussed in the 2008 final rule and in the corresponding proposed rule (70 FR 6184), and is laid out in the final rule crosswalk (comparing the old CfCs with the new ones) at 73 FR 20451.

While we intended to delete most of the definitions at Part 405 Subpart U, we inadvertently omitted the regulations text that would have made those changes. Subpart U, at § 405.2102, still has 32 definitions, most of them unnecessary and several of them

obsolete. This creates confusion for ESRD stakeholders, patients, and suppliers.

B. Summary of the Proposed Provisions and Responses to Comments on the CY 2015 ESRD PPS

In the CY 2015 ESRD PPS proposed rule, we proposed to make a technical correction that deletes the outdated terms and definitions at § 405.2102. Specifically, we proposed to delete these terms and definitions: agreement, arrangement, dialysis, end-stage renal disease (ESRD), ESRD facility, renal dialysis center, renal dialysis facility, self-dialysis unit, special purpose renal dialysis facility, ESRD service, dialysis service, inpatient dialysis, outpatient dialysis, staff-assisted dialysis, self-dialysis, home dialysis, self-dialysis and home dialysis training, furnishes directly, furnishes on the premises, medical care criteria, medical care norms, medical care standards, medical care evaluation study, qualified personnel, chief executive officer, dietitian, medical record practitioner, nurse responsible for nursing service, physician-director, and social worker. We also proposed to delete the term and definition for ''ESRD network organization,'' as it is duplicated within § 405.2102 as ''network organization.'' We would retain the terms and definitions for ''network, ESRD,'' and ''network organization.'' These changes are also outlined in Table 30 below.''

TABLE 30—TECHNICAL CORRECTIONS TO § 405.2102

Term	Proposed action	Other CFR location
Agreement	Delete	—
Arrangement	Delete	—
Dialysis	Delete	—
End-Stage Renal Disease (ESRD)	Delete	406.13(b)
ESRD facility introductory text	Delete	—
Renal dialysis center	Delete	—
Renal dialysis facility	Delete	494.10
Self-dialysis unit	Delete	—
Special purpose renal dialysis facility	Delete	494.120
ESRD Network organization	Delete	—
ESRD service introductory text	Delete	—
Dialysis service	Delete	—
Inpatient dialysis	Delete	—
Outpatient dialysis	Delete	—
Staff-assisted dialysis	Delete	—
Self-dialysis	Delete	494.10
Home dialysis	Delete	494.10
Self-dialysis and home dialysis training	Delete	—
Furnishes directly	Delete	494.10
Furnishes on the premises	Delete	494.180(d)
Medical care criteria	Delete	—
Medical care norms	Delete	—
Medical care standards	Delete	—
Medical care evaluation study (MCE)	Delete	—
Network, ESRD	Retain	N/A
Network organization	Retain	N/A
Qualified personnel	Delete	—
Chief executive officer	Delete	—
Dietitian	Delete	494.140(c)
Medical record practitioner	Delete	—
Nurse responsible for nursing service	Delete	494.140(b)
Physician-director	Delete	494.140(a)
Social worker	Delete	494.140(d)

We did not receive any public comments addressing this technical correction. Therefore, we are finalizing the deletion of obsolete definitions in § 405.2102 as proposed.

V. Methodology for Adjusting DMEPOS Payment Amounts Using Information From Competitive Bidding Programs

A. Background

1. Fee Schedule Payment Basis for Certain DMEPOS

Section 1834(a) of the Act governs payment for durable medical equipment (DME) covered under Part B and under Part A for a home health agency and provides for the implementation of a fee schedule payment methodology for DME furnished on or after January 1, 1989. Sections 1834(a)(2) through (a)(7) of the Act set forth separate payment categories of DME and describe how the fee schedule for each of the following categories is established:

- Inexpensive or other routinely purchased items,
- Items requiring frequent and substantial servicing,
- Customized items,
- Oxygen and oxygen equipment,
- Other covered items (other than DME), and
- Other items of DME (capped rental items).

Section 1834(h) of the Act governs payment for prosthetic devices, prosthetics, and orthotics (P&O) and sets forth fee schedule payment rules for P&O. Effective for items furnished on or after January 1, 2002, payment is also made on a national fee schedule basis for parenteral and enteral nutrition (PEN) in accordance with the authority under section 1842(s) of the Act. The term ''enteral nutrition'' will be used throughout this document to describe enteral nutrients supplies and equipment covered as prosthetic devices in accordance with section 1861(s)(8) of the Act and paid for on a fee schedule basis and enteral nutrients under the Medicare DMEPOS Competitive Bidding

Program (CBP), as authorized under section 1847(a)(2)(B) of the Act. Additional background discussion about DMEPOS items subject to section 1834 of the Act, rules for calculating reasonable charges, and fee schedule payment methodologies for PENs and for DME prosthetic devices, prosthetics, orthotics, and surgical dressings, was provided in the proposed rule (79 FR 40275 through 40277).

2. DMEPOS Competitive Bidding Programs Payment Rules

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary to establish and implement CBPs in competitive bidding areas (CBAs) throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The programs mandated by section 1847(a) of the Act are collectively referred to as the ''Medicare DMEPOS Competitive Bidding Program.'' Section 1847(a)(2) of the Act provides that the items and services to which competitive bidding applies are:

- Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act;
- Enteral nutrients, equipment and supplies described in section 1842(s)(2)(D) of the Act; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

The DME and medical supplies category includes items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME, but excludes class III devices under the Federal Food, Drug, and Cosmetics Act and Group 3 or higher complex rehabilitative power wheelchairs and related accessories when furnished with such wheelchairs. Sections 1847(a) and (b) of the Act specify certain requirements and conditions for implementation of the Medicare DMEPOS CBP.

3. Adjusting Payment Amounts Using Information From the DMEPOS Competitive Bidding Program

Section 1834(a)(1)(F)(ii) of the Act provides authority for using information from the DMEPOS CBPs to adjust the DME payment amounts for covered items furnished on or after January 1, 2011, in areas where competitive bidding is not implemented for the items. Similar authority exists at section 1834(h)(1)(H)(ii) of the Act for OTS orthotics, and at section 1842(s)(3)(B) of the Act for enteral nutrition. Section 1834(a)(1)(F) also requires adjustments to the payment amounts for all DME items subject to competitive bidding furnished in areas where CBPs have not been implemented on or after January 1, 2016.

For items furnished on or after January 1, 2016, section 1834(a)(1)(F)(iii) requires us to continue to make such adjustments to DME payment amounts where CBPs have not been implemented, as additional covered items are phased in or information is updated as contracts are recompeted.

Section 1834(a)(1)(G) of the Act requires that the methodology used to adjust payment amounts for DME and OTS orthotics using information from the CBPs be promulgated through notice and comment rulemaking. Section 1834(a)(1)(G) of the Act also requires that we consider the ''costs of items and services in areas in which such provisions [sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii)] would be applied compared to the payment rates for such items and services in competitive acquisition [competitive bidding] areas.''

B. Summary of the Proposed Provisions and Responses to Comments on the Methodology for Adjusting DMEPOS Payment Amounts Using Information From Competitive Bidding Programs

The proposed rule for implementing section 1834(a)(1)(G) of the Act to establish a methodology for using information from CBPs to adjust the fee schedule amounts in accordance with sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii) of the Act was published on July 1, 2014 (79 FR 40208). We proposed applying the methodology proposed in this rule in making adjustments to the payment amounts for enteral nutrition as authorized by section 1842(s)(3)(B) of the Act (79 FR 40281). We received 89 public comments on the proposed rule, including comments from patient organizations, patients, manufacturers, health care systems, and DME suppliers. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received, our responses to the comments, and the policies we are finalizing for DMEPOS furnished under section 1834 of the Act. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

We proposed establishing three methodologies for adjusting DMEPOS fee schedule amounts in areas where CBPs have not been established for these items and services based on single payment amounts SPAs established in accordance with the payment rules at § 414.408 (79 FR 40281). We stated that the use of SPAs that may be established in accordance with the payment rules proposed in section VI of the proposed rule to adjust DMEPOS fee schedule amounts in areas where CBPs have not been established for these items and services would be addressed in future notice and comment rulemaking. The first methodology we proposed is summarized in subsection V. B. 1 below and would utilize regional adjustments limited by national parameters for items bid in more than 10 CBAs throughout the country. The second methodology we proposed is summarized in subsection 2 below and would be used for lower volume items or other items that were bid in no more than 10 CBAs for various reasons. The third methodology we proposed is summarized in subsection 5 and would be used for mail order items furnished in the Northern Mariana Islands. We also proposed rules that would apply to all of these proposed methodologies, which are discussed in sections V.B.3, V.B.4, and V.B.6 below.

1. Proposed Regional Adjustments Limited by National Parameters

CBPs are currently in place in 100 of the largest metropolitan statistical areas (MSAs) in the country for items and services that make up over 80 percent of the total allowed charges for items subject to the DMEPOS CBP. SPAs are currently used in 109 CBAs that include areas in every state throughout the country except for Alaska, Maine, Montana, North Dakota, South Dakota, Vermont, and Wyoming. The number of CBAs that are fully or partially located within a given state range from one to twelve. One CBA is for a non-contiguous area of the United States (Honolulu, Hawaii) and was phased in under Round 2 of the program. Suppliers submitting bids for furnishing items and services in these areas have received extensive education that they should factor all costs of furnishing items and services in an area as well as overhead and profit into their bids.

For items and services that are subject to competitive bidding and have been included in more than 10 CBAs throughout the country, we proposed to adjust the fee schedule payment amounts for these items and services

using a methodology that is modeled closely after the regional fee schedule payment methodology in effect for P&O to allow for variations in payment based on bids for furnishing items and services in different parts of the country (79 FR 40281). Under the proposed methodology, adjusted fee schedule amounts for areas within the contiguous United States would be determined based on regional SPAs or regional single payment amounts (RSPAs) limited by a national floor and ceiling. The RSPA would be established using the average of the SPAs for an item from all CBAs that are fully or partially located in the region. The adjusted payment amount for the item would be equal to its RSPA but not less than 90 percent and not more than 110 percent of the average of the RSPAs established for all states. This limits the range in the regional fee schedule amounts from highest to lowest to no more than 20 percent, 10 percent above the national average and 10 percent below the national average. By contrast, the fee schedule payment methodology for DME only allows for a variation in statewide fees of 15 percent below the median of statewide fees for all the states. The national limits to the fee schedule amounts for P&O and DME have not resulted in a barrier to access to items and services in any part of the country. We believe this reflects the fact that the costs of furnishing DMEPOS items and services do not vary significantly from one part of the country to another and that national limits on regional prices is warranted. We therefore proposed to limit the variation in the RSPAs using a national ceiling and floor in order to prevent unnecessarily high or low regional amounts that vary significantly from the national average prices for the items and services (79 FR 40284). The national ceiling and floor limits would be based on 110 percent and 90 percent, respectively, of the average of the RSPAs applicable to each of the 48 contiguous states and the District of Columbia (that is, the average of RSPAs is weighted by the number of contiguous states including the District of Columbia per region). We proposed that any RSPA above the national ceiling would be brought down to the ceiling and any RSPA below the national floor would be brought up to the floor. We proposed that the national ceiling would exceed the average of the RSPAs by the same percentage that the national floor would be under the average of the RSPAs. This allows for a maximum variation of 20 percent from the lowest RSPA to the highest RSPA. We believe that a variation in payment amounts both above and below the national average price should be allowed, and we believe that allowing for the same degree of variation (10 percent) above and below the national average price is more equitable and less arbitrary than allowing a higher degree of variation (20 percent) above the national average price than below (10 percent), as in the case of the national ceiling and floor for the P&O fee schedule, or allowing for only 15 percent variation below the national average price, as in the case of the national ceiling and floor for the DME fee schedule.

Under the DMEPOS CBP, the statute prohibits competitions before 2015 in new CBAs that are rural areas or MSAs with a population of less than 250,000. Even if competitions were to begin in these areas in 2015, it is very unlikely that the SPAs from these areas would be computed and finalized by January 1, 2016. Therefore, we proposed that the proposed RSPAs initially be based solely on information from existing programs implemented in 100 MSAs, which are generally comprised of more densely populated, urban areas than areas outside MSAs (79 FR 40284). We therefore believe that the initial RSPAs would not directly account for unique costs that may be associated with furnishing DMEPOS in states that have few MSAs and are predominantly rural or cover large geographic areas and are sparsely populated. However, in keeping with the discussion above, we do not believe that the cost of furnishing DMEPOS in these areas should deviate significantly from the national average price established based on supplier bids for furnishing items and services in different areas throughout the country.

The DMEPOS fee schedule amounts are based primarily on supplier charges for furnishing items and services in urban areas and this has not resulted in problems associated with access to these items and services in rural areas or large, sparsely populated areas. Nonetheless, for the purpose of ensuring access to necessary items and services in states that are more rural or sparsely populated than others, we proposed that the adjusted fee schedule amounts for states that are more rural than urban and defined as ''rural states'' or states where a majority of the counties are sparsely populated and defined as ''frontier states'' would be no lower than the national ceiling amount discussed above.

We proposed in § 414.202 that a *rural state* be defined as a state where more than 50 percent of the population lives in rural areas within the state as determined through census data, since a majority of the general population of the state lives in rural areas, it is likely that a majority of DMEPOS items and services are furnished in rural settings in the state (79 FR 40284). This is in contrast to other states where the majority of the general population of the state lives in urban areas, making it more likely that a majority of DMEPOS items and services are furnished in urban settings or in MSAs. We believe that for states where a majority of the general population lives in rural areas, adjustments to the fee schedule amounts should be based on the national ceiling amount if the RSPA is lower than the national ceiling amount. This higher level of payment would provide more assurance that access to items and services in states within a region that are more rural than urban is preserved in the event that costs of furnishing DMEPOS items and services in rural areas is higher than the costs of furnishing DMEPOS items and services in urban areas.

We proposed in § 414.202 that a *frontier state,* would be defined as a state where at least 50 percent of counties in the state have a population density of 6 people or less per square mile (79 FR 40284). In such states, the majority of counties where DMEPOS items and services may be needed are very sparsely populated and suppliers may therefore have to drive considerably longer distances in furnishing these items and services as opposed to other states where the beneficiaries live closer to one another. The designation of states as frontier states or frontier areas is currently used under Medicare Part A to make adjustments to the wage index for hospitals in these remote areas in order to ensure access to services in these areas. The definition of frontier state that we proposed for the purpose of implementing section 1834(a)(1)(F) and (G) of the Act is consistent with the current definition in section 1886(d)(3)(E)(iii)(II) and (III) of the Act and 42 CFR 412.64(m) of the regulations related to implementation of the hospital wage index adjustments and prospective payment system for hospitals under Part A. We believe that states designated as frontier states have a significant amount of area that is sparsely populated and are more likely to be geographically removed from (that is, a considerable driving distance from) areas where population is more concentrated. However, we solicited comments on alternative definitions of frontier states.

Based on the 2010 Census data, states designated as rural would include

Vermont, Maine, West Virginia, and Mississippi. Other than one CBA that is fully located in Mississippi, one CBA that is partially located in Mississippi, and two CBAs that are partially located in West Virginia, the RSPAs would not include SPAs that reflect the costs of furnishing items and services in these states based on where the CBAs are currently located. Current frontier states include North Dakota, South Dakota, Montana, and Wyoming, and the RSPAs would not include SPAs that reflect the costs of furnishing items and services in any of these states based on where the CBAs are currently located. We proposed that the designation of rural and frontier states could change as the U.S. Census information changes. We proposed that when a state that is not designated as a rural state or frontier becomes a rural state or frontier state based on new, updated information from the U.S. Census Bureau, that adjustments to the fee schedule amounts in accordance with the proposed provision of this section would take effect as soon as such changes can be implemented. Likewise, we proposed that at any time a state that is designated as a rural state or frontier no longer meets the proposed definition in this section for rural state or frontier state based on new, updated information from the U.S. Census Bureau, that adjustments to the fee schedule amounts in accordance with the proposed provision of this section would take effect as soon as such changes can be implemented (79 FR 40285). We proposed that the changes to the state designation would occur based on the decennial Census. The decennial Census uses total population of the state to determine whether the state is predominately rural or frontier. The U.S. Census Bureau also uses current population estimates every 1, 3, and 5 years through the American Community Survey but only samples a small percentage of the population every year, not the total population. Therefore, we proposed that the designation of a rural or frontier state occur approximately every 10 years when the total population data is available. For the current proposed fee schedule adjustments, we proposed to use the 2010 Census Data. The next update would reflect the 2020 Census Data and any changes in the designation of a rural or frontier state and corresponding fee schedule changes would be implemented after the 2020 Census Data becomes available. For this and subsequent updates, we proposed to include a listing of the qualifying rural and frontier States in program guidance that is issued quarterly and to provide at least 6 months advance notice of any adjustments.

We indicated in the proposed rule (79 FR 40285) that some of the comments received on the advance notice of proposed rulemaking indicated that the costs of furnishing DMEPOS items and services in rural areas is significantly higher than the costs of furnishing DMEPOS items and services in urban areas. Other commenters suggested that the adjustments to the payment amounts based on information from CBPs be phased in to give suppliers time to adjust to the new payment levels. Although we believe that the costs of furnishing items and services in rural areas are different than the costs of furnishing items and services in urban areas, there is no evidence to support a statement that the difference in costs is significant. In summary, we proposed that adjustments to payment amounts for areas within different regions of the contiguous United States would be based on the un-weighted average of SPAs from CBAs that are fully or partially located within these regions. The regional amounts would be limited by a national ceiling and floor and the adjusted payment amounts for all states designated as rural or frontier states would be equal to the national ceiling. In addition, we solicited public comments on whether payment in rural areas of states that are not designated as rural or frontier states should be set differently. For the purpose of ensuring access to necessary items and services in states that are more rural or sparsely populated than others, we proposed that the adjusted fee schedule amounts for states that are more rural than urban and defined as ''rural states'' or states where a majority of the counties are sparsely populated and defined as ''frontier states'' would be no lower than the national ceiling amount.

In addition, we proposed that the adjustments to the fee schedule amounts for areas outside the contiguous United States would not be based on the RSPAs. Rather, we proposed that the adjustments to the fee schedule amounts for these areas be based on the higher of the average of SPAs for CBAs in areas outside the contiguous United States (for example, Honolulu) or the national ceiling limit applied to the payment adjustments for areas within the contiguous United States (79 FR 40285). These proposals were made in consideration of the unique costs of furnishing DMEPOS items and services in remote, isolated areas outside the contiguous United States such as Alaska, Guam, Hawaii, Puerto Rico, the United States Virgin Islands and other areas. We proposed that any SPAs from programs in these areas be excluded from the calculation of the RSPAs in section a. In addition, we proposed that the adjustments to the fee schedule amounts for areas outside the contiguous United States would not be based on the RSPAs. Rather, we proposed that the adjustments to the fee schedule amounts for these areas be based on the higher of the average of SPAs for CBAs in areas outside the contiguous United States (for example, Honolulu) or the national ceiling limit applied to the payment adjustments for areas within the contiguous United States. We believe that, to the extent that SPAs from non-contiguous areas are available, these amounts should be used in making adjustments to the payment amounts for other areas outside the contiguous United States since the challenges and costs of furnishing DMEPOS items and services in all remote, isolated areas is similar. We also believe that the payment adjustments for these areas, like those for the proposed rural and frontier states, should not be lower than the national ceiling established for items and services furnished in the contiguous United States. Areas outside the contiguous United States generally have higher shipping fees and other costs. We believe the SPAs in Honolulu and other areas outside the contiguous United States reflect these costs and could be used to adjust the fee schedule amounts for these areas without limiting access to DMEPOS items and services. However, in the event that the national ceiling limit described in section b above is greater than the average of the SPAs for CBPs in areas outside the contiguous United States, we proposed that the higher national ceiling amount be used in adjusting the fee schedule amounts for areas outside the contiguous United States in order to better ensure access to DMEPOS items and services (79 FR 40285).

For the purpose of establishing the boundaries for the regions, we proposed using 8 regions developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce (79 FR 40282). Research and analysis conducted by the BEA indicated that the states in each region share economic ties. Further information can be obtained at: *https://www.bea.gov/regional/definitions/nextpage.cfm?key=Regions*. The information provided at this link states that:

BEA Regions are a set of Geographic Areas that are aggregations of the states. The following eight regions are defined: Far West,

Great Lakes, Mideast, New England, Plains, Rocky Mountain, Southeast, and Southwest. The regional classifications, which were developed in the mid-1950s, are based on the homogeneity of the states in terms of economic characteristics, such as the industrial composition of the labor force, and in terms of demographic, social, and cultural characteristics. For a brief description of the regional classification of states used by BEA, see U.S. Department of Commerce, Census Bureau, Geographic Areas Reference Manual, Washington, DC, U.S. Government Printing Office, November 1994, pp. 6–18; 6–19.

Therefore, we proposed to revise the definition of *region* in § 414.202 to mean a region developed for economic analysis purposes by the BEA within the Department of Commerce for the purpose of calculating regional single payment amounts (RSPAs); the definition of region for the purposes of the P&O regional fee schedule would also continue to apply for those items and services not adjusted based on prices in competitively bid areas. According to the BEA, the regional classifications are based on the homogeneity of the states in terms of economic characteristics, such as the industrial composition of the labor force, and in terms of demographic, social, and cultural characteristics. The contiguous areas of the United States that fall under the 8 BEA regions under our proposal the proposed rule are listed in Table 31 below. Further information can be obtained at *http://www.bea.gov/.*

TABLE 31—BUREAU OF ECONOMIC ANALYSIS REGIONS

Region	Name	States/areas (count)
1	New England	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont (6).
2	Mideast	Delaware, District of Columbia, Maryland, New Jersey, New York, and Pennsylvania (6).
3	Great Lakes	Illinois, Indiana, Michigan, Ohio, and Wisconsin (5).
4	Plains	Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota (7).
5	Southeast	Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia (12).
6	Southwest	Arizona, New Mexico, Oklahoma, and Texas (4).
7	Rocky Mountain	Colorado, Idaho, Montana, Utah, and Wyoming (5).
8	Far West	California, Nevada, Oregon, and Washington (4).

We solicited public comments on whether different regional boundaries should be considered that would better reflect potential regional differences in the costs of furnishing items and services subject to the DMEPOS CBP.

The comments on these proposals and our responses are set forth below.

Comment: Many commenters stated that the DMEPOS CBP and the SPAs established under the program are flawed because the bids they are based on are not binding and therefore result in the submission of non-bona fide bids and because the SPA is based on the median of supplier bids for an item rather than the maximum bid resulting in some suppliers being paid less than the amount they bid. The commenters therefore believe that the SPAs should not be used to adjust payment amounts for items and services furnished in other areas of the country. A few commenters said that no decisions should be made before future Office of the Inspector General (OIG) reports on competitive bidding are published because these reports might validate their claims that the SPAs are flawed.

Response: We do not agree that the DMEPOS CBP and the SPAs established under the program are flawed because the bids they are based on are not binding and therefore result in the submission of non-bona fide bids or because the SPA is based on the median of supplier bids for an item rather than the maximum bid resulting in some suppliers being paid less than the amount they bid. Bids are screened to ensure that they are bona fide. Suppliers that submit the lowest bids are required to provide invoices and other information to validate the bid and bids that are not validated are rejected. Regarding calculation of the SPA using the median rather than maximum bid, suppliers offered contracts under the program do not have to accept these amounts, but if they do, they are accepting the payment amounts in the contract and suppliers have successfully furnished items at these amounts with no impact on access. Over 90 percent of suppliers accept contracts they are offered, indicating that the SPAs are appropriate. We therefore do not agree with the commenters that the SPAs should not be used to adjust payment amounts for items and services furnished in other areas of the country and we do not agree that waiting for an OIG evaluation of this issue is necessary. Section 1834(a)(1)(F)(ii) of the Act mandates use of information on the payment determined under CBPs to adjust the payment amount that would otherwise be made for DME for an area that is not a CBA by no later than January 1, 2016, therefore, we believe it is appropriate to establish the methodology in rulemaking so that it takes effect on January 1, 2015, allowing time for calculation and implementation of the adjusted fee schedule amounts on January 1, 2016.

Comment: Some commenters suggested that a survey of supplier costs in areas outside of CBAs should be conducted to determine whether the costs in these areas are greater than the costs in CBAs or to otherwise provide information on how the payment amounts in areas outside CBAs should be adjusted.

Response: We disagree with this comment. The statute requires CMS to use CBP information (as opposed to survey data of supplier costs as the commenters suggest).

Comment: Many commenters suggested that as an alternative to using SPAs to adjust payment amounts, the methodology should use either the highest bid submitted for each item under the competition or the highest bid submitted for the item by the suppliers in the winning range.

Response: We disagree with this suggestion. We believe that the median bid is a better reflection of the costs of furnishing items by suppliers as whole as reflected in their bids than either the lowest bid or the highest bid. Medicare payment methods at 42 CFR 405.502 used in the past for DME have relied on customary charges from suppliers based on the median of their charges as well as fee schedule amounts based on average reasonable charges. In no case have the highest supplier charges or highest reasonable charges been used to establish Medicare allowed amounts for DME in the past, and in no case has use of median or average charges in establishing Medicare allowed payment amounts resulted in significant

problems related to obtaining access to items and services in the past.

Comment: Some commenters stated that bids submitted by suppliers unable to fulfill the terms of their contract, for example, due to problems associated with meeting State licensure requirements, should be excluded and SPAs should be recalculated before they are used to determine the adjusted fee schedule amounts.

Response: We disagree with this comment. We have observed no significant negative impacts on access to items and services under the CBPs since they were initially phased in on January 1, 2011. In the limited situations where bids used in the calculation of the SPAs were from suppliers that later were determined to be ineligible, these bids did not impact access to items and service.

Comment: One commenter indicated that the boundaries for the regions based on the 8 regions developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce are too broad and are not representative of current regional economic characteristics.

Response: We disagree. The BEA regional designations have been evaluated and have evolved over the years to continue to encompass socio-economic patterns.

Comment: Many commenters stated that the proposed methodology does not adequately address the costs of furnishing items and services in areas of the country where CBPs have not been established, particularly for rural areas, non-contiguous areas, or remote areas where suppliers must incur extraordinary delivery expenses. Some commented that the SPA-based pricing is too low for a supplier to stay in business and for the beneficiaries to receive equipment. Some commenters believe that the quality of items and services furnished will be compromised by the proposed methodology for adjusting payment amounts. Many commenters did not agree with the proposed methodology for using the national ceiling or 110 percent of the average of the RSPAs as a payment floor for rural states and frontier states and suggested varied ways to adjust prices in rural areas, including raising the national ceiling to 120 or 150 percent, or having rural and low population density areas add-on payments at the ZIP code or county level similar to the add-on payments allowed for rural areas under the ambulance fee schedule. Commenters believe that considerations should be made for all rural areas within states regardless of whether the state meets the proposed definitions of rural or frontier state. Some commenters stated that the SPAs do not account for unique costs of delivering items to extremely remote locations and should not be used to adjust payments in these areas.

Response: We agree that the proposed methodology for using the national ceiling or 110 percent of the average of the RSPAs as a payment floor for rural states and frontier states should be applied to all rural areas and on a statewide basis depending on whether or not the state meets the proposed definitions for rural or frontier state. We believe the proposed methodology for using the national ceiling or 110 percent of the average of the RSPAs as a payment floor should be applied, at least initially, in other areas within a state that are designated as rural areas rather than entire states in order to ensure access to items and services in these areas. Although we do not have direct evidence that cost in rural areas are higher than costs in urban areas or vice versa or that the SPAs do not cover costs in rural areas, we believe it is prudent for the sake of ensuring access to items and services in these areas to proceed cautiously in adjusting fee schedule amounts in these areas. Therefore, in response to comments that considerations should be made for all rural areas within states regardless of whether the state meets the proposed definitions of rural or frontier state, we are finalizing a definition for rural area at § 414.202 to mean a geographic area represented by a postal zip code of at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any metropolitan area (MSA). The definition of rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area in accordance with the authority provided by section 1847(a)(3)(A) of the Act at the time the rules at § 414.210(g) are applied. As part of the methodology we are finalizing for adjusting fee schedule amounts using information from CBPs, we are finalizing a provision that the adjusted fee schedule amounts for any area meeting the definition of rural area will be no lower than the national ceiling amount. We are not finalizing the proposed definitions of rural state and frontier state because we have decided to apply provisions proposed for these areas (79 FR 40284) to all rural areas based on comments received and as explained in more detail below. Lastly, we note that Medicare program guidance at section 60 of chapter 20 of the Medicare Claims Processing Manual (Pub. 100–04) allows for payment of separate charges for delivery expenses in rare and unusual circumstances in order to meet the needs of beneficiaries living remote areas that are not served by a local supplier.

Comment: Some commenters recommended a 4 year phase-in of the adjusted fees by payment amounts or regions so suppliers have time to adjust to the change in payment amounts.

Response: We agree that phasing in the adjustments to the payment amounts would allow time for suppliers to adjust to the new payment rates and would allow time to monitor the impact of the change in payment rates on access to items and services; however, we do not believe that a phase in period of 4 years is necessary. We believe that time frame is excessive. Therefore, we are finalizing a phase in of 6 months, which we believe provides suppliers with an adequate amount of time to make adjustments to their businesses in light of the reduced payment amounts and is more than enough time to determine if the payment amounts are impacting access to items and services in any part of the country. CMS will monitor access and health outcomes using real time claims data and analysis. Therefore, in this final rule at § 414.210(g)(9), we finalizing the adjustments to the fee schedule amounts for use in paying claims with dates of service from January 1, 2016, thru June 30, 2016, based on 50 percent of the un-adjusted fee schedule amount and 50 percent of the adjusted fee schedule amount. For example, if the fee schedule amount that would have gone into effect on January 1, 2016, without any adjustments would have been $100.00, and the amount resulting from the methodology established in this rule would have been $75.00, the fee schedule amount taking effect on January 1, 2016, will be $87.50. Beginning on July 1, 2016, the fully adjusted fees will apply.

Comment: Many commenters urged CMS to monitor patient access, utilization, and satisfaction levels after the implementation of the adjusted fees. Commenters also recommended adding a methodology to adjust prices if access problems develop.

Response: We concur with the recommendation to closely monitor the impact of the reductions in payment on access to items and services and health outcomes. We do not believe that the reductions in payment will negatively impact access to items and services, so we do not find it necessary to adopt an additional methodology to account for access problems; however, we can

address the matter in future rulemaking, if necessary.

After consideration of the public comments, and for the reasons we discussed in the proposed rule and above, we are finalizing the proposed provisions summarized above and in the proposed rule (79 FR 40208), with the exception of the proposed definitions for rural state and frontier state and the proposed provision to use the national ceiling or 110 percent of the average of the RSPAs as a payment floor for adjusting the fee schedule amounts for these states. We are finalizing a definition of rural area and revising the definition of ''Region'' as described above at § 414.02. We are finalizing the proposed § 414.210(a) and (g), except we have amended 42 CFR 414.210(g) to note the application of competitive bidding information and limitation of inherent reasonableness authority, and the payment adjustments for areas within and outside the contiguous United States using information from CBPs.

2. Methodology for Items and Services Included in Limited Number of Competitive Bidding Programs

In some cases, there may not be a sufficient number of CBAs and SPAs available for use in computing RSPAs, and therefore, a different methodology for implementing section 1834(a)(1)(F)(ii) of the Act would be necessary. For items and services that are subject to competitive bidding and have been included in CBP in no more than 10 CBAs, we proposed that payment amounts for these items in all non-competitive bidding areas be adjusted based on 110 percent of the average of the SPAs for the areas where CBPs are implemented (79 FR 40285). Using a straight average of the SPAs rather than a weighted average of the SPAs gives SPAs for the various CBAs equal weight regardless of the size of the CBA. We believe this avoids giving undo weight to SPAs for more heavily populated areas. We proposed the additional 10 percent adjustment to the average of the SPAs to account for unique costs such as delivering items in remote, isolated locations, but would make this a uniform adjustment for program simplification purposes.

Under the DMEPOS CBP, there may be items and services for which implementation of CBPs could generate significant savings for the beneficiary and/or program, but which are furnished infrequently in most MSAs. In some cases, such items and services could be combined with other items and services under larger PCs or included in mail order competitions, to the extent that these are feasible options. For example, combining infrequently used traction equipment and frequently used hospital beds in the same product for bidding purposes would ensure that any beneficiary that needs traction equipment in the CBA would have access to the item from the suppliers also contracted to furnish hospital beds in the area. This would make it feasible to include traction equipment in numerous MSAs throughout the country and would allow use of the RSPA methodology described above. However, if a PC was established just for traction equipment for bidding purposes, the volume of items furnished in certain MSAs may not be sufficient to generate viable competitions under the program because there may be a limited number of suppliers interested in competing to furnish the items in local areas. Nonetheless, if savings for the beneficiary and/or program are possible for the equipment, we are mandated to phase the items in under the DMEPOS CBP.

In addition, for lower volume items within large PCs, such as wheelchair accessories, we proposed to include these items in a limited number of local competitions rather than in all CBAs to reduce the burden for suppliers submitting bids under the programs as a whole. In these cases, for the purposes of implementing section 1834(a)(1)(G) of the Act, we proposed that payment amounts for these items in all areas where CBPs are not implemented be adjusted based on 110 percent of the average of the SPAs for the areas where CBPs are implemented. We proposed the additional 10 percent adjustment to the national average price to account for unique costs in certain areas of the country such as delivering items in remote, isolated locations. For example, the PC for standard mobility in the 9 Round 1 CBAs includes 25 HCPCS codes for low volume wheelchair accessories that are not included in the PC for standard wheelchairs, scooters, and related accessories in the 100 Round 2 CBAs. We proposed that payment amounts for these items in areas where CBPs are not implemented be adjusted based on 110 percent of the average of the SPAs for the 9 Round 1 areas where CBPs are implemented (79 FR 40285). Alternatively, we could include these low volume items in all PCs in all 109 CBAs and suppliers would need to develop bid amounts and enter bids for these 25 codes for low volume items such as toe loop holders, shock absorbers and IV hangers. Including these 25 Healthcare Common Procedure Coding System (HCPCS) codes for low volume wheelchair accessories in the PCs under the 9 Round 1CBAs means that suppliers submitting bids for wheelchairs have 25 bid amounts to develop and enter per CBA for these items, or a total of 225 bid amounts to develop and enter for these low volume items if bidding for wheelchairs in all 9 Round 1 CBAs. In contrast, including these codes in the PCs under all 109 CBAs means that suppliers submitting bids for wheelchairs have 2,725 bid amounts to develop and enter for these low volume items, if biding for wheelchairs in all 109 CBAs. We believe that adjusting fee schedule amounts based on SPAs from 10 or fewer CBAs achieve the savings mandated by the statute for these items while greatly reducing the burden on suppliers and the program in holding competitions for these items in all 109 CBAs across the country.

Finally, if contracts and SPAs for low volume items included in a limited number of CBAs expire and the items are not included in future CBPs, we proposed to use the information from the past competitions to adjust the payment amounts for these items nationally based on 110 percent of the average of the SPAs for the areas where CBPs were implemented (79 FR 40286). Even though the SPAs may no longer be in effect, we believe it is reasonable to use the information to reduce excessive payment amounts for items and services as long as the SPAs did not result in a negative impact on access to quality items and services while they were in effect and as long as the amounts are adjusted to account for increases in costs over time. For example, 4 codes for adjustable wheelchair seat cushions were included in the Round 1 Rebid, with SPAs that were approximately 25 percent below the fee schedule amounts being in effect in 9 CBAs from January 2011 thru December 2013. These items were not bid in future rounds due to the low volume of use relative to other wheelchair seat cushions. During the course of the 3-year contract period when the SPAs were in effect in the 9 areas, there were no reports of access problems and there were no negative health outcomes as a result of including these items under CBPs. For the future, savings for these items could be achieved by including them in future competitions or by using the previous SPAs, updated by an economic update factor to account for increases in costs. If the decision is made not to include these items in future competitions, we believe savings can and should still be obtained based on information from the

previous competitions. The comments and our responses are set forth below.

Comment: Several commenters suggested that in the instances where the items and services included in limited number of CBPs, the adjusted fee schedule amounts for rural, frontier and non-contiguous areas should be greater than 110 percent of the average of the SPAs because the commenters believe that the cost of furnishing DMEPOS items in these areas are more than 10 percent higher than the cost of furnishing DMEPOS items in the CBAs. The commenters suggested using greater than 110 percent of the average of the SPAs to adjust the fee schedule amounts for rural, frontier, and non-contiguous areas.

Response: We disagree with this comment because we do not have direct evidence that the cost of furnishing DMEPOS items in rural, frontier, or non-contiguous areas is greater than the costs of furnishing the items in CBAs. In some cases, the cost of furnishing DMEPOS items in the CBAs may be greater than the costs of furnishing the items in rural, frontier, or non-contiguous areas, but we have no direct evidence of this either. Our proposal struck a balance by using 110 percent of the average of the SPAs rather than 100 percent of the average of the SPAs to account for the possibility that there may be slightly higher costs for furnishing items and services in certain areas than the cost of furnishing the items in the CBAs. Absent additional evidence, we believe that paying more than 110 percent of the average of the SPAs for the CBAs is not appropriate. However, we can consider making changes in the future if new information is made available.

Comment: Some commenters stated that that items that were excluded from CBP after initially being in the program should be excluded from the adjustment of fees One commenter argued that the SPAs for items only included in CBPs during the Round 1 Rebid are no longer reflective of the true and current cost of the items. Also, one commenter argued that if CMS included items in CBPs and then decides not to include the items in subsequent CBPs, this is an indication that CMS believes the items are not well-suited for competitive bidding. Other commenters stated that data from less than 10 CBPs is not enough data to determine what the payment amounts should be for the items on a national basis.

Response: We disagree with these comments. We believe that SPAs based on supplier bids from CBPs established in recent years are far more reflective of the true and current cost of the items than fee schedule amounts based on supplier charges from 1986 and/or 1987. There may be reasons why items are not included in subsequent CBPs, such as the fact that the item is a low volume item such as one of the hundreds of HCPCS codes for wheelchair options and accessories that is not included in subsequent CBPs to reduce the burden and cost of suppliers submitting bids for a product category (for example, wheelchairs) that already includes over a hundred higher volume items (HCPCS codes). It does not mean that CMS believes that the item is not suitable for competitive bidding. We believe that recent data from less than 10 CBPs is enough data to determine what the payment amounts should be for the items on a national basis, especially for those items that are furnished on a limited basis to a small number of beneficiaries throughout the United States yet are items for which implementation of CBPs or adjustments to payment amounts using information from CBPs is mandated by the statute. Using pricing from 10 or fewer CBPs allows for implementation of the statutory requirement to implement competitive bidding for the item.

After consideration of the public comments, we are finalizing the rule in § 414.210(g)(3) to include payment adjustments for items and services included in no more than ten competitive bidding programs reduced to 110 percent of the unweighted average of the single payment amounts. We added technical changes to the final regulation text from the proposed regulation text by adding the term ''ten or fewer'' for added clarification. We are also finalizing the rule in § 414.210(g)(4) for payment adjustments using data on items and services included in competitive bidding programs no longer in effect and specify that we will be updating the payment amounts prior to adjusting the fee schedule amounts as described above.

3. Adjusted Payment Amounts for Accessories Used With Different Types of Base Equipment

There may be situations where the same accessory or supply identified by a HCPCS code is used with different types of base equipment, and the item (HCPCS code) is included in one or more PCs under competitive bidding for use with some, but not all of the different types of base equipment it is used with. For these situations, we proposed (79 FR 40286) to use the weighted average of the SPAs from CBPs and PCs where the item is included for use in adjusting the payment amounts for the item (HCPCS code). We believe that it would be unnecessarily burdensome to have different fee schedule amounts for the same item (HCPCS code) when it is used with similar, but different types of base equipment. We believe that the costs of furnishing the accessory or supply should not vary significantly based on the type of base equipment it is used with. Therefore, we sought public comments on addressing situations where an accessory or supply identified by a HCPCS code is included in one or more PCs under competitive bidding for use with more than one type of base equipment. In these situations, we proposed to calculate the SPA for each CBA by weighting the SPAs from each PC in that CBA by national allowed services. This would result in the calculation of a single SPA for the item for each CBA. The single SPA per code per CBA would then be used in applying the payment adjustment methodologies proposed above. For example, HCPCS code Exxx1 describes a tray used on a wheelchair. Exxx1 was included in a PC for manual wheelchairs in all CBAs and in a separate, second PC for power wheelchairs in all CBAs. SPAs for Exxx1 under the manual wheelchair PC are different than the SPAs for Exxx1 under the power wheelchair PC. Under the proposed methodology, national allowed services would be used to compute a weighted average of the SPAs for code Exxx1 in each of the CBAs. So, rather than having 2 different SPAs for the same HCPCS code in the same CBA, we would have 1 SPA for the code for the CBA. If the item is included in only one PC, we proposed to use the SPAs for the item from that PC in applying the payment adjustment methodologies proposed above (79 FR 40287). The comments and our responses are set forth below.

Comment: Several commenters argued that accessories used with different base equipment have higher service costs. They pointed out cases where CMS established different SPAs for the same accessories when used with different base equipment included in different PCs. The commenters do not believe that SPAs established for a HCPCS code describing an accessory used with one type of base item (for example, standard power wheelchair) should be used to adjust the fee schedule amounts for the HCPCS code that would govern payment for the accessory when it is used with a different type of base item (for example, complex rehabilitative power wheelchair).

Response: We disagree. We believe that using the weighted average of the SPAs established for accessories used

with different base equipment takes into account any difference in the cost of furnishing the accessories with different types of base equipment in setting the overall rate for the accessories. We believe it is administratively burdensome and unnecessary to have more than one fee for the same item.

Comment: Some commenters suggested that composite bids and items weights make some accessories under-bid when they have a low weight relative to other items in the PC or relative to the same item in a different PC. For example, a HCPCS code describing a wheelchair accessory included in two different PCs, one for power wheelchairs and one for manual wheelchairs might be underbid in one PC if the item weight for the item is very low relative to the item weight for the item in the other PC. The commenter argued that, creating a weighted payment amount from the SPAs for the item from the manual and power wheelchair PCs distorts the true cost of the item if the item was under-bid in one PC because it had a low weight.

Response: We disagree. Suppliers are required to submit a bona fide bid for every item in every product category and the bids are screened to ensure that they are all bona fide. In addition, we believe that the costs of the accessories described by a single HCPCS code do not vary depending on what type of base equipment the item is used with. To the extent that the costs do vary, combining the SPAs for the accessories from different product categories results in payment amounts that reflect the average costs of the accessory when used in conjunction with various types of base equipment. If an item was underbid due to its low volume, that bid would not be considered for a contract.

After consideration of the public comments, we are finalizing the rule as proposed in § 414.210(g)(5) for adjusted payment amounts for accessories used with different types of base equipment, when included in more than one product category in a CBA under competitive bidding, a weighted average of the single payment amounts for the code is computed for each CBA based on the total number of allowed services for the item on a national basis for the code from each product category prior to applying the payment adjustment methodologies under the section. We also made an additional change to the regulation from the proposed rule for added clarification by specifying that ''the total number of allowed services for the item on a national basis for the code from each product category'' is completed ''prior to applying the payment adjustment methodologies under the section.''

4. Adjustments to Single Payment Amounts That Result From Unbalanced Bidding

Within the HCPCS there are instances where there are multiple codes for an item that are distinguished by the addition of a hierarchal feature(s). Under competitive bidding, the code with the higher utilization would receive a higher weight and the bid for this item would have a greater impact on the composite bid and competitiveness of the supplier's overall bid for the product category (PC) within the CBP than the bid for the less frequently used alternative. This can result in unbalanced bidding where the bids and SPAs for the item without the additional features is higher than the bids and SPAs for the item with the additional features due to the fact that the item with the features is utilized more than the item without the features and therefore receives a higher weight. In the proposed rule (79 FR 40287), we identified the case where unbalanced bidding resulted in higher SPAs for enteral infusion pumps without alarms than enteral infusion pumps with alarms, even though pumps without alarms have become virtually obsolete. In this case, the alarm is the hierarchal feature. Only 0.3 percent of beneficiaries using enteral infusion pumps received a pump without an alarm in 2012 according to Medicare claims data. Clearly, separately identifying pumps with alarms and pumps without alarms is no longer necessary, yet the codes for both types were included in the CBPs, resulting in a case of unbalanced bidding that could have been avoided if only one code for enteral infusion pumps existed. Likewise, in 2006, codes were added for portable power wheelchairs and power wheelchairs with less functionality (Group 1) than those commonly used by beneficiaries (Group 2). All of the codes for standard power wheelchairs meet the same needs for power wheelchairs used in the patient's home. The features of being more expensive, sturdier non-portable power wheelchairs or higher performing power wheelchairs are the hierarchal features for the standard power wheelchairs. Although the codes for portable power wheelchairs and Group 1 power wheelchairs were added in order to provide a less expensive alternative for power wheelchairs used in the home, beneficiaries did not take advantage of the lower priced, alternative equipment. Only 0.9 percent of beneficiaries using standard power wheelchairs received a portable or Group 1 power wheelchair in 2012 according to Medicare claims data. The goal of creating savings for beneficiaries by having codes for economy power wheelchairs did not materialize, yet the codes for these types of power wheelchairs were included in the CBPs, resulting in a case of unbalanced bidding that could have been avoided if the codes for the economy power wheelchairs did not exist. For the purpose of implementing section 1834(a)(1)(G) of the Act, and in making adjustments to payment amounts under sections 1834(a)(1)(F)(ii), 1834(h)(1)(H)(ii), and 1842(s)(3)(B) of the Act, we proposed that the payment amounts for infrequently used codes that describe items and services with fewer features than codes with more features be adjusted so that they are no higher than the payment amounts for the more frequently used codes with more features (79 FR 40287). We sought public comments on this issue and our proposed provision to address this issue. The comments and our responses are set forth below.

Comment: A commenter suggested that ''hierarchal feature'' be better defined. Another commenter suggested that weighing based on utilization rates ignores whether there were supply issues that affected the utilization rates. One commenter also suggested that balanced bidding does not reflect SPA cost differences based on the features of equipment.

Response: We agree that hierarchal features should be clearly identified for the purpose of implementing the proposed rule. We will limit the final policy by identifying two specific scenarios where the hierarchal features involved are additional features or features with additional functionality. In the future, we will either add other scenarios or develop a definition of ''hierarchal features.'' Therefore, the final policy will only apply to the specific cases of unbalanced bidding that were identified in the proposed rule that clearly show that certain equipment has features that exceed that of other equipment.

After consideration of the public comments, we will limit the final policy by identifying two specific scenarios where the hierarchal features involved are additional features or features with additional functionality. In the future, we will either add other scenarios or develop a way to define ''hierarchal features'' in general, or in a way that would identify various scenarios, which we expect to address in future rulemaking. Therefore, the final policy will only apply to the specific cases of unbalanced bidding that were identified

in the proposed rule (79 FR 40287) that clearly show that certain equipment has features that exceed that of other equipment. Specifically, we are adding § 414.210(g)(6) and requiring that adjusted fee schedule amounts for Group 1 power wheelchairs or Group 2 portable power wheelchairs cannot exceed the adjusted fee schedule amounts for Group 2, non-portable power wheelchairs in order to avoid situations where Medicare allowed payment amounts for power wheelchairs with less functionality are established that are higher than fee schedule amounts for power wheelchairs with more functionality. We are also finalizing a rule at § 414.210(g)(6) that adjusted fee schedule amounts for enteral infusion pumps without alarm cannot exceed the adjusted fee schedule amounts for enteral infusion pumps with alarm. We believe that wheelchairs that can go farther, faster, can climb over higher obstacles, or are not portable and more sturdy have features that exceed wheelchairs that travel shorter distances, go slower, climb over lower obstacles, or are portable and less sturdy. Payment amounts for shorter distance, slower, smaller obstacle climbing, less sturdy, power wheelchairs should not be higher than the payment amounts for longer distance, faster, higher obstacle climbing, sturdy, power wheelchairs. An enteral feeding pump with a safety alarm includes additional features than a pump without such an alarm. Payment amounts for enteral feeding infusion pumps without an alarm should not be higher than the payment amounts for pumps with an alarm. We will consider whether to add a definition of hierarchal feature, or to apply the rule we proposed to other items not identified above through future notice and comment rulemaking.

5. National Mail Order Program—Northern Mariana Islands

While Section 1847(a)(1)(A) of the Act provides that CPBs be established throughout the United States, the definition of United States at section 210(i) of the Act does not include the Northern Mariana Islands. We therefore previously determined that the Northern Mariana Islands are not considered an area eligible for inclusion under a national mail order CBP. For the purpose of implementing the requirements of section 1834(a)(1)(F)(ii) of the Act, we proposed that the payment amounts established under a national mail order CBP would be used to adjust the fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands (79 FR 40287). We proposed that the adjusted fee schedule amounts would be equal to 100 percent of the amounts established under the national mail order CBP (79 FR 40287).

We solicited comments on these proposals. The comments and our responses are set forth below.

Comment: A few commenters recommended waiting for the second round of bidding for the national mail-order CBP before applying the payment amount in order to allow more time to determine if the competitive bidding payment amounts allow access to items and services and acquire more pricing points over an extended period of time. They further recommended increasing payment amounts for the national mail order SPA for the Northern Mariana Islands to limit any access or pricing complications.

Response: We disagree with these suggestions. The national mail order SPAs currently apply to items shipped to various remote areas of the United States and have not resulted in any problems with access to mail order items in these areas. Therefore, we believe these amounts can be used to adjust the mail order fee schedule amounts for the Northern Mariana Islands effective January 1, 2016.

After consideration of the public comments and for the reasons we previously articulated, we are finalizing the proposal regarding the National Mail Order Program and the Northern Mariana Islands at § 414.210(7) to provide that the fee schedule amounts for mail order items furnished in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order program.

6. Updating Adjusted Payment Amounts

In accordance with section 1834(a)(1)(F)(iii) of the Act, the adjusted payment amounts for DME must be updated as additional items are phased in or information is updated. We proposed to add regulation text indicating that we would revise the adjusted payment amounts for DME, enteral nutrients, supplies, and equipment, and OTS orthotics each time a SPA is updated following one or more new competitions, which may occur at the end of a contract period, as additional items are phased in, or as new programs in new areas are phased in (79 FR 40287). This is required by section 1834(a)(1)(F)(iii) for DME. Since we believe it is reasonable to assume that updated information from CBPs would better reflect current costs for furnishing items and services, we proposed regulations to require similar updates for enteral nutrients, supplies, and equipment, and OTS orthotics.

As we indicated above, if the only SPAs available for an item are those that were established under CBP that are no longer in effect, we proposed to use these SPAs to adjust payment amounts using the methodologies described above and we proposed to do so following application of inflation adjustment factors. We proposed that the inflation adjustment factor would be based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) from the mid-point of the last year the SPAs were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into effect. The adjusted payment amounts would continue to be updated every 12 months using the percentage change in the CPI–U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect (79 FR 40288).

The payment amounts that would be adjusted in accordance with sections 1834(a)(1)(F)(ii) and (iii) of the Act for DME, section 1834(h)(2)(H)(ii) of the Act for orthotics, and section 1842(s)(2)(B) of the Act for enteral nutrients, supplies, and equipment shall be used to limit bids submitted under future competitions of the DMEPOS CBP in accordance with regulations at § 414.414(f). Section 1847(b)(2)(A)(iii) prohibits the awarding of contracts under a CBP unless total payments made to contract suppliers in the CBA are expected to be less than the payment amounts that would otherwise be made. In order to assure savings under a CBP, the fee schedule amount that would otherwise be paid is used to limit the amount a supplier may submit as their bid for furnishing the item in the CBA. The payment amounts that would be adjusted in accordance with sections 1834(a)(1)(F)(ii) and (iii) of the Act for DME, section 1834(h)(2)(H)(ii) of the Act for orthotics, and section 1842(s)(2)(B) of the Act for enteral nutrients, supplies, and equipment would be the payment amounts that would otherwise be made if payments for the items and services were not made through implementation of a CBP. Therefore, the adjusted fee schedule amounts would become the new bid limits (79 FR 40288).

We solicited comments on these proposals. The comments and our responses are set forth below.

Comment: Some commenters suggested updating adjusted fees yearly with CPI–U and not freeze it for 3 years until the next.

Response: We disagree. Contracts and SPAs are replaced at least once every 3 years, following one or more new competitions and as other items are added to programs established under Subpart F of this part, and increased costs in doing business are factored into the bids with each new competition. In addition, suppliers submitting bids under the CBPs are educated that their bids will be used in establishing SPAs that will be in effect for the entire duration of the contract period. Therefore, we believe that suppliers take increased costs and prices into account when developing their bids. In addition, because section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under a CBP if the total amounts paid to contract suppliers are expected to be more than the total amounts that would otherwise be paid, we believe that the intent of competitive bidding is to product a reduction in payment amounts rather than an increase in payment amounts. In lieu of establishing a CBP in an area, the authorities under the statute for adjusting fee schedule amounts based on information from CBPs must be used; however, in no case should it result in an increase in the amounts that would otherwise be paid. If an inflation adjustment factor is applied to fee schedule amounts that are adjusted by the methodologies we are adopting in this final rule, it could result in an amount that is greater than the fee schedule amount that would otherwise be paid, and we believe that this is contrary to the intent of the statute.

After consideration of the public comments, for the reasons we set forth above, we are finalizing the proposals and are adding § 414.210(g)(8) to indicate that adjusted fee schedule amounts are revised each time an SPA for an item or service is updated following one or more new competitions and as other items are added to programs established under Subpart F of this part.

Table 32 provides a summary of the final methodologies intended to achieve savings by adjusting fee schedule amounts using information from CBPs. With regard to all methodologies in this final rule that are intended to achieve savings by adjusting fee schedule amounts using information from CBPs, we are adding a provision specifying that in any case where application of these methodologies results in an increase in the fee schedule amount, the adjustment to the fee schedule amount is not made.

TABLE 32—SUMMARY OF FINAL METHODOLOGIES FOR ADJUSTING PAYMENT IN NON-BID AREAS

Proposed Methodology	Calculations
(1) Adjustments for Items Included in More than 10 CBAs*:	
(a) Regional Adjustments Limited by National Parameters for Items Furnished Within the Contiguous United States.	—Adjusted payment equal to the RSPA (calculated using the un-weighted average of SPAs from CBAs that are fully or partially located with a BEA region) limited by a national floor and ceiling. The national ceiling and floor would be set at 110 percent and 90 percent, respectively, of the average of the RSPAs calculated for each of the 48 contiguous states and District of Columbia (national average RSPA).
(b) Adjustments for Rural Areas	—Adjusted payment for areas designated as rural areas based on 110 percent of the national average RSPA.
(c) Adjustments for Items Furnished Outside the Contiguous United States.	—Adjusted payment for non-contiguous areas (e.g., Alaska, Guam, Hawaii) based on the higher of the average of SPAs for CBAs in areas outside the contiguous U.S. or 110 percent of the national average RSPA applied to adjustments within the contiguous U.S.
(2) Adjustments for Lower Volume or Other Items Included in 10 or Fewer CBAs*.	—Adjusted payment based on 110 percent of the un-weighted average of the SPAs for the areas where CBPs are implemented for contiguous and non-contiguous areas of the United States.
(3) Adjustments for Items Where the Only Available SPA is from a CBP No Longer in Effect.	—Payment based on adjusted payment determined under 1) or 2) above and adjusted on an annual basis based on the CPI–U update factors from the mid-point of the last year the SPAs were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into effect.
(4) Adjustments for Accessories Used with Different Types of Base Equipment:	
(a) Adjustments for Accessories Included in One CBP Product Category.	—SPAs for the item from that one Product Category would be used in determining the adjusted payment amounts under methodologies 1) or 2).
(b) Adjustments for Accessories Included in One or More CBP Product Category.	—A weighted average of the SPAs for the item in each CBA where the item is included in more than one Product Category would be used to determine the adjusted payment amounts under methodologies 1) or 2).
(5) Payment Adjustments to Northern Mariana Islands Using the National Mail Order SPAs.	—Fee schedule amounts adjusted to equal the SPAs under the national mail order CBP.

VI. Final Payment Methodologies and Payment Rules for Durable Medical Equipment and Enteral Nutrition Furnished Under the Competitive Bidding Program

A. Background

The payment rules for DME have changed significantly over the years since 1965, resulting in the replacement of the original monthly rental payment methodology with lump sum purchase and capped rental payment rules, as well as separate payment for repairs, maintenance and servicing, and replacement of expensive accessories for beneficiary-owned equipment. In our experience, these payment rules have been burdensome to administer and have added program costs associated with expensive wheelchair repairs and payment for loaner equipment, and have significantly increased costs associated with frequent replacement of expensive accessories at regular intervals for items such as continuous positive airway pressure (CPAP) devices.

We believe that we have general authority under section 1847(a) and (b) of the Act to establish payment rules for DME and enteral nutrition equipment that are different than the rules established under section 1834(a) of the Act for DME, section 1842(s) for enteral nutrients, supplies, and equipment, and, section 6112(b) of Omnibus Budget Reconciliation (OBRA) Act of 1989 (Pub. L. 101–239) for enteral pumps. We

believe that lump sum purchase and capping rentals for certain DME and enteral nutrition may no longer be necessary to achieve savings under the program when competitive bidding can be used to establish a reasonable monthly payment. We also believe that payment on a continuous rental basis—that is, ongoing monthly payments not subject to a cap—could help to ensure that medically necessary DME and enteral nutrition equipment is kept in good working order for the entire duration of medial need and would make it easier for beneficiaries to change from one supplier to another since the new supplier would not be faced with a finite number of rental payments. Currently, there is no requirement that a supplier take responsibility for repairing equipment once it is owned by a beneficiary, which may cause difficulties for the beneficiary to find a supplier to undertake such services. We believe that continuous rental payment would eliminate such issues because the supplier of the rented equipment would always be responsible for keeping the equipment in good working order. We do not believe that continuous monthly rental payments for DME and enteral nutrition would negatively impact access to items and services and could potentially be implemented in a manner that does not increase program expenditures since suppliers would be paid based on bids for furnishing the same general items and services they would otherwise provide. In addition, since Medicare payment for rental of DME and enteral nutrition equipment include payment for maintenance and servicing of the rented equipment, the suppliers would be directly responsible for meeting the monthly needs of the beneficiary in terms of keeping the rented equipment in good working order.

As explained in more detail below, we proposed to revise the regulation by adding a new section at 42 CFR 414.409 with special payment rules to replace existing payment rules at § 414.408 for certain items and services in no more than 12 CBPs where these rules are applied. We also proposed to revise § 414.412 to address the submission of bids for furnishing items and services paid in accordance with these proposed special payment rules.

B. Summary of the Proposed Provisions and Responses to Comments on the Payment Methodologies and Payment Rules for Durable Medical Equipment and Enteral Nutrition Furnished Under the Competitive Bidding Program

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the DMEPOS CBP. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

We proposed to update the regulations to include proposed special payment rules for paying claims for certain DME or enteral nutrition under a limited number of CBPs. We proposed to revise the regulation by adding a new section at 42 CFR 414.409 with special payment rules to replace specific payment rules at § 414.408 for these items and services in CBPs where the special rules are applied. We also proposed to revise § 414.412 regarding submission of bids for furnishing items and services paid in accordance with these special payment rules.

We believe that alternative payment models for certain DME and enteral nutrition may achieve savings under the program when competitive bidding can be used to establish a reasonable monthly payment. We also believe that payment on a continuous rental basis—that is, ongoing monthly payments not subject to a cap—could help to ensure that medically necessary DME and enteral nutrition equipment is kept in good working order for the entire duration of medial need and would make it easier for beneficiaries to change from one supplier to another since the new supplier would not be faced with a finite number of rental payments. Currently, there is no requirement that a supplier take responsibility for repairing equipment once it is owned by a beneficiary, which may cause difficulties for the beneficiary to find a supplier to undertake such services. We believe that continuous rental payment would eliminate such issues because the supplier of the rented equipment would always be responsible for keeping the equipment in good working order. We do not believe that continuous monthly rental payments for DME and enteral nutrition would negatively impact access to items and services and could potentially be implemented in a manner that does not increase program expenditures since suppliers would be paid based on bids for furnishing the same general items and services they would otherwise provide. In addition, since Medicare payment for rental of DME and enteral nutrition equipment include payment for maintenance and servicing of the rented equipment, the suppliers would be directly responsible for meeting the monthly needs of the beneficiary in terms of keeping the rented equipment in good working order. We sought comments on these proposals.

We proposed (79 FR 40291 through 40292) to phase-in the special payment rules described in sections VI.B.1 and VI.B.2 below in a limited number of areas for a limited number of items initially to determine whether it is in the best interest of the Medicare program and its beneficiaries to phase these rules in on a larger scale based on evaluation of the rules' effects on Medicare program costs, quality of care, and access to items and services. In order to monitor the impact of phasing in the special payment rules in no more than 12 CBAs, we proposed that, at a minimum, we would utilize evaluation criteria that are consistent with the current evaluation criteria for monitoring the impact of the CBP on utilizers of items and services in CBAs. To evaluate the quality of care for beneficiaries affected by the special payment rules, we proposed that, at a minimum, we would utilize health status outcomes based criteria that would measure specific indicators such as mortality, morbidity, hospitalizations, emergency room, and other applicable indicators unique to each product category. To evaluate beneficiary access to necessary items and services we proposed that, at a minimum, we would monitor utilization trends for each product category and track beneficiary complaints related to access issues. To evaluate the cost of the program, we proposed that, at a minimum, we would analyze the claims data for allowed services and allowed cost for each product category and the associated accessories, supplies and repair cost in the 12 CBAs and the comparator CBAs. We proposed to analyze the effect of the proposed payment rules on beneficiary cost sharing.

We proposed that in any competition where these rules are applied, suppliers and beneficiaries would receive advance notice about the rules at the time the competitions that utilize the rules are announced. The combined, total number of CBAs where the proposed rules in either section 1 or 2 would apply would be limited to twelve. In other words, it would not be twelve CBAs for the rules in section 1 and an additional twelve CBAs for the rules in section 2, but 12 CBAs total. In addition, we proposed that the PCs listed below would be phased in to include one or more of the CBAs that would number no more than twelve total. In addition, if a determination is made to phase-in these rules on a larger scale in additional

areas and for additional items based on program evaluation results regarding cost, quality, and access, the process for phasing in the rules and the criteria for determining when the rules would be applied would be addressed in future notice and comment rulemaking. This rulemaking would also address how the methodology for using these SPAs to adjust fee schedule amounts would need to be revised.

We proposed that separate payment for all repairs, maintenance and servicing, and replacement of supplies and accessories for beneficiary-owned DME or enteral nutrition equipment would cease in the CBAs where the payment rules proposed under this section are in effect. We proposed that if the beneficiary has a medical need for the equipment, the contract supplier would be responsible for furnishing new equipment and servicing that equipment. This option would ensure that beneficiaries continue to receive medically necessary equipment; including the supplies, accessories, maintenance and servicing that may be needed for such equipment. Please note that this would not apply to items which are not paid on a bundled, continuous rental basis. We proposed to revise the regulations at § 414.409 to specify that any beneficiary who owns DME or enteral nutrition equipment and continues to have a medical need for the items should these rules take effect in a CBA where they reside, would have the option to obtain new equipment, if medically necessary, and related servicing from a contract supplier. We requested comment as to whether a transitional process should be considered when claims are selected for review to determine whether they are reasonable and necessary and other safeguards are required to ensure timely delivery of the replacement DME so that individuals' mobility and ability to live independently is not adversely impacted by delays. While this could potentially increase beneficiary cost sharing, it would eliminate issues associated with repair of beneficiary-owned equipment.

The Affordable Care Act (Patient Protection and Affordable Care Act of 2010, Pub. L. 111–148 (March 23, 2010), Sec. 3021) establishes the Center for Medicare and Medicaid Innovations (CMMI) which is authorized to test models to reduce Medicare and Medicaid expenditures while preserving or improving quality for beneficiaries of those two programs. We solicited comments on the option for testing the above special payment rules for DME and enteral nutrition using the CMMI demonstration authority in no more than 12 CBAs that would allow us to test and evaluate the special payment rules on a wider scale and determine whether the special payment rules reduce Medicare expenditure while preserving or improving the quality for Medicare beneficiaries. Regardless of the authority used to phase-in or test these special payment rules, we proposed to undertake rigorous evaluation to determine the rules' effects on program costs, quality, and access.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the DMEPOS CBP. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

We received 28 public comments on this proposal from manufacturers, DMEPOS suppliers, coalitions, and beneficiaries. The comments and our responses are set forth below.

1. Payment on a Continuous Rental Basis for Select Items

Under our general authority under section 1847(a) and (b) of the Act to establish payment rules for DME and enteral nutrition equipment, we proposed (79 FR 40292) to revise the regulation at 42 CFR 414.409 to allow for payment on a continuous monthly rental basis under future competitions in no more than 12 CBAs for one or more of the following categories of items and services: enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, CPAP and respiratory assist devices (RADs), and hospital beds. We proposed that the SPAs established under the special payment rules would be based on bids submitted and accepted for furnishing rented DME and enteral nutrition on a monthly basis. We proposed that the SPAs would represent a monthly payment for each month that rented DME or enteral nutrition is medically necessary. The SPA for the monthly rental of DME would include payment for each item and service associated with the rental equipment including the ongoing maintenance and servicing of the rental equipment, and replacement of supplies and accessories that are necessary for the effective use of the equipment.

Comment: Several commenters indicated that CMS does not have the authority to use bundled payments under the CBP.

Response: We do not agree with this comment. The existing payment rules under section 1834 of the Act govern DMEPOS paid under the various fee schedules and do not directly apply to the CBP; therefore, CMS is not explicitly required to apply such rules to the CBP. Section 1847 of the Act mandates the implementation of CBPs throughout the United States for the purpose of awarding contracts for furnishing competitively priced items and services described under section 1847(a)(2) of the Act. As discussed in the proposed rule (79 FR 40290), we believe we have broad authority under section 1847 to establish payment rules for the CBP. In particular, consistent with section 1847(a)(6), the general payment rules for the CBPs are governed by section 1847(b) which mandates payment based on bids submitted and accepted by Medicare for the competitively priced items and services. Therefore, we believe that we have discretion to establish rules on whether covered items are paid for on a purchase or rental basis as long as total payments to contract suppliers are expected to be less than the total amounts that would otherwise be paid.

Comment: Several commenters felt that CMS has not demonstrated that a CBP that includes bundling meets the criteria for a demonstration under the CMMI.

Response: We thank the commenters for their comments. If a decision is made to use CMMI demonstration authority to implement and evaluate payment on a bundled, continuous rental basis for DME and/or enteral nutrition, it would only be after CMMI has determined that a particular payment model meets the criteria established for such a demonstration.

Comment: Many commenters expressed concerns that monthly bundled payments for DME and enteral nutrition would reduce quality and access to care. For example, they believe that if separate payments are not made for certain items, such as the ongoing replacement of CPAP accessories, contract suppliers will not have an incentive to replace the items when they need to be replaced. Other commenters suggested that specific parameters or guidelines for replacement of such items, such as the usual maximum number of accessories needed as provided in DME MAC local coverage policies, be established under the programs. Commenters were particularly vocal about the fact that these rules should not be phased in for enteral nutrition and that enteral nutrition is not a suitable product category for bundled monthly payments.

Response: We do not agree. The rules are not being phased-in in limited areas due to concerns that suppliers contracted to provide items and services under these rules will not provide those items and services. The rules are being phased in to gauge whether rental caps are necessary in order to save money for items used on a longer term basis and whether the rules can address problems associated with repair of beneficiary-owned equipment. Suppliers awarded contracts under the programs must be in compliance with DMEPOS quality standards and supplier standards in order to remain a contract supplier and in order to continue to be an enrolled DMEPOS supplier under Medicare. As always, we will closely monitor contract suppliers and real time claims data and health outcomes data to ensure that suppliers are in compliance with the standards. Guidelines for the usual maximum amount of accessories expected to be medically necessary have already been established under local DME MAC policies, and suppliers will be educated to take the cost of replacing these accessories into account when establishing their bids. Suppliers submitting bids under the program will be educated that they cannot receive payment for furnishing DME without furnishing everything the patient needs each and every month they continue to need and use the equipment. As stated in the proposed rule, the impact of the rules on program expenditures, beneficiary cost sharing, access to items and services, and quality of care will be closely monitored and compared to impacts under comparator areas. However, in light of concerns regarding the impact of the rules on access to quality items and services, we are further limiting the scope of the phase in to CPAP devices and standard power wheelchairs, and we are not finalizing the remaining categories of items at this time. These two categories of items generate the greatest amount of separate payments for accessories and repair compared to enteral nutrition or any other category of DME described in section 1847(a)(2) of the Act.

We will apply a focused and intense monitoring program to these two categories of items to evaluate quality of care and access to items and services, including specific accessories prescribed for beneficiaries under the programs to these two categories. Using real time claims analysis and health outcomes data, we will quickly identify potential problems and take action to ensure that contract suppliers are providing access to quality items and services under the programs. We believe these two DME categories will provide sufficient information in order to determine the overall effect of the special payment rules on program and beneficiary costs, quality, and access to items and services.

Comment: Some commenters supported bundling for enteral nutrition. They noted that the beneficiary would not be responsible for maintaining the pump and temporary cessation of therapy would not occur while the pump is being repaired if it is not owned. Other commenters believed that bundled payment for enteral nutrition would be beneficial for short term nutritional therapy because the patient would no longer own a pump that is not needed. However, other commenters argued that CMS should exclude enteral nutrition from the bundled initiative because of the wide variation in cost of the enteral nutrients. Some commenters recommended establishing a monthly rental bundled payment based upon mode of delivery. Other commenters recommended establishing a separate bundled payment amount that would only cover the supplies and equipment used for each mode of delivery (syringe, gravity and pump) and would exclude enteral formulas from the bundle because of wide variation in cost and treatment.

Response: We thank the commenters for their support and input. After careful consideration of the comments received on this topic, we will not be finalizing the proposal to phase in bundled, continuous monthly rental payment for enteral nutrition at this time.

Comment: One commenter made suggestions for calculating the bundled payment rates for oxygen and oxygen equipment.

Response: We thank the commenter for their input. We will not be finalizing the proposal to phase in bundled, continuous monthly rental payment for oxygen at this time.

Comment: Many commenters opposed bundling monthly payment for all standard manual wheelchair bases with accessories or all standard power wheelchair bases with accessories or all standard and power wheelchair bases with accessories because they feel the different types are wheelchair bases are unique and should not be bundled together. Some recommended a bundled bid approach for standard manual or standard power wheelchairs and only those accessory items that are tied to the same medical necessity as the wheelchair. Some suggested bundling only 3 codes or 6 accessory codes with each base code for wheelchairs based on utilization in order to simplify billing. Some suggested excluding repair and replacement items from the bundle. Commenters believed that bundling of multiple HCPCS codes into a single code for payment will further decrease access and quality of products and services and is complex. The commenters believes that a single bid code cannot accommodate the characteristics of the various technologies and varying manufacturing costs for standard manual or power wheelchairs. The commenters believe that there will be no mechanism to track utilization to ensure the beneficiaries still have access to the range of medically necessary technology. If base codes are combined then distinguishing coverage policies that reflect the medical and functional needs of beneficiaries cannot be developed. It provides a disincentive to suppliers to avoid high risk or complex beneficiaries and decreases beneficiary choices.

Response: We will not be finalizing the proposal to phase in competitions for bundled, continuous monthly rental payment for standard manual wheelchairs at this time. The specific power wheelchair items and HCPCS codes included in competitions where special payment rules are applied will be announced to suppliers and beneficiaries in advance of the competitions with an explanation of why wheelchair bases are bundled together to the extent that they are under the competition.

Comment: Many commenters were opposed to applying bundled monthly continuous rental payment rules to CPAP devices and RADs. Some commenters recommended enforcing the current replacement schedule for CPAP and RAD accessories as outlined in DME MAC local coverage policies under the CBPs that utilize the special payment rules. Other commenters stressed that the CPAP supply replacement schedules should be factored into the development of any bundled payment data and should be used to determine bundles and their respective amounts. In addition, commenters were concerned that bundling of CPAP removes all ability of CMS and providers to ensure that beneficiaries receive medically necessary equipment because they will not see claims for the items to know how often they are being replaced. For CPAP, some commenters urged CMS to craft policies integral to bundling such as a minimum service/contract level requirement for the provider to maintain with the beneficiary. Some commenters suggested that we require suppliers to check in on supply requirements with the beneficiaries.

Response: After consideration of the public comments we received, we will not be finalizing the proposal to phase in competitions for bundled, continuous monthly rental payment for respiratory assist devices. But we will be finalizing the proposal to phase in competitions for bundled, continuous monthly rental payment for CPAP devices. We note that Medicare paid on a bundled, continuous monthly rental basis for CPAP devices under the fee schedules from 1989 thru 1993 and did not encounter any problems related to access to necessary items and services during this time. The tables in the DME MAC local coverage policies listing the usual maximum amount of CPAP accessories expected to be reasonable and necessary are not tables that indicate how often these items need to be replaced. They represent how often claims for the accessories would be paid without the need to have additional medical documentation in the patient's record. They can be used as guidelines for the usual maximum amount that are typically needed, but under a bundled, continuous rental payment method for CPAP devices, the supplier would be expected to replace the accessories as often as necessary for the effective use of the CPAP device. If the usual number of masks needed is once every 6 months, the masks may need to be replaced less often in the case of some beneficiaries and more often than once every 6 months in the case of other beneficiaries. In any case where a replacement of an accessory is needed during a month, the contract supplier would be responsible for furnishing the necessary accessory, just as they would be responsible for repairing rented equipment whenever necessary. We will closely monitor contract suppliers to ensure that they are doing so.

Comment: Two commenters opposed our proposal that the bids submitted for furnishing CPAP devices on a bundled, continuous monthly rental basis cannot exceed the 1993 fee schedule amounts for these items, increased by the covered item update factors provided for these items in section 1834(a)(14) of the Act. The commenters contended that equipment features developed since the establishment of the base year fees, such as a heated humidifier, would not be encompassed in the bid limits and instead suggested using a more recent base period for these items. Other commenters noted that the proposal to set bid limits for CPAP to 1993 fee schedule is inconsistent with the proposed methodology for the other bundled product categories which would use recent expenditures per beneficiary.

Response: We do not agree with these comments. Historical bundled, monthly rental fee schedule amounts are available for CPAP devices and reflect a bundled monthly rental payment that was previously mandated and established for these items under the Medicare program. We believe that separate payment for CPAP accessories has led to overutilization of the accessories based on complaints received from beneficiaries over the years about suppliers shipping unnecessary quantities of accessories. Therefore, we believe that the average payment per beneficiary for equipment and accessories could result in a bid limit that is artificially high when compared to historic Medicare bundled monthly rental fees for CPAP devices that were in place for 5 years and did not result in any problems with access to necessary items and services. The 1993 fee schedule amounts for CPAP devices are based on historic reasonable charges that are representative of payment made to a supplier for furnishing these items on a bundled, continuous rental basis over a period of 5 years. The application of the covered item updates for DME in general, in section 1834(a)(14) of the Act, account for changes in the costs of furnishing covered items and services. Historic continuous bundled fee schedule amounts are not available to use to set the bid limit for the standard power wheelchair bundled category, therefore, current expenditure data would be used to set bid limits for the standard power wheelchair product category.

Comment: Many commenters believed that continuous monthly rental payments for DME would increase the financial burden of the beneficiaries because instead of being limited to paying coinsurance for no more than 13 months of continuous use, they would be required to make coinsurance payments for as long as they use the equipment.

Response: Our analysis strongly suggests that the benefits associated with paying on a continuous monthly rental basis outweigh the potential of increased copayments for the beneficiary. For items that are paid on a capped rental basis where title to the item transfers to the beneficiary after conclusion of the 13-month rental period, beneficiaries are responsible for maintaining and repairing the item after title transfer. Under the special payment rules that provide for payment on a continuous rental basis, beneficiaries will no longer be responsible for repair and maintenance of equipment because they will not own the equipment. The supplier will retain the title to the equipment and will be responsible for repair and maintenance. Although beneficiaries who use a CPAP device or power wheelchair for more than 13 months of continuous use will pay coinsurance payments for additional rental months beyond 13 months of continuous use, the monthly payments include payment for ongoing costs such as replacement of accessories and repair and maintenance of equipment, which are also ongoing costs that exist under the current capped rental payment methodology. The cost of furnishing items and services is the same regardless of whether payment is made on a capped rental basis for equipment with separate payment for accessories, maintenance and servicing or on a bundled, continuous rental basis.

Most importantly, the statute prohibits the awarding of contracts under a CBP if the total payments to contract suppliers under the CBP are expected to be more than what would otherwise be paid and we would confirm that this requirement is met prior to implementing prices established under these special payment rules.

Comment: Some commenters were concerned that beneficiaries would not have the choice of opting out of the program although they would be notified about the alternative payment initiative.

Response: We proposed to phase-in the special payment rules because we believe they will have a positive impact on beneficiary access to quality equipment that continues to remain in good working order, while lowering the administrative costs of the program, and eliminating the need for beneficiaries to locate suppliers willing to repair equipment they own. In order to receive payment for equipment subject to this program, beneficiaries do not have the option to opt out. The programs will be closely monitored.

Comment: Most commenters were supportive of phasing in or testing the continuous rental bundled payment methodology on select products in limited areas. Some stakeholders suggested that bundled payment should be pilot tested first with a small subset of items and exclude complex items. Many commenters agreed that bundling will simplify complex administration procedures.

Response: We agree with commenters that a phase-in limited to only a few select categories would be the best way to evaluate the impact of the special payment rules at this time. As such, we are not finalizing bundled, continuous payment rules for the following

categories of items: Enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, respiratory assist devices and hospital beds. The special payment rules would only be phased in initially for the following categories of DME items: CPAP devices and standard power wheelchairs. We selected the category of CPAP devices because we believe the cost of paying separately for the expensive accessories used with these devices exceeds the amount of savings achieved from capping the rental payments for the equipment. We selected the category of power wheelchairs because we believe that payment on a separate, piecemeal basis for hundreds of various power wheelchair options and accessories is unnecessary and overly complex. In addition, power wheelchairs are the most frequently repaired DME item and we believe that phasing in payment on a continuous monthly rental basis would ensure access to power wheelchairs that are in good working order. As discussed in our proposal (79 FR 40291), the CBPs would be phased in as early as 2017, and would be closely monitored. Subsequent rulemaking would be necessary to adopt special payment rules for other items or in more than 12 CBAs.

Comment: Some commenters recommended a bundled bid approach comprised of products associated with a single medical necessity or single coverage and payment policy. Some suggested accessories that are included in a bundle with the base equipment must be tied to the same medical necessity as the base equipment. One commenter suggested that beneficiaries meeting medical necessity for a support surface may also meet the medical necessity for a hospital bed; however, support surfaces and hospital beds should never be included in the same bundle.

Response: These are issues that would be addressed in Medicare program guidance.

Comment: Some commenters were concerned that CMS has not provided information about how the Agency will administer a bundled bid program so the lack of information violates the Administrative Procedure Act (APA). The commenter's claim the proposed rule only gives general outline of the bundling program but does not explain what makes up a bundle, how bids will be evaluated or pivotal bids will be selected to establish payment amounts. These commenters stated that CMS must publish a new proposed rule soliciting comments on the elements of the bidding program.

Response: We disagree. We have issued rules concerning the general dictates of the CBP and this competition would be consistent with those rules. We would evaluate suppliers and bids consistent with those provisions except that the bids and the SPAs established based on those bids would be for the monthly rental of DME and all items and services necessary for the effective use of the DME (that is, all related supplies, accessories, maintenance and servicing, etc.). Bids would not be submitted for purchase of any item or for separate payment for accessories used with base DME items. Under the existing CBP, CMS specifies certain parameters, but then through the Request for Bids (RFB) and competitive bidding process, further addresses certain details. Similar to other CBPs that do not employ the special payment rules, we intend to conduct extensive education outreach programs prior to implementing competitions that apply the bundled continuous rental methodology so that suppliers are educated about the rules and understand what is required of the bidding suppliers. This includes advance notice of bidding and comparator areas and defining the bundled categories. We believe that our proposed rules were sufficiently detailed to enable the public to provide meaningful comments on them.

Comment: Many commenters urged CMS to share the bundled bidding methodology with stakeholders and establish quality metrics before beginning the program. Some commenters suggested that to facilitate accurate bidding CMS must give suppliers per patient utilization and expenditures data by HCPCS codes. Some commenters argued that CMS states in the proposed rule that it will monitor and evaluate the quality and success of bundled payments but no metrics have been determined or shared by CMS. Some suggested that submitted claims data versus paid claims data must be used. Those commenters stated that bid limits must take into account all repairs, accessories, and rental payments divided by number of patients to create a monthly per patient allowable. Commenters stated that bids must include only patients with active rental periods in calculating the bid limit. Commenters also stated that CMS must identify the data parameters from which it will take data. Many commenters recommended that CMS establish quality metrics before implementing the bundled payment. Some commenters recommended providing safeguards for Medicare beneficiaries, setting proper expectations with providers and evaluating the feasibility of the bundled payment methodology by creating methods to identify beneficiaries not identified in claims data, establishing minimum standards of quality and quantity of services, tracking products provided to the beneficiaries furnished with equipment paid on a bundled continuous rental basis as compared to all other Medicare beneficiaries to ensure quality care is being provided and beneficiaries have access to most innovative products. Commenters suggested we conduct a long term longitudinal study to determine comorbidity costs and access to care with bundled payments.

Response: We thank the commenters for their input. Consistent with the current CBP monitoring and oversight, CMS will employ a wide range of monitoring techniques before beginning any competition that applies the special payment rules. We will provide advance notice of the areas and comparator areas, defining bundles, verifying bona fide bids, and setting up monitoring techniques before beginning the competition. As we proposed in the proposed rule (79 FR 40291), in any competition where these final special payment rules are applied, we will provide advance notice of the rules at the time the competitions that utilize the rules are announced.

In order to monitor the impact of phasing in the special payment rules in the no more than 12 CBAs we are finalizing, we will utilize evaluation criteria that are consistent with the current evaluation criteria for monitoring the impact of the CBP on utilizers of items and services in CBAs. To evaluate the quality of care for beneficiaries affected by the special payment rules, we will at a minimum, utilize health status outcomes based criteria that would measure specific indicators such as mortality, morbidity, hospitalizations, emergency room and other applicable indicators unique to each product category. To evaluate beneficiary access to necessary items and services we will monitor utilization trends for each product category and track beneficiary complaints related to access issues. To evaluate the cost of the program, we intend to analyze the claims data for allowed services and allowed cost for each product category and the associated accessories, supplies and repair cost in the 12 CBAs and the comparator CBAs. We will also analyze the effect of the proposed payment rules on beneficiary cost by analyzing number of monthly rental payments made compared to reductions in coinsurance

payments. Medicare has established quality standards, supplier standards, local medical review policies and other requirements that currently address furnishing medically necessary items and services, and CMS monitors whether these requirements have been met by suppliers, as applicable. Submitted charge data is not used to establish Medicare allowed payment amounts and therefore would not be a good bid limit or a limit used to ensure that payments under the programs are less than what would otherwise be paid.

Comment: Some commenters argued that CMS did not provide information on how bids will be evaluated, what constitutes a bundle or how the pivotal bid will be selected to establish payment amounts. Commenters also indicated that CMS did not identify CBAs and comparator areas. Commenters also stated that there is no baseline for what constitutes a bundle in a product category so suppliers will not know what to bid. Commenters raised concerns that CMS has no way to compare bids because there is no consensus on what it takes to service patients who receive the bundle. Without an assessment tool and a baseline tool, those commenters believe that CMS has no way of comparing bids, or determining pivotal bids or verifying bona fide bids because there is no consensus on what is in the bundle or the intensity of the services patients who receive the bundle need. It would be difficult for suppliers to determine the appropriate amount to bid under a bundled payment method because there are many factors that would influence the cost associated with supplies, maintenance and repairs. Some expressed concerns about supplier challenges in determining the appropriate amount to bid because of factors such as case mix, variable cost of different types of base equipment and accessories and the variable cost associated with supplies, maintenance, repairs and frequency of replacement parts. Suppliers will have to guess the type of equipment and frequency of services different patients may need. Under a bundled bid, commenters were concerned that CMS will not be able to track utilization patterns that could be harmful to the beneficiaries.

Response: We thank the commenters for their input. Although specific CBAs were not identified in the proposed rule, we will be identifying the areas and comparator areas, defining the bundles, and setting up monitoring techniques before beginning the competition as we have done during the previous rounds. As we proposed in the proposed rule (79 FR 40291), in any competition where these final special payment rules are applied, we will provide advance notice of implementation at the time the competitions that utilize the rules are announced. This notice could take the form of the competitive bidding request for bids or a CMS web posting or programs instructions or listserv messages and would define the related products and services included in a category's single bundled grouping. The process for setting the SPA and determining the pivotal bid in competitions where the special payment rules are applied would follow the existing process that is in place for a product category and outlined in sections 42 CFR 414.414 and 414.416 of our regulations.

Using the CPAP and standard power wheelchair bid limits, which we will announce in advance of the competitions and calculate, consistent with what we proposed in the proposed rule (79 FR 40291) and are finalized in this rule, as well as past CBA utilization data for these bundled items, we believe bidding suppliers can use their experience in furnishing these items to develop a monthly bundled rental bid that would be reflective of their costs and profit for all items identified in the bundle. In competitions where the single bundled bid rules apply, CMS would continue to employ the wide range of resources used to monitor the CBP including use of real-time claims analysis to monitor the health outcomes status of groups in CBAs. Suppliers are responsible for providing all items and services to beneficiaries in accordance with the orders of their physicians. This responsibility does not change depending on whether one payment is made for the monthly rental of DME and all related supplies, accessories, and services or whether piece meal payments are made for each individual item or service. For example, a supplier furnishes a CPAP device and accessories in accordance with the physician's order and replaces the accessories and services the rented equipment for up to 13 months of continuous use for individual beneficiaries.

As stated in the proposed rule, the impact of the rules on program expenditures, beneficiary cost sharing, access to items and services, and quality of care will be closely monitored and compared to impacts under comparator areas. To evaluate the quality of care for beneficiaries affected by the special payment rules, we will at a minimum, utilize health status outcomes based criteria that would measure specific indicators such as mortality, morbidity, hospitalizations, emergency room and other applicable indicators unique to each product category. To evaluate beneficiary access to necessary items and services we will monitor utilization trends for each product category and track beneficiary complaints related to access issues. To evaluate the cost of the program, we intend to analyze the claims data for allowed services and allowed cost for each product category and the associated accessories, supplies and repair cost in the 12 CBAs and the comparator CBAs. We will also analyze the effect of the proposed payment rules on beneficiary cost by analyzing number of monthly rental payments made compared to reductions in coinsurance payments.

Comment: Some commenters contended that payment on a continuous rental basis for select bundled items instead of on a capped rental basis would result in additional administrative burden for suppliers because they would have to submit more than 13 claims for rental of equipment to a beneficiary. Commenters reacted unfavorably to repeated billings for monthly rental claims for as long as the item is medically necessary.

Response: While suppliers may need to submit additional claims for the monthly rental of CPAP devices and power wheelchairs, they would no longer have to submit separate claims for accessories and repairs and would no longer have to keep track of periods of continuous use or when a rental cap is approaching. In addition, suppliers would no longer have to transfer title to equipment after 13 months of continuous use, and would therefore need to replace items in their inventory less often.

Comment: Numerous commenters requested a delay in the implementation of payment on a continuous rental basis for select bundled items. One commenter stated that more time is needed to educate practitioners, suppliers, and patients along with receipt of adequate program guidance. Several commenters stated CMS should convene advisory groups to study bundling payment methods and bidding factors. Another comment from a manufacturer's association requested CMS establish an additional HCPCS Advisory Panel to review and revise current HCPCS codes for improved bundling.

Response: The final rule does not set forth an exact timeframe for when the special payment rules will be implemented. CMS will be providing additional guidance and education, if needed.

Comment: Various commenters expressed concern that our proposal did not include a listing of existing HCPCS

base codes along with HCPCS accessory codes that may comprise a bundled item code. As a result, several commenters submitted recommended coding bundles of existing HCPCS codes for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, power wheelchairs, CPAP, RADs, and hospital beds.

Response: CMS will follow the HCPCS coding process. We appreciate these comments and thank the commenters for their helpful suggestions for coding bundles. When further steps for implementing a continuous rental basis for select bundled items are developed, we will review the submitted information to ensure compliance with the Medicare coverage and coding guidelines. As noted in an earlier response, specific information on the items that comprise a bundled bid for the CPAP category or standard power wheelchairs category will be announced well in advance of a competition that would use the continuous rental payment methodology.

Comment: Commenters stated that the proposed change in payment rules will be adopted by payers other than Medicare and therefore should not be adopted.

Response: Such issues are beyond the scope of this rulemaking and we have not taken such things into consideration when finalizing our policies for the Medicare program. We appreciate that changes in Medicare policy may affect other insurers who choose to base their payments on Medicare payment rules; however, it is our obligation to set our policies based upon the needs of Medicare and its beneficiaries.

Comment: One commenter asked for clarification on how CMS will establish coverage criteria for a bundle of HCPCS codes consisting of a base and all options and accessories including what data will be used to establish the coverage criteria that will identify whether or not a beneficiary qualifies for a bundle of equipment, services, and supplies.

Response: These comments are outside the scope of the proposed rule, and therefore are not addressed in this final rule. The process for reviewing coverage for an item or bundle of items is not addressed in this payment rule.

We received many additional comments that were out of the scope of this rule.

In this final rule we are finalizing our proposal for only two items, CPAP devices and standard power wheelchairs. This rule finalizes the phase-in of special payment rules for CPAP and power wheelchairs as noted previously in the proposed rule (79 FR 40293) under the DMEPOS CBP in no more than 12 CBAs at 42 CFR 414.408, 414.409, and 414.412.

Comment: Some commenters noted that making payments for DME on a bundled, continuous rental basis will not eliminate repair issues and will increase financial burden on the beneficiaries. Some commenters noted that the ability for a beneficiary to switch to another provider should he/she feel the service is not appropriate would drive competition for better care but bundling would not eliminate the need for patients to requalify for equipment when they change suppliers. Beneficiaries would still need to re-establish medical necessity when changing suppliers. Some suggested allowing beneficiaries to switch suppliers without restarting documentation. Some commented that mandating suppliers repair will not solve beneficiary's inability to obtain repairs for beneficiary-owned equipment.

Response: Contract suppliers paid for furnishing DME paid for on a bundled, continuous rental basis would be responsible for all necessary repairs, maintenance and servicing needed to keep the rental equipment in good working order or for replacing rental equipment that no longer functions and cannot be repaired. The process for documenting medical necessity for items would be addressed outside the rulemaking process.

We proposed to revise the regulation at 42 CFR 414.409 to the include supplier transition rules for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, CPAP and respiratory assist devices, and hospital beds that would be paid in accordance with the rules proposed in this section. We also proposed to revise the regulation at 42 CFR 414.408 to provide a cross reference to proposed § 414.409. We proposed that changes in suppliers from a non-contract supplier to a contract supplier at the beginning of the CBP where the proposed payment rules would apply would simply result in the contract supplier taking on responsibility for meeting all of the beneficiary's monthly needs while receiving payment for each month of service. We developed these proposed rules based on that fact that for capped rented DME and oxygen and oxygen equipment, since rental caps would not apply under the proposed rules, there would be no need to restart or extend capped rental periods when a beneficiary transitions from a non-contract supplier to a contract supplier. We proposed that supply arrangements for oxygen and oxygen equipment, and rental agreements for standard manual wheelchairs, standard power wheelchairs, CPAP devices, respiratory assist devices, and hospital beds entered into before the start of a CBP and application of the payment rules proposed in this section would be allowed to continue so long as the supplier agrees to furnish all necessary supplies and accessories used in conjunction with the rented equipment and needed on a monthly basis. We proposed that non-contract suppliers in these cases would have the option to continue rental agreements; however, we proposed that as part of the process of allowing the rental agreements to continue, the grandfathered supplier would be paid based on existing rules at § 414.408. We solicited comments on this proposed process. We did not receive any specific comment for this section and therefore, for the reasons we discussed previously, we are finalizing the proposed transition rules. This rule finalizes the transition rules as noted previously in the proposed rule (79 FR 40293, 40294) under the DMEPOS CBP at 42 CFR 414.409.

2. Responsibility for Repair of Beneficiary-Owned Power Wheelchairs Furnished Under CBPs

We proposed (79 FR 40294) to revise the regulation at 42 CFR 414.409 to add a new payment rule that would apply to future competitions for standard power wheelchairs in no more than 12 CBAs where payment is made on a capped rental basis. In these CBPs, we proposed that contract suppliers for power wheelchairs would be responsible for all necessary repairs and maintenance and servicing of any power wheelchairs they furnish during the contract period under the CBP, including repairs and maintenance and servicing of power wheelchairs after they have transferred title to the equipment to the beneficiary. We proposed that this responsibility would end when the reasonable useful lifetime established for the power wheelchair expires, medical necessity for the power wheelchair ends, the contract period ends, or the beneficiary relocates outside the CBA. We proposed that the contract supplier would not receive separate payment for these services and would factor the costs of these services into their bids. We proposed that the contract supplier would not be responsible for repairing power wheelchairs they did not furnish. We proposed that services to repair beneficiary-owned equipment furnished prior to the start of the contract period

would be paid in accordance with the standard payment rules at § 414.210(e).

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: Some commenters argued that adding a requirement specifying that contract suppliers are responsible for repairing power wheelchairs they furnish will not eliminate problems beneficiaries are experiencing related to obtaining repairs for beneficiary-owned equipment.

Response: We agree that this requirement would not address situations where a beneficiary owns a power wheelchair in need of repairs that they received prior to the start of the CBP or prior to moving into the CBA where the proposed rule would be in effect. It would also not address situations where a beneficiary owns a power wheelchair in need of repairs that they received prior to enrolling in Medicare part B. As stated in our proposal (79 FR 40294) we proposed that a contract supplier would not be responsible for repairing power wheelchairs they did not furnish. As a result, we proposed that services to repair beneficiary-owned equipment furnished prior to the start of the contract period would be paid in accordance with the standard payment rules at § 414.210(e), which allows any Medicare enrolled DME supplier to perform this service and receive payment.

We also proposed that in the event that a beneficiary relocates from a CBA where the rules proposed in this section apply to an area where rental cap rules apply, that a new period of continuous use would begin for the capped rental item, enteral nutrition equipment, or oxygen equipment as long as the item is determined to be medically necessary. We believe these rules are necessary to safeguard beneficiary access to covered items and services and plan to closely monitor the impact these rules have on beneficiary cost sharing before phasing in these rules in more than a limited number of CBAs. We sought comments on these proposals, did not receive any specific comment for these proposals, and are therefore, for the reasons we discussed previously, we are finalizing these proposals. This rule finalizes the sections Beneficiary-Owned Equipment and Responsibility for Repair of Beneficiary-Owned Power Wheelchairs furnished under CBPs as noted previously in the proposed rule (79 FR 40294) under the DMEPOS CBP at 42 CFR 414.409

We proposed that the CBAs where the proposed rules in (79 FR 40294) above would be applied would be for MSAs with a general population of at least 250,000 and a Medicare Part B enrollment population of at least 20,000 that are not already included in Round 1 or 2. Based on 2012 population estimates from the Census Bureau and 2011 Medicare enrollment data, there are approximately 80 MSAs that would satisfy this criteria. Selecting MSAs not already included in Round 1 or 2 would allow competitions and rules associated with these competitions to begin after the final rule would take effect in areas that are comparable to existing CBAs. We proposed that the boundaries of the CBAs would be established in accordance with the rules set forth at §§ 414.406 and 414.410. We proposed that additional CBPs for the items identified in sections 1 and 2 above be established in ''comparator'' CBAs concurrent with CBPs where the proposed rules would be applied. Payment for items and services in the comparator CBAs would be made in accordance with the existing payment rules in § 414.408. We proposed that these additional comparator CBAs and CBPs be established to facilitate our analysis of the effect of the payment rules proposed in sections 1 and 2 above compared to the effect of the existing payment rules in § 414.408. We proposed that for each CBP where either the rules in section 1 or 2 above are implemented, a comparator CBA and CBP would be established. We proposed that the comparator CBAs be selected so that they are located in the same state as the CBA where the special payment rules would apply and are similar to the CBAs in which the proposed payment rules would be implemented based on a combination of factors that could include geographic location (region of the country), general population, beneficiary population, patient mix, and utilization of items. We proposed to establish the comparator CBAs and CBPs to enable us to review the impact of the proposed payment rules on expenditures, quality, and access to items and services in order to determine whether to pursue future rulemaking to expand the proposed payment rules to additional areas and or items. We sought comments on this proposal, did not receive any specific comment for this proposal, and are therefore finalizing this proposal.

We proposed that payment to a supplier that elects to be a grandfathered supplier of DME furnished in CBPs where these special payment rules apply is made in accordance with § 414.408(a)(1). We sought comments on this proposal, did not receive any specific comment for this proposal, and are therefore finalizing this proposal.

We are finalizing a change to add special payment rules at § 414.409 that will be phased in. In no more than 12 CBAs, payment is made on a bundled, continuous monthly rental basis for standard power wheelchairs and CPAP devices. In addition, in no more than 12 CBAs, payment for power wheelchairs is made on a continuous rental basis, for power wheelchairs furnished in conjunction with competitions that begin after January 1, 2015, contract suppliers that furnish power wheelchairs under contracts awarded based on these competitions shall continue to repair power wheelchairs they furnish following transfer of title to the equipment to the beneficiary. The responsibility of the contract supplier to repair, maintain and service beneficiary-owned power wheelchairs does not apply to power wheelchairs that the contract supplier did not furnish to the beneficiary. For power wheelchairs that the contract supplier furnishes during the contract period, the responsibility of the contract supplier to repair, maintain and service the power wheelchair once it is owned by the beneficiary continues until the reasonable useful lifetime of the equipment expires, coverage for the power wheelchair ends, or the beneficiary relocates outside the CBA where the item was furnished. In accordance with § 414.408(c), the contract supplier may not charge the beneficiary or the program for any necessary repairs or maintenance and servicing of a beneficiary-owned power wheelchair it furnished during the contract period.

VII. Scope of Hearing Aid Coverage Exclusion

A. Background

Section 1862(a)(7) of the Act states notwithstanding any other provision of title XVIII, no payment may be made under part A or part B for any expenses incurred for items or services ''where such expenses are for . . . hearing aids or examinations therefor. . . .'' This policy is codified in the regulation at 42 CFR 411.15(d), which states that hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids are excluded from Medicare coverage. Historically, CMS has periodically addressed the scope of the Medicare hearing aid coverage exclusion through program instructions and national coverage policies or determinations. We briefly discuss the relevant changes that have occurred over time with regard to Medicare

coverage and payment of hearing devices.

Cochlear implants (CIs) were the first device covered for Medicare payment for adult beneficiaries in October 1986, when no other hearing device was being covered under Medicare, and such coverage was supported by the Office of Health Technology Assessment's ''Public Health Service Assessment of Cochlear Implant Devices for the Profoundly Hearing Impaired'', dated June 30, 1986 found at *https://archive.org/stream/cochlearimplantd00feig/cochlearimplantd00feig_djvu.txt.* Medicare coverage was restricted to CIs that treated patients with post lingual, profound, bilateral, sensorineural deafness who are stimulable and who lack the unaided residual auditory ability to detect sound.

Effective January 1, 2003, we clarified that the hearing aid exclusion broadly applied to all hearing aids that utilized functional air and/or bone conduction pathways to facilitate hearing (see section 15903, Hearing Aid Exclusion, Medicare Carriers Manual, Part 3—Claims Process (HCFA-Pub. 14–3), which was later moved to section 100, Hearing Aids and Cochlear Implants, of Chapter 16, of the Medicare Benefit Policy Manual, CMS-Pub. 100–02). Any device that does not produce at its output an electrical signal that directly stimulates the auditory nerve is a hearing aid for purposes of coverage under Medicare. Devices that produce air conduction sound into the external auditory canal, devices that produce sound by mechanically vibrating bone, or devices that produce sound by vibrating the cochlear fluid through stimulation of the round window are considered hearing aids and excluded from Medicare coverage.

Effective April 4, 2005, Medicare's national coverage policy for CIs was modified through the NCD process (see section 65–14 of the Medicare Coverage Issues Manual (HCFA-Pub. 6), which was later moved to section 50.3, Cochlear Implantation, of Chapter 1, Part 1 of the Medicare National Coverage Determinations Manual (CMS-Pub. 100–03)). Our findings under the NCD, in part, state that ''CMS has determined that cochlear implants fall within the benefit category of prosthetic devices under section 1861(s)(8) of the Social Security Act.'' Medicare is a defined benefit program. An item or device must not be statutorily excluded and fall within a benefit category as a prerequisite to Medicare coverage. Additional changes, regarding coverage criteria, have been made to section 50.3 over time, however, the NCD decision regarding benefit category and Medicare coverage for cochlear implantation has remained consistent. The NCD states that a cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

The regulation at 42 CFR 419.66 was revised to add new requirements, effective January 1, 2006, for transitional pass-through payments for medical devices. The auditory osseointegrated implant (AOI) device, referred to as a bone anchored hearing aid (BAHA), was determined to be a new device category according to the new requirements for transitional pass-through payment. Medicare coverage was also expanded to cover AOI and auditory brainstem devices payable as prosthetic devices. Currently, section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02) reads as follows:

> Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.
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> Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.
>
> The following are considered prosthetic devices:
>
> • Cochlear implants and auditory brainstem implants, that is, devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.
>
> • Osseointegrated implants, that is, devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.

B. Current Issues

We received several benefit category determination requests in recent years for the consideration of non-implanted, bone conduction hearing aid devices for single-sided deafness (SSD), as prosthetic devices under the Medicare benefit. We have received similar requests for several other types of implanted and non-implanted devices as well. In response to these requests, we have re-examined the scope of the statutory hearing aid exclusion.

C. Proposed Provisions

The proposed rule (79 FR 40297) stated that after further considering the statutory Medicare hearing aid exclusion under section 1862(a)(7) of the Act, and re-examining the different types of non-implanted and implanted devices, we proposed to interpret the term ''hearing aid'' to include all types of air or bone conduction hearing aid devices, whether external, internal, or implanted, including, but not limited to, middle ear implants, AOI devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea.

We believed that the hearing aid exclusion did not apply to brainstem implants and CIs as discussed in the proposed rule (79 FR 40297). Therefore, we did not propose any changes to our current policy about brainstem implants and CIs and how such implants fall outside of the hearing aid statutory exclusion (that is, such devices would fall outside the Medicare coverage exclusion for hearing aids and remain covered subject to the Medicare NCD 50.3 found at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part1.pdf*). We proposed, however, to modify § 411.15(d)(2) to specifically note that such devices do not fall within the hearing aid exclusion.

We sought public comment on this proposal and received approximately 2,635 public comments on this provision. After consideration of the comments received we have decided not to finalize our proposal to further interpret the hearing aid statutory exclusion, but in response to comments, this final rule will codify the current program instructions found at section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02) noted above. We believe AOIs that provide focused stimulation to the temporal bone structures, through an implant that is physically integrated into the bone of the skull, to the cochlea are outside the scope of the hearing aid exclusion. At the time section 1862(a)(7) of the Act was initially established, hearing aids consisted of non-implanted air and bone conduction devices. AOIs did not exist at the time the coverage

exclusion was drafted and there are clinical distinctions that separate AOIs from all non-implanted air and bone conduction hearing aids. Air conduction and non-osseointegrated bone conduction hearing aids have been in existence since 1965 and have not been covered by Medicare. In accordance with section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02), we believe the coverage exclusion applies to all air conduction and non-osseointegrated bone conduction hearing aids or technological refinements of non-implanted air and bone conduction devices that are not osseointegrated. Cochlear devices, brainstem implants, and AOIs are invasive devices and are significantly different than the hearing devices in existence at the time the Medicare coverage exclusion for hearing aids was enacted. We therefore do not consider them to be the hearing aids or technological refinements of the hearing aids excluded from the program in 1965 and after 1965. We consider all types of air conduction and non-osseointegrated bone conduction hearing devices utilized today to be technological refinements of the devices excluded from Medicare coverage; and therefore, we consider all types of air conduction and non-osseointegrated bone conduction hearing devices utilized today to be hearing aids excluded from coverage under the Medicare program. However, we recognize that new technology in this area continues to emerge that may benefit the Medicare population and we will continue to examine this issue as more information becomes available and new devices are introduced.

The comments and responses are set forth below.

Comment: We received many comments relating personal stories on the profound difference the AOI has made on themselves, friends, and relatives who have suffered hearing loss. Many people shared tremendous improvement in the quality of life the AOI has provided for them.

Response: We appreciate these comments. We have reexamined AOIs and the statutory exclusion for hearing aids. We have come to the conclusion that AOIs are not hearing aids because of the clinical distinctions that separate them from hearing aids excluded from coverage under the Medicare program in 1965. Cochlear devices, brainstem implants, and AOIs are invasive devices and are significantly different than the hearing devices in existence at the time the Medicare coverage exclusion for hearing aids was enacted. We therefore do not consider them to be the hearing aids or technological refinements of the hearing aids excluded from the program in 1965 and after 1965. We consider all types of air conduction and non-osseointegrated bone conduction hearing devices utilized today to be technological refinements of the devices excluded from Medicare coverage. Therefore, we have modified the regulation at § 414.15 to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: Many commenters stated an AOI is a prosthetic device that replaces all or part of an internal organ and should remain classified as such. The commenters stated that the AOI is not simply a hearing aid but rather the device replaces the function of the ear. An AOI device meets the definition of a prosthetic device as it requires an implantable post which helps by-pass an impaired ear canal and/or middle ear system to directly stimulate a functional sensory nerve via bone conduction. One commenter stated the AOI replaces the function of the ossicles by (1) converting acoustic energy to mechanical energy, (2) magnifying that mechanical energy, and (3) transmitting that mechanical energy to the inner ear, functions a hearing aid cannot perform. Another commenter added when the implantable post is surgically placed by an otolaryngologist, the post must osseointegrate with the skull and then becomes part of the patient's skull anatomy. It will also compensate for the loss of the cochlea in a single sided deafness (SSD) due to trauma, surgery, infection, nerve injury or congenital defect. One commenter stated these types of hearing loss result from the loss of organ function. Therefore, an AOI does replace all or part of the internal body organ making it a prosthetic.

Response: The hearing aid statutory exclusion under section 1862(a)(7) of the Act does not identify a particular benefit category. However, we agree that the AOI is distinguishable in that it functions as a prosthetic device that is designed to restore hearing for a limited class of individuals with conductive hearing loss (CHL), mixed hearing loss, or SSD by replacing the function of the middle ear and providing mechanical energy to the cochlea via a mechanical transducer. Therefore, we do not believe it is a hearing aid excluded from coverage by section 1862(a)(7) of the Act. The AOI is functionally and clinically distinct from the hearing aids excluded from coverage in 1965. In this final rule, we are modifying § 411.15 to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: Many commenters stated an AOI is not a hearing aid and does not provide traditional aid to hearing. Those commenters believe that hearing aids are designed to compensate the hearing loss by amplifying the incoming sound to the ear. By design, hearing aids do not replace the function of the ear but rather restore hearing loss using the existing anatomical parts and organ. Several commenters stated air conduction hearing aids operate by amplifying sound to overcome damaged hair cells in the cochlea or inner ear. Other commenters provided the following differences of an AOI compared to a conventional air conduction hearing device: (1) The AOI is surgically implanted in the patients skull where it osseointegrates with the bone and becomes part of the patients anatomy, (2) The components of the AOI function by bypassing the ear canal and middle ear stimulating the hearing nerve directly through bone conduction and (3) The implant replaces the function of outer and middle ear. Bone conduction hearing aids utilize a tight band placed around the user's head to transmit vibrations of sound to the bones in the head. One commenter stated an AOI is physically and functionally distinguishable from a bone conduction hearing aid in that they: (1) Are never retained by a headband, and (2) supply focused stimulation to the temporal bone structures through an implant that is physically integrated into the bone of the skull. Further, traditional hearing aids require no surgery, may be purchased without a physician's prescription, and are removed and placed ''in the drawer'' by the hearing impaired person. In addition, traditional hearing aids treat presbycusis which is the cumulative effect of aging on hearing. One commenter stated candidates for the AOIs do not have a functioning ear(s) and cannot benefit even from the most advanced hearing aid. While an AOI does provide access to sound to patients that would not, in most cases, otherwise have that access it is not a hearing aid. Several commenters stated a hearing aid is just that; it ''aids'' what residual hearing an individual has, it does not restore hearing. An AOI restores hearing loss in a completely non-functioning ear.

Response: We agree with commenters that an AOI is not a hearing aid excluded from coverage under the Medicare statute for some of the same clinical and technological reasons set forth by the commenters. Therefore, we are modifying § 411.15 in this final rule to reflect that AOI's are outside the scope of the hearing aid exclusion.

Comment: We received many comments stating that candidates for

AOI devices typically have no other reasonable option for hearing assistance or restoration and do not get benefit from hearing aids. Instead, an AOI is the modality of last resort for many of patients, CMS's current coverage position provides that AOIs are indicated only when hearing aids are medically inappropriate or cannot be utilized. Additionally, commenters were concerned that patients with congenital malformations and chronic diseases (Treacher Collins, Aural Atresia and Microtia) will be left without an effective option as they are not candidates for traditional hearing aids. AOI technology is for a small and very special group. AOIs have specific indications—for example unilateral anacousis (deafness), and particular patterns of severe conductive and mixed hearing loss. Patients with a conductive or mixed hearing loss with a chronic draining ear are unable to wear a conventional air conduction hearing device. The air conduction device blocks the ear canal, which exacerbates the build-up of infectious material in the ear canal. The AOI is remote from the ear canal. Therefore, chronic ear drainage is often stopped or minimized in these patients.

Response: We have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids given how they are functionally and clinically distinct from the hearing aids excluded from coverage in 1965., as noted in section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02). An AOI is an osseointegrated device that is implanted in the skull that replaces the function of the middle ear and provides mechanical energy to the cochlea via a mechanical transducer. Therefore, we are finalizing changes to § 414.15 to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: Some commenters stated that although there are other options for treatment of SSD, patients report that the sound quality of the AOI is far superior to these other treatment options for SSD (for example, CROS hearing system, TransEar hearing device). In addition the use of conventional non-osseointegrated bone conduction aids may be associated with complications including: discomfort and breakdown of skin at stimulation point; feedback from mechanical coupling via a steel headband; poor compliance for consistent wear due to discomfort, difficulty with fit and feedback as well as poor sound quality through all of the options that were attempted prior to being fit with AOI devices.

Response: We understand there are other bone conduction hearing aids that may be used instead of the AOI devices for some individuals with SSD. In addition, as technology continues to evolve there will be other new hearing aid devices coming onto the market for the treatment of SSD. However, non-osseointegrated air and bone conduction hearing aids were in use in 1965 when the coverage exclusion for hearing aids was enacted and have not been covered under the program. We believe that given how they function, they should continue to fall under the hearing aid exclusion. However, osseointegrated hearing devices were not in use in 1965 and as commenters have pointed out, there are significant clinical and technological difference between osseointegrated hearing devices and non-osseointegrated hearing devices reasons.

Comment: A few commenters stated if the fiscal impact on Medicare is so insignificant why would you deny thousands of men, women, children and infants the ability to hear?

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying the § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: We received many comments stating without Medicare coverage patients who use AOIs would otherwise benefit greatly in terms of quality of life, productivity, engagement in their community's life, etc. will not have the opportunity. Several commenters stated denial of coverage of these AOIs will affect not only hearing and communication ability in older adults but because CMS also provides benefits under Social Security Disability Insurance (SSDI) program, denial of coverage also will prevent the normal development of language and speech ability in young children. It would cost much more not having the AOI option than to have the relatively inexpensive surgery that would help them for the rest of their lives.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying the § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: Some commenters believe most private insurers follow CMS policies as they design their own coverage which will inevitably lead to the loss of this very valuable technology for everyone. Others stated, not covering this procedure will mean many thousands of people with this condition will forego treatment. A great many people benefit from an AOI and otherwise will not be able to afford it if insurance no longer covered the device. Another commenter stated private third party payers would eventually eliminate coverage for AOIs, affecting both children and adults, as these payers' looks to Medicare for coverage guidelines.

Response: Coverage by private insurers is outside the scope of this rulemaking. However, we have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: Several commenters stated that AOIs have been in use for over 30 years and have been shown to provide significant, cost-effective benefit for recipients. There is a large body of published literature to support the use of this technology for appropriate indications.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: One commenter stated given the recent research on increased presence of cognitive decline in individuals with hearing loss, one would think that the CMS would be looking for ways to improve access to sound for our Medicare and Medicaid patients, thereby decreasing the overall costs of managing dementia, not for ways to make that situation even worse. Hearing allows people to stay connected to people; it increases their earning potential thus increasing the tax base of our society. In the retired population, good access to hearing keeps people engaged in their community, volunteering, helping to raise grandchildren, and in general participating in life. As we all know the more connected and engaged in society and life around us, the lower financial burden we present to society.

Response: We appreciate the comments. However, Congress excluded hearing aids from the Medicare program in section 1862(a)(7) of the Act. We have reexamined this issue and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified § 414.15 to specify that AOIs

are outside the scope of the hearing aid exclusion.

Comment: Other commenters stated AOIs restore a sense of safety to individuals who have SSD as the implant allows them to hear sounds on the dead ear. In the SSD application, a patient must have an unaidable ear (meaning the hearing loss is so great or their ability to understand speech is so poor that use of a hearing aid is not possible as a hearing aid would not correct that degree of hearing loss). In these cases, the AOI can be implanted on the bad ear and allow patients to have awareness of the sounds on the dead ear because the sound is delivered via bone conduction to the good ear which can process the speech signal. In unilateral hearing losses (such as described above), individuals experience difficulty localizing sounds, an inability to hear sounds immediately to the side with hearing loss and they also experience difficulty understanding in background noise. The recovery of sound on the dead ear can provide a sense of stability and safety as they no longer have to work about people sneaking up on the dead side.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: Some commenters stated there was no rationale provided articulating reasoning or new evidence that a change in Medicare policy, after 8 years of coverage, is necessary due to law or for the benefit of Medicare patients was necessary. Another commenter stated AOIs function the same way they did in 2006 when CMS correctly recognized them as prosthetics. One commenter stated that the decision in 2005 that AOIs replace the function of the middle ear and are prostheses was made based on an extensive record. In contrast, the proposed rule fails to cite any evidence on which CMS now contends that its position has reversed. There are no studies or other data mentioned, no professional standards are cited, nor is there any description of the content of the benefit category determination requests that are mentioned. Since CMS has not disclosed the basic clinical or legal information underlying the proposed reversal of its benefit policy and its interpretation of Section 1862(a)(7), CMS should defer any action.

Response: As discussed in the proposed rule, CMS has received several new benefit category determinations that initiated a new review of devices that are considered hearing aids. However, in light of the comments and upon further examination, we have decided not to change the policy in section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02), that AOIs are not hearing aids and therefore, are modifying § 414.15 to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: One commenter provided their interpretation of the Congressional intent and scope of the hearing aid exclusion as meant to exclude routine items and services, and not medical treatment for disability created by disease, trauma, infection, or congenital deformity. They provided a comparison of various Court decisions on the eyeglass exclusion. Another commenter stated while Medicare does not cover eye glasses and/or contact lenses, they do cover intraocular lenses because the patient's sensory organ cannot benefit from nonsurgical treatment-the same logic should hold for implantable hearing devices, for patients who are not able to benefit from amplification.

Response: The eyeglass exclusion is not an appropriate comparison to the hearing aid exclusion. Congress amended the Social Security Act to make allowances for eyeglasses and intraocular lenses by amendments to section 1862(a)(7) of the Act. There has not been a similar allowance made for hearing aids. As noted above, upon consideration of the comments and for the reasons outlined, we are modifying the final regulation, as discussed above.

Comment: Several commenters discussed the National Coverage Determination for CIs stating that CMS states in the NCD CIs are prosthetic devices primarily because a CI replaces the function of the cochlear by creating an electrical output that stimulates the auditory nerve as opposed to the mechanical output of a bone conduction device. There is no scientific, clinical, or legal rational for distinguishing the devices based on the type of energy output. Nor does the agency provide any medical or other justification as to why the replacement of the function of the cochlea meets the requirement of replacing an organ function, but replacing the function of the middle ear does not. Another commenter stated in both cases, the device in question bypasses an organ and replaces its function, in one case; it is part of the cochlea, in the other, the ossicles and/or auditory canal. Since in both cases a device replaces the function of a component of the ear, there is no basis on which to classify one as a hearing aid and the other as a prosthetic.

Response: A National Coverage Determination (NCD) is provided upon request or internally generated, and is vetted through a thorough scientific and medical review. The information provided for NCD 50.3 was provided specifically for CIs. It is important to understand that an item or device must not be statutorily excluded and fall within a benefit category as a prerequisite to Medicare coverage. We believe that AOIs are not ''hearing aids'' given that such devices do more than ''aid'' in hearing and instead replace the function of an internal body organ (i.e., a part of the ear). Therefore, we've concluded that AOIs are not hearing aids and do not fall within the statutory exclusion.

Comment: One commenter stated a policy that deems which technology is a Medicare benefit based on whether that technology replaces hearing by a particular means (electrical versus mechanical energy), or whether it has a surgically implanted component or not (osseointegrated versus a dental anchored device), or whether the deafness is bilateral or unilateral, are arbitrary distinctions without clinical justification. Medicare policy should focus on whether attributes of a device replace the function of all or part of the ear to restore hearing, not the means by which it is accomplishes this task.

Response: We disagree that our policy creates an arbitrary distinction. The policy is based on whether a device qualifies as a hearing aid as defined in section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02), or whether a device functions in such a way that it falls outside this definition.

Comment: A few commenters stated withdrawing coverage of these devices will preclude coverage and designing new innovations that improve SSD treatment and are more cost effective than existing alternatives. One commenter explained its concern that the proposal will stifle innovation and advances in auditory prosthetics and will send a negative and damaging message to the medical technology development community as a whole—that Medicare coverage is unpredictable, even when there is long established policy in favor of coverage. Such unreliability makes it impossible for investors to make reasoned decisions about future investments and will lead to the freezing of meaningful innovation.

Response: We do not agree. We believe new innovations will continue to be pursued without Medicare coverage as other payers would continue to provide AOIs. However, we

have reexamined AOIs and the applicability of the hearing aid statutory exclusion. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: Some commenters equated removing coverage of the AOI as to denying coverage for glasses, a prosthetic leg, and colostomy.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: Several commenters provided their definition of a hearing aid. Several commenters stated the definition should include ''wearable'' and another commenter stated it should include ''amplify sound'' and another stated it should be ''air conduction devices.'' Commenters provided additional criteria as well, such as there must be a medical evaluation and physician prescription. In addition several commenters advocated for a plain and ordinary meaning of hearing aid provided in the dictionary.

Response: We disagree with the commenters' definition of a hearing aid; as stated in the proposed rule, in section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02) Medicare defines hearing aids as ''amplifying devices that compensate for impaired hearing.'' Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.'' We believe the Medicare definition captures the provisions we are finalizing and accurately defines a hearing aid. Upon re-examining the Medicare hearing aid exclusion provision at section 1862(a)(7) of the Act, and its applicability to AOIs, we have determined that AOIs are not hearing aids because they are functionally and clinically distinct from the hearing aids excluded from coverage in 1965. They are implants that replace the function of the middle ear and are physically integrated into the temporal bone structure of the skull to provide mechanical stimulation through the temporal bone to the cochlea. Therefore, we have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: One commenter stated according to the Food and Drug Administration (FDA) definition of a hearing aid and state hearing aid dispensing laws, the AOI is in fact not a hearing aid because it is not removable, is not available to the general public for purchase and the primary purpose is not to amplify sound. Another commenter believed CMS should recognize the FDA's classification system as these devices are Class II whereas hearing aids are Class I devices.

Response: Medicare does not adhere to the same definition as the FDA regarding hearing aids. For the reasons state above, we have come to the conclusion that AOIs are not hearing aids in the context of section 1862(a)(7) of the Act and the Medicare program and coverage exclusion and therefore have modified our final rule to reflect that AOIs are outside the scope of the hearing aid exclusion.

Comment: A few commenters stated neither the statute nor its legislative authority support the broad interpretation CMS seeks in order to prohibit AOIs under the hearing aid exclusion. After review of the Congressional Record and hearings held by Congress before enactment of this provision clearly shows Congress' intent was to exclude ''routine care'' from the Medicare program. The majority of the technologies that would be considered hearing aids under this proposed rule were not available in 1965. In particular, AOIs could not have been contemplated by Congress at the time the hearing aid exclusion was enacted, because they did not exist. At that time patients could self-select available hearing aids, no physician order was required, and patients where accustomed to paying out of pocket for these items.

Response: We believe we understand the Congressional intent in 1965 regarding the hearing aid exclusion. We believe air and bone conduction devices were available and commonly used when the exclusion was established and therefore are excluded. However, since AOIs were not in existence and are clinically and functionally distinct from bone conduction hearing aids in 1965, we do not believe the exclusion applies. Different refinements of bone conduction hearing aid technologies have been introduced over the years that represent variations of non-implanted devices that send mechanical energy to the cochlea through bone without the need to surgically implant a transducer into the patient's skull. These implanted, osseointegrated devices were not part of the general technology and category of devices excluded from coverage from 1965 to the present. We have therefore come to the conclusion that AOIs are not hearing aids and have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: One commenter stated the AOI has a record of demonstrated cost effectiveness in studies conducted around the world. One example includes a significant reduction in the number of medical visits and prescribed medications to address repeated infections for individuals with chronic suppurative otitis media following AOI surgery. Another commenter stated for patients that have failed previous surgical attempts at hearing reconstruction using conventional techniques, it makes better sense for Medicare to provide AOIs for these patients in lieu of repeated, costly traditional surgical attempts without an AOI.

Response: CMS is bound by the statutory coverage rules and to the extent an items falls within a statutory exclusion, it cannot be covered under Medicare. Therefore, we are modifying § 414.15 to further specify the scope of the hearing aid exclusion.

Comment: A few commenters stated current users on Medicare who are benefiting from an AOI will be unable to maintain and upgrade their equipment. Several commenters stated discontinuing coverage for the numerous existing recipients of AOIs is unethical and discriminatory. These individuals have existing AOIs that require maintenance and fully functioning systems in order to hear and communicate. By discontinuing coverage, the medical community is forced to unjustly discontinue care of these individuals unless they can financially assume the cost of their implant. This is an unreasonable assumption, as many Medicare recipients are no longer working and living on a fixed income.

Response: As we stated above, we have determined that AOIs are outside the scope of the hearing aid exclusion. So Medicare beneficiaries with existing AOIs will continue to receive upgrades and maintenance of these devices.

Comment: One commenter stated that the patient's medical condition should be the primary consideration for providing coverage, not the technology. Many commenters stated there are currently very specific patient selection criteria for AOIs.

Response: We disagree; while the patient's medical condition is important, we do not believe it should

be the primary consideration for providing coverage of a particular device. Medicare is a defined benefit program. It is important to understand that an item or device must not be statutorily excluded and fall within a benefit category as a prerequisite to Medicare coverage. We must analyze whether the device is a hearing aid as they are statutorily excluded from coverage. We have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: One commenter stated hearing aids cost on average $1,675 per device. AOIs including surgery cost are in the range of $12,000 and that cost is moderated by the significant availability of insurance coverage. This cost would likely double in the absence of insurance coverage, which would clearly make AOIs unaffordable for many people. Another commenter stated CMS is undermining the goals of the Medicare program by decreasing access and affordability to Medicare patients.

Response: We understand, however, Medicare is a defined benefit program with certain coverage requirements. We have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

Comment: Several commenters urged CMS to continue to provide coverage of CIs, brain stem implants, and AOIs, to extend coverage to dental anchored bone conduction devices since these devices also meet the definite of covered prosthetics and are not hearing aids, and to provide coverage to other clinically proven bone conduction hearing device technologies with restrictive principles applied.

Response: We will continue to cover AOI devices that replace the function of the middle ear and provide mechanical energy directly to the cochlea, because we do not consider them to be hearing aids and excluded from coverage.

Comment: One commenter stated over the past 8 years CMS has established a precedent for providing coverage of AOIs for Medicare beneficiaries, upon which Medicare beneficiaries who have received these technologies and health care providers who establish patient treatment plans have relied.

Response: While CMS had established a precedent for coverage of AOIs, we reexamined AOIs and the statutory exclusion applicability. CMS received requests for informal benefit category determinations from manufacturers of certain non-implanted hearing devices. We elected to address the issue of the applicability of the Medicare coverage exclusion for hearing aids to all hearing devices in light of these requests and initially determined and proposed (79 FR 40296) that all external, internal, and implanted air conduction and bone conduction hearing devices were subject to the coverage exclusion for hearing aids. Based on our review and in light of comments received on the proposed rule, for the reasons stated above, CMS has decided that AOIs are not hearing aids subject to the statutory exclusion.

Comment: One commenter opposed the classification of middle ear implants as a hearing aid, stating these devices do not meet the definition of a hearing aid and do bypass or supersede a non-functioning organ in the auditory pathway. In addition, this commenter stated CMS is over-reaching its authority in including implantable bone conduction hearing aids in this definition. This commenter recommended seeking input from the medical and scientific community convening a public meeting to discuss the definitions at stake in this rule.

Response: For the reasons stated above, CMS has decided to continue covering AOIs because we have decided they are not hearing aids subject to the statutory exclusion.

Comment: One commenter felt the current proposal would reverse the 2005 NCD.

Response: The proposed rule (79 FR 40297) would not reverse the NCD. As we stated in the proposed rule, ''we continue to believe that the hearing aid exclusion does not apply to brain stem implants and CIs because these devices directly stimulate the auditory nerve, replacing the function of the inner ear rather than aiding the conduction of sound as hearing aids do.'' Therefore, we did not propose any changes to our current policy about brain stem implants and CIs and how such implants fall outside of the hearing aid statutory exclusion.

Comment: Several commenters agreed with the decision CMS made in 2005 by providing coverage for AOIs as prosthetics and not hearing aids.

Response: We agree the decision in 2005 to provide coverage for AOIs was correct. We believe AOIs are not hearing aids since they are functionally and clinically distinct from the hearing aids excluded from coverage in 1965. Therefore, this final rule will codify the current program instructions found at section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02).

Comment: One commenter stated the statute at section1861(s)(8), regulations at 42 CFR 414.202, and program manuals in the Medicare Benefit Policy Manual, Ch. 15, 120 set out a straightforward test for defining a covered prosthetic device which have not been changed.

Response: We have reexamined AOIs and the statutory exclusion applicability. We have come to the conclusion that AOIs are not hearing aids and therefore, have modified the final regulation to specify that AOIs are outside the scope of the hearing aid exclusion.

After consideration of the comments received we have decided not to finalize § 411.15, as proposed. In response to comments, this final rule will codify the policy in the current program instructions found at section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100–02) noted above.

VIII. Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding

A. Background

Section 1847(a)(1)(A) of the Act mandates the implementation of CBPs throughout the United States for awarding contracts for furnishing competitively priced items and services, including OTS orthotics described in section 1847(a)(2)(C) of the Act (leg, arm, back or neck braces described in section 1861(s)(9) of the Act for which payment would otherwise be made under section 1834(h)) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. The regulation at 42 CFR 414.402 currently defines ''minimal self-adjustment'' as ''an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual who is certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.'' This current definition was proposed in the 71 FR 25669 (May 1, 2006) proposed rule but did not include the term ''individual with specialized training.'' The definition was finalized in the 72 FR 18022 (April 10, 2007) Final Rule with the term ''individual with specialized

training'' added after receiving comments that disagreed with the May 2006 definition and pointed out that occupational therapists, physical therapists, and physicians are licensed and trained to provide orthotics.

B. Current Issues

Since adoption of the minimal self-adjustment definition there has been some concerns raised by industry and other stakeholders regarding who is considered an individual with specialized training. We have had many inquiries and comments that this term is too ambiguous and left open for interpretation. In addition, questions were raised regarding when it is appropriate for a supplier to bill for a prefabricated orthotic as having been custom fitted versus one furnished OTS. In order to address this specific question, the DME MACs issued a policy article on March 27, 2014, which details what custom fitting of an orthotic involves and indicating that furnishing custom fitted orthotics ''requires the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements.'' The DMEPOS quality standards have been updated to reflect this requirement and we decided to revise the definition of minimal self-adjustment in the regulation to address this issue as well.

In order to identify OTS orthotics for the purpose of implementing CBPs for these items and services in accordance with the statute, we need a clearer distinction between OTS orthotics and those that require more than minimal self-adjustment and expertise in custom fitting. In doing so, we believed it was essential to identify the credentials and training a supplier needs to have in order to be considered a supplier with expertise in custom fitting; therefore, we believed the term ''individual with specialized training'' must be clarified in regulations as well as in contractor policies and DMEPOS quality standards. In addition, we believed that suppliers who are not certified orthotists should not be allowed to furnish custom fitted orthotics unless they have specialized training equivalent to a certified orthotist for the provision of custom fitted orthotic devices. We believed that these suppliers must satisfy requirements concerning higher education, continuing education requirements, licensing, and certification/registration requirements so that they meet a minimum professional skill level in order to ensure appropriate care and safety for Medicare beneficiaries.

C. Summary of the Proposed Provisions and Responses to Comments on the Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding

For reasons discussed above, we proposed that physicians, treating practitioners, occupational therapists, and physical therapists are considered ''individuals with specialized training'' that possess training equivalent to a certified orthotist for the provision of custom fitted orthotic devices through their individual degree programs and continuing education requirements. We proposed these types of practitioners because we believe physicians, treating practitioners, occupational therapists, and physical therapists possess equivalent or higher educational degrees, continuing education requirements, licensing, and certification and/or registration requirements. Each of these professionals has undergone medical training in various courses such as kinesiology and anatomy.

Specifically, we proposed to update the definition of minimal self-adjustment in § 414.402 to recognize as an individual with specialized training: a physician defined in section 1861(r) of the Act, a treating practitioner defined at section 1861(aa)(5) (physician assistant, nurse practitioner, or clinical nurse specialist), an occupational therapist defined at 42 CFR 484.4, or physical therapist defined at 42 CFR 484.4, who is in compliance with all applicable Federal and State licensure and regulatory requirements.

At this time, we have decided not to finalize any changes to the definition of minimal self-adjustment in § 414.402 to recognize as an individual with specialized training. We may address this provision in future rulemaking.

IX. Revision To Change of Ownership Rules To Allow Contract Suppliers To Sell Specific Lines of Business

A. Background

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary to establish and implement competitive bidding programs (CBPs) in competitive bidding area (CBAs) throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The programs mandated by section 1847(a) of the Act are collectively referred to as the ''Medicare DMEPOS Competitive Bidding Program.'' The 2007 DMEPOS competitive bidding final rule (Medicare Program; Competitive Acquisition for Certain DMEPOS and Other Issues published in the **Federal Register** on April 10, 2007 (71 FR 17992)), required CBPs for certain Medicare Part B covered items of DMEPOS throughout the United States. The CBP, which was phased in over several years, utilizes bids submitted by qualified suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items for beneficiaries receiving services in designated CBAs.

CMS awards contracts to those suppliers who meet all of the competitive bidding requirements and whose composite bid amounts fall at or below the pivotal bid (the bid at which the capacity provided by qualified suppliers meets the demand for the item). These qualified suppliers will be offered a competitive bidding contract for that PC, provided there are a sufficient number of qualified suppliers (there must be at a minimum of 2) to serve the area. Contracts are awarded to multiple suppliers for each PC in each CBA and will be re-competed at least once every 3 years.

CMS specifies the duration of the contracts awarded to each contract supplier in the Request for Bid Instructions. We also conduct extensive bidder education where we inform bidders of the requirements and obligations of contract suppliers. Each winning supplier is awarded a single contract that includes all winning bids for all applicable CBAs and PCs. A competitive bidding contract cannot be subdivided. For example, if a contract supplier breaches its contract, the entire contract is subject to termination. In the Physician Fee Schedule final rule published on November 29, 2010, we stated that ''once a supplier's contract is terminated for a particular round due to breach of contract under the DMEPOS CBP, the contract supplier is no longer a DMEPOS contract supplier for any DMEPOS CBP PC for which it was awarded under that contract. This termination applies to all areas and PCs because there is only one contract that encompasses all CBAs and PCs for which the supplier was awarded a contract.'' (75 FR 73578)

A competitive bidding contract cannot be sold. However, CMS may permit the transfer of a contract to an entity that merges with or acquires a competitive bidding contract supplier if the new owner assumes all rights, obligations, and liabilities of the

competitive bidding contract pursuant to regulations at 42 CFR 414.422(d).

For the transfer of a contract to be considered, the Change of Ownership (CHOW) must include the assumption of the entire contract, including all CBAs and PCs awarded under the contract.

B. Summary of the Proposed Provisions and Responses to Comments on the Revision to Change of Ownership Rules To Allow Contract Suppliers To Sell Specific Lines of Business

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the DMEPOS CBP. We received 1 public comment on this proposal from a manufacturer and supplier. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

Specifically, we proposed (79 FR 40298) to revise § 414.422(d) to permit transfer of part of a competitive bidding contract under specific circumstances. We believe requiring a transfer of the entire contract to a successor entity in all circumstances may be overly restrictive, and may be preventing routine merger and acquisition activity. To maintain integrity of the bidding process we award one contract that includes all the CBA/PCs combinations for which the supplier qualifies and accepts as a contract supplier. We proposed to establish an exception to the prohibition against transferring part of a contract by allowing a contract supplier to sell a distinct company (for example, an affiliate, subsidiary, sole proprietor, corporation, or partnership) which furnishes one or more specific PCs or serves one or more specific CBAs and transfer the portion of the contract initially serviced by the distinct company, including the PC(s), CBA(s), and location(s), to a new qualified successor entity who meets all competitive bidding requirements (that is, financial standards, licensing, and accreditation) (79 FR 40299). The exception would not apply to existing contracts but would apply to contracts issued in all future rounds of the program, starting with the Round 2 Recompete. As required in § 414.422(d), we also proposed that a contract supplier that wants to sell a distinct company which furnishes one or more specific PCs or serves one or more specific CBAs would be required to notify CMS 60 days before the anticipated date of a change of ownership. If documentation is required to determine if a successor entity is qualified that documentation must be submitted within 30 days of anticipated change of ownership, pursuant to § 414.422(d)(2)(ii). We proposed that CMS would then modify the contract of the original contract supplier by removing the affected PC(s), CBA(s) and locations from the original contract. For CMS to approve the transfer, we proposed that several conditions would have to be met. First, we proposed that every CBA, PC, and location of the company being sold must be transferred to the new owner. Second, we proposed that all CBAs and PC's in the original contract that are not explicitly transferred by CMS must remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW. Third, we proposed that all requirements in 42 CFR 414.422 (d)(2) must be met. Fourth, we proposed that the sale of the company must include all of the company's assets associated with the CBA and/or PC(s). Finally, we proposed that CMS must determine that transferring part of the original contract will not result in disruption of service or harm to beneficiaries. No transfer would be permitted for purposes of this program if we determine that the new supplier does not meet the competitive bidding requirements (such as financial requirements) and does not possess all applicable licenses and accreditation for the product(s). In order for the transfer to occur, the contract supplier and successor entity must enter into a novation agreement with CMS and the successor entity must accept all rights, responsibilities and liabilities under the competitive bidding contract. Part of a novation agreement requires successor entity to ''seamlessly continue to service beneficiaries.'' We believe that these proposed conditions are necessary for proper administration of the program, to ensure that payments are made correctly and also to ensure continued contract accountability and viability along with continuity of service and access to beneficiaries. We specifically invited comments on whether more or different conditions would be appropriate.

We proposed to update the current CHOW regulation at § 414.422(d) to clarify the language to make it easier to comprehend. The proposed changes reformat the regulation so that the requirements applicable to successor entities and new entities are listed separately. These proposed changes to the regulation are technical, and not substantive in nature. CMS sought comments on all changes proposed for § 414.422. The comment and our responses are set forth below.

Comment: One commenter recommended that CMS implement financial penalties for suppliers who sell their contracts along with selling their organizations prior to providing the product/service at the contracted payment rate, and/or remove an entity's bid from calculation of the SPA if they have failed to supply the awarded contract items for a period of time prior to re-sale. The commenters also believed that bids by suppliers who have no intention of providing services to Medicare beneficiaries should not be given the same weight as those of reputable suppliers in the community.

Response: CMS does not agree with the suggestions raised by this commenter. CMS cannot require a contract supplier to furnish a certain amount of competitive bid items. However, contract suppliers must be ready, available and willing to furnish contracted competitive bid items starting on day one of implementation to any beneficiary within a CBA. A contract supplier is not permitted to sell just its competitive bidding contract. CMS ensures that the successor entity (1) assumes all rights, obligations, and liabilities of the entire competitive bidding contract, (2) meets all requirements applicable to a contract supplier, and (3) is acquiring the assets of the existing supplier. In addition, the competitive bidding contract specifically states that CMS does not guarantee a minimum amount of business. In response to the comment on the recalculation of the single payment amount (SPA), CMS carefully screens and evaluates bids to ensure that they are bona fide (rational and feasible) before determining the single payment amounts and offering contracts. Since only bona fide bids from qualified suppliers are included in the array of bids used to set prices, recalculating payment amounts based on contract rejections would not improve the validity of the single payment amounts. Also, the SPAs are set at the time of contract award and cannot be changed. It would not be possible for CMS to re-calculate the SPAs each time a contract supplier goes through a change of ownership. Contract offers include the SPAs applicable throughout the duration of the contract period for each HCPCS code in each CBA. Therefore, it is not possible for CMS to re-compute the SPAs whenever there is a change in contract suppliers as this would require continued re-contracting.

Therefore, for the reasons CMS stated above, CMS is finalizing the proposed changes to § 414.422(d) of the regulation and making one additional technical change to replace certain terms with ''a new qualified entity,'' when referring to a company that is approved to purchases a contract supplier and assume the competitive bidding contract in whole or in part. We are making this technical change for purposes of consistency and to avoid possible confusion.

X. Changes to the Appeals Process for Termination of Competitive Bidding Contract

We proposed (79 FR 40299) to modify the DMEPOS CBPs appeals process for termination of competitive bidding contracts under § 414.423. First, we proposed to modify the effective date of termination in the termination notice CMS sends to a contract supplier found to be in breach of contract. Currently, the regulation at 42 CFR 414.423(b)(2)(vi) indicates that the effective date of termination is 45 days from the date of the notification letter unless a timely hearing request ''has been'' filed or corrective action plan ''has been'' submitted within 30 days of the effective date of the notification letter (emphasis added). We proposed to change these references to emphasize that the contract will automatically be terminated if the supplier does not file a hearing request or submit a corrective action plan.

In 42 CFR 414.423(l), we also proposed (79 FR 40299) deleting the lead-in sentence, as it does not properly lead into the first paragraph. Additionally, we proposed inserting language from the lead-in sentence in the second paragraph to indicate that the contract supplier, ''whose contract has been terminated,'' must notify beneficiaries of the termination of their contract. Second, we proposed to modify the deadline by which a supplier whose competitive bidding contract is being terminated must notify affected beneficiaries that it is no longer a contract supplier. Current regulations at 42 CFR 414.423(l)(2)(i) require a contract supplier to provide this notice within 15 days of receipt of a final notice of termination. We proposed to change the beneficiary notification deadline to no later than 15 days prior to the effective date of termination. This proposed change is intended to provide beneficiaries with the protection of advanced notice prior to a contract supplier being terminated from the CBP so they have sufficient time to plan/coordinate their current and future DMEPOS needs. We did not receive any comments on this proposal (79 FR 40299). For the reasons we noted previously, we are finalizing these changes to § 414.423, with two modifications to the regulation text to address errors in citation references. First, in the proposed regulation of the proposed rule (79 FR 40315), we incorrectly referenced § 414.423(b)(1) instead of § 414.423(b)(2), so we are correcting that citation in this final rule. Second, although we made clear in the preamble our proposal to delete the lead-in language in § 414.423(l), we inadvertently failed to note that deletion in the proposed regulation text. Therefore, we are making technical corrections in the final rule to reflect final decision to delete the lead-in sentence in § 414.423(l).

XI. Technical Change Related to Submitting Bids for Infusion Drugs Under the DMEPOS Competitive Bidding Program

The standard payment rules for drugs administered through infusion pumps covered as DME are located at section 1842(o)(1)(D) of the Act, and mandate that payment for infusion drugs furnished through a covered item of DME on or after January 1, 2004, is equal to 95 percent of the average wholesale price for such drug in effect on October 1, 2003. The regulations implementing section 1842(o)(1)(D) of the Act are located at 42 CFR 414.707(a), under Subpart I of Part 414. Section 1847(a)(2)(A) of the Act mandates the establishment of CBPs for covered DME and medical supplies. The statute specifically states that this category includes ''items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME.'' Implementation of CBPs for infusion drugs is therefore specifically mandated by the statute.

Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under a CBP unless the total amounts to be paid to contract suppliers are expected to be less than would otherwise be paid. The regulations implementing section 1847(b)(2)(A)(iii) of the Act with respect to items paid on a fee schedule basis under Subparts C and D of Part 414 are located at 42 CFR 414.412(b)(2), and specify that ''the bids submitted for each item in a PC cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of this part.'' In addition, the regulations regarding the conditions for awarding contracts under the DMEPOS CBP at 42 CFR 414.414(f) state that ''a contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a CBP are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D.'' The regulations implementing of section 1847(b)(2)(A)(iii) of the Act did not address payments for drugs under subpart I, which was an oversight. We therefore proposed to revise §§ 414.412(b)(2) and 414.414(f) to include a reference to drugs paid under subpart I in addition to items paid under subparts C or D. We proposed to revise § 414.412(b)(2) to specify that the bid amounts submitted for each drug in a PC cannot exceed the payment limits that would otherwise apply to the drug under subpart I of part 414. Infusion drugs have payment limits equal to 95 percent of the average wholesale price for the drug in effect on October 1, 2003, in accordance with § 414.707(a)(3). See *http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=7065f17b411e37b3788b6e7fcce21f89&rgn=div8&view=text&node=42:3.0.1.1.1.9.1.3amp;idno=42.* We proposed to revise § 414.414(f) to specify that a contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for infusion drugs provided with respect to external infusion pumps under a CBP are expected to be less than the amounts that would otherwise be paid to suppliers for the same drug under subpart I of part 414. We sought comments on this proposal and received 4 comments. The comments and responses are set forth below.

Comment: Some commenters stated that CMS does not have authority to change payment amounts for infusion drugs using competitive bidding. One commenter stated that home infusion therapy is one of the most clinically complex therapies covered under the DME benefit and involves more than the delivery of infusion drugs to patients. The commenter believed that payment amounts for infusion drugs could be improperly reduced if CMS sets the payment rate using bids from inexperienced providers who do not adequately account for the cost of the services.

Response: Section 1847(a)(2)(A) of the Act includes infusion drugs in the list of items subject to the DMEPOS Competitive Bidding Program. Therefore, we are finalizing our proposal to modifying § 414.414(f) of the regulations, with an additional modification to make a general reference to Subpart I. We note, however, that at this time there are no CBPs in effect that include infusion drugs. The phase-in of

infusion drugs would occur under a future CBP(s).

XII. Accelerating Health Information Exchange

HHS believes all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, ''Principles and Strategies for Accelerating Health Information Exchange).'' The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (health IT) across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies, (2) adoption of common standards and certification requirements for interoperable health IT, (3) support for privacy and security of patient information across all HIE-focused initiatives, and (4) governance of health information networks. These initiatives are designed to encourage HIE among health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive programs, and are designed to improve care delivery and coordination across the entire care continuum. For instance, to increase flexibility in the Office of the National Coordinator for Health Information Technology's (ONC) regulatory certification structure Health IT Certification Program, ONC expressed in the 2014 Edition Release 2 final rule (79 FR 54472 through 54473) an intent to propose future changes to the program that would permit the certification of health IT for other health care settings, such as long-term and post-acute care and behavioral health settings.

We believe that HIE and the use of certified EHRs can effectively and efficiently help ESRD facilities and nephrologists improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of electronically specified clinical quality measures (eCQMs).

XIII. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement 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.

B. Requirements in Regulation Text

In section II.E and section II.G of this final rule, we are implementing changes to regulatory text for the ESRD PPS in CY 2015. However, the changes that are being finalized do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, this final rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP

The information collection requirements associated with the ESRD QIP are currently approved under OMB control number 0938–0386.

a. Data Validation Requirements for the PY 2017 ESRD QIP

Section III.F.9 in this final rule outlines our data validation studies for PY 2017. Specifically, we proposed to randomly sample records from 300 facilities as part of our continuing pilot data-validation program. Each sampled facility would be required to produce approximately 10 records, and the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimated that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities × 2.5 hours). According to the Bureau of Labor Statistics, the mean hourly wage of a registered nurse is $33.13/hour. Since we anticipate that nurses (or administrative staff who would be paid at a lower hourly wage) would submit this data, we estimated that the aggregate cost of the CROWNWeb data validation would be $24,847.50 (750 hours × $33.13/hour) total or $82.83 ($24,847.50/300 facilities) per facility in the sample.

We sought comments on these estimates but did not receive any comments.

Under the feasibility study for validating data reported to the NHSN Dialysis Event Module, we proposed to randomly select nine facilities to provide CMS with a quarterly list of all positive blood cultures drawn from their patients during the quarter, including any positive blood cultures collected on the day of, or the day following, a facility patient's admission to a hospital. A CMS contractor will review the lists to determine if dialysis events for the patients in question were accurately reported to the NHSN Dialysis Event Module. If we determine that additional medical records are needed to validate dialysis events, facilities will be required to provide those records within 60 days of a request for this information. We estimated that the burden associated with this feasibility study will be the time and effort necessary for each selected facility to compile and submit to CMS a quarterly list of positive blood cultures drawn from its patients. We estimated that it will take each participating facility approximately two hours per quarter to comply with this submission. If nine facilities are asked to provide lists, we estimated the quarterly burden for these facilities would be 72 hours per year (9 facilities × 2 hours/quarter × 4 quarters/year). Again, we estimated the mean hourly wage of a registered nurse to be $33.13/hour, and we anticipated that nurses (or administrative staff who would be paid at a lower hourly wage) would be responsible for preparing and submitting the list. Because we anticipated that nurses (or

administrative staff who would be paid at a lower hourly rate) would compile and submit these data, we estimated that the aggregate annual cost of the feasibility study to validate NHSN data would be $2,385.36 (72 hours × $33.13/hour) total or $265.04 per facility ($2,385.36/9 facilities).

We sought comments on these estimates. The comment we received and our response is set forth below.

Comment: One commenter stated that the cost estimate provided for the proposed NHSN Data Validation study is too low, because the study requirements will likely be completed by the facility's Nurse Manager, who is paid more than a Registered Nurse.

Response: We understand the commenter's concerns; however, the Bureau of Labor Statistics does not separately itemize Nurse Managers. Based on our experience, Nurse Managers are typically Registered Nurses; therefore, we believe that the costs of collecting this information have been estimated correctly.

b. NHSN Healthcare Personnel Influenza Vaccination Reporting Measure for PY 2018

We proposed to include, beginning with the PY 2018 ESRD QIP, a measure requiring facilities to report healthcare personnel influenza vaccination data to NHSN. The NHSN is a secure, Internet-based surveillance system which is maintained and managed by CDC. Many dialysis facilities already submit NHSN Bloodstream Infection clinical measure data to NHSN. Specifically, we proposed to require facilities to submit on an annual basis an HCP Influenza Vaccination Summary Form to NHSN, according to the specifications available in the NHSN Healthcare Personnel Safety Component Protocol. We estimated the burden associated with this measure to be the time and effort necessary for facilities to complete and submit the HCP Influenza Vaccination Summary Form on an annual basis. We estimated that approximately 5,996 facilities will treat ESRD patients in PY 2018. We estimated it will take each facility approximately 75 minutes to collect and submit the data necessary to complete the Healthcare Personnel Influenza Vaccination Summary Form on an annual basis. Therefore, the estimated total annual burden associated with reporting this measure in PY 2018 is 7,495 hours [(75/60) hours × 5,996 facilities]. Again, we estimated the mean hourly wage of a registered nurse to be $33.13, and we anticipated that nurses (or administrative staff who would be paid at a lower hourly wage) would be responsible for this reporting. In total, we stated that we believe the cost for all ESRD facilities to comply with the reporting requirements associated with the NHSN Healthcare Personnel Influenza Vaccination reporting measure would be approximately $248,309 (7,495 hours × $33.13/hour) total, or $41.37 ($248,309/5,996 facilities) per facility.

We sought comments on these estimates but did not receive any comments.

XIV. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We examined the impacts of this rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 11, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits of reducing costs, harmonizing rules, and promoting flexibility. This rule has been designated economically significant under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the final rule.

2. Statement of Need

This rule finalizes a number of routine updates for renal dialysis services in CY 2015 and implements several policy changes to the ESRD PPS. The routine updates include: wage index values, wage index budget-neutrality adjustment factor, and the outlier payment threshold amounts. The final policy changes to the ESRD PPS include the revisions to the ESRDB market basket, changes in the CBSA delineations, changes to the labor-related share, clarifications of the low-volume payment adjustment and the billing of short frequent hemodialysis services, and additions and corrections to the ICD–10–CM codes that will be used for the co-morbidity payment adjustment when compliance with ICD–10–CM is required beginning October 1, 2015. In addition, this rule implements sections 1881(b)(14)(F)(i) and (I) of the Act, as amended by section 217 (b)(1) and (2) of PAMA, under which the drug utilization adjustment transition is eliminated and a 0.0 percent update to the ESRD PPS base rate is imposed in its place. This rule also implements the delay in payment for oral-only drugs used for the treatment of ESRD under the ESRD PPS until January 1, 2024 as required by section 217(a) of PAMA. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2015.

This final rule implements requirements for the ESRD QIP by adopting measure sets for the PYs 2017 and 2018 programs, as directed by section 1881(h) of the Act. Failure to finalize requirements for the PY 2017 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2016. In addition, finalizing requirements for the PY 2018 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

This final rule establishes a methodology for adjusting DMEPOS fee schedule amounts using information from the Medicare DMEPOS CBP. The final rule phases in special payment rules for certain DME in a limited number of areas under the Medicare DMEPOS CBP. This rule also clarifies the Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act. Finally, this final rule modifies the rules for a CHOW under the Medicare DMEPOS CBP.

3. Overall Impact

We estimate that the proposed revisions to the ESRD PPS will result in an increase of approximately $30 million in payments to ESRD facilities in CY 2015, which includes the amount associated with updates to outlier threshold amounts, updates to the wage index, changes in CBSA delineations, and the labor-related share.

For PY 2017, we estimate that the finalized requirements related to the ESRD QIP will cost approximately $27 thousand total, and the payment reductions will result in a total impact of approximately $12 million across all facilities. For PY 2018, we estimate that the finalized requirements related to the ESRD QIP will cost approximately $248 thousand total, and the payment reductions will result in a total impact of approximately $12.7 million across all facilities, resulting in a total impact from the ESRD QIP of approximately $13 million.

We estimate that the final methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs would save over

$4.4 billion in gross payments over FYs 2016–2020. The gross savings would be primarily achieved from the reduced payment amounts for items and services.

We estimate the special payment rules at § 414.409 would not have a negative impact on beneficiaries and suppliers, or on the Medicare program. Contract suppliers are responsible for furnishing items and services needed by the beneficiary, and the cost to suppliers for furnishing these items and services generally would not change based on whether or not the equipment and related items and services are paid for separately under a capped rental payment method. Because the supplier's bids would reflect the cost of furnishing items in accordance with the new payment rules, we expect the fiscal impact generally would be the same as is under the current payment rules. Furthermore, as indicated above, the special payment rules would be phased in under a limited number of areas to gradually determine effects on the program, beneficiaries, and suppliers, including their effects on cost, quality, and access before expanding to other areas after notice and comment rulemaking, if supported by evaluation results. We believe that the special payment rules will give beneficiaries more choice and flexibility in changing suppliers. We estimate the clarification of the statutory Medicare hearing aid coverage exclusion will not have a significant fiscal impact on the Medicare program because we are not changing the current coverage for devices for Medicare payment purposes. This regulation at § 411.15(d) will provide guidance as to coverage of DME with regard to the statutory exclusion.

We estimate finalizing a change to the CHOW rules under the Medicare DMEPOS CBP will have no significant impact to DMEPOS suppliers.

B. Detailed Economic Analysis

1. CY 2015 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2014 to estimated payments in CY 2015. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2014 and CY 2015 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used the June 2014 update of CY 2013 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2013 claims to 2014 and 2015 using various updates. The updates to the ESRD PPS base rate are described in section II.C of this rule. Table 33 shows the impact of the estimated CY 2015 ESRD payments compared to estimated payments to ESRD facilities in CY 2014.

TABLE 33—IMPACT OF FINAL CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2015 FINAL RULE

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2015 changes in outlier policy	Effect of 2015 changes in wage indexes, CBSA designations and labor-related share	Effect of 2015 changes in payment rate update	Effect of total 2015 changes
	A	B	C (%)	D (%)	E (%)	F (%)
All Facilities	6,096	43.6	0.3	0.0	0.0	0.3
Type						
Freestanding	5,615	40.7	0.3	0.0	0.0	0.3
Hospital based	481	2.9	0.3	0.2	0.0	0.5
Ownership Type						
Large dialysis organization	4,209	30.5	0.3	−0.1	0.0	0.2
Regional chain	890	6.6	0.2	0.2	0.0	0.5
Independent	599	4.1	0.2	0.2	0.0	0.3
Hospital based [1]	398	2.4	0.3	0.1	0.0	0.4
Geographic Location						
Rural	1,230	6.5	0.3	−0.8	0.0	−0.5
Urban	4,866	37.0	0.3	0.1	0.0	0.4
Census Region						
East North Central	1,000	6.5	0.3	−0.1	0.0	0.2
East South Central	504	3.2	0.3	−1.2	0.0	−0.9
Middle Atlantic	672	5.2	0.3	0.7	0.0	0.9
Mountain	356	2.1	0.2	0.0	0.0	0.2
New England	179	1.4	0.3	1.2	0.0	1.4
Pacific [2]	725	6.1	0.2	1.7	0.0	1.9
Puerto Rico and Virgin Islands	44	0.3	0.3	−3.9	0.0	−3.6
South Atlantic	1,353	10.1	0.3	−0.5	0.0	−0.2
West North Central	441	2.3	0.2	−0.3	0.0	−0.1
West South Central	822	6.3	0.3	−0.9	0.0	−0.6
Facility Size						
Less than 4,000 treatments [3]	1,283	3.2	0.3	−0.2	0.0	0.1
4,000 to 9,999 treatments	2,261	11.8	0.3	−0.3	0.0	0.0
10,000 or more treatments	2,536	28.6	0.3	0.1	0.0	0.4
Unknown	16	0.0	0.3	−2.2	0.0	−1.9
Percentage of Pediatric Patients						
Less than 2	5,978	43.1	0.3	0.0	0.0	0.3
Between 2 and 19	52	0.4	0.3	−0.2	0.0	0.1

TABLE 33—IMPACT OF FINAL CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2015 FINAL RULE—Continued

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2015 changes in outlier policy	Effect of 2015 changes in wage indexes, CBSA designations and labor-related share	Effect of 2015 changes in payment rate update	Effect of total 2015 changes
	A	B	C (%)	D (%)	E (%)	F (%)
Between 20 and 49	12	0.0	0.1	0.0	0.0	0.1
More than 50	54	0.1	0.1	0.1	0.0	0.1

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.
[3] 1,283 ESRD facilities with less than 4,000 treatments, only 407 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these low-volume facilities is a 0.1 percent decrease in payments.
Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the changes to the outlier payment policy described in section II.C.4 of this final rule is shown in column C. For CY 2015, the impact on all ESRD facilities as a result of the changes to the outlier payment policy will be a 0.3 percent increase in estimated payments. The estimated impact of the changes to outlier payment policy ranges from a 0.1 percent to a 0.3 percent increase. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2015 payments as a result of the outlier policy changes.

Column D shows the effect of the wage index, new CBSA delineations, and labor-related share on ESRD facilities and reflects the CY 2015 wage index values for the ESRD PPS payments. Facilities located in the census region of Puerto Rico and the Virgin Islands would receive a 3.9 percent decrease in estimated payments in CY 2015. Since most of the facilities in this category are located in Puerto Rico, the decrease is primarily due to the change in the labor-related share. The other categories of types of facilities in the impact table show changes in estimated payments ranging from a 2.2 percent decrease to a 1.7 percent increase due to the update of the wage indexes, CBSA delineations and labor-related share.

Column E shows the effect of the ESRD PPS payment rate update of 0.0 percent as required by sections 1881(b)(14)(F) and (I) as amended by section 217 of PAMA.

Column F reflects the overall impact (that is, the effects of the outlier policy changes, the wage index, the CBSA delineations, the labor-related share, and the effect of the payment rate update. We expect that overall ESRD facilities will experience a 0.3 percent increase in estimated payments in 2015. ESRD facilities in Puerto Rico and the Virgin Islands are expected to receive a 3.6 percent decrease in their estimated payments in CY 2015. This larger decrease is primarily due to the negative impact of the change in the labor-related share. The other categories of types of facilities in the impact table show impacts ranging from a decrease of 1.9 percent to increase of 1.9 percent in their 2015 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, ESRD facilities are paid directly for the renal dialysis bundle and other provider types such as laboratories, DME suppliers, and pharmacies, may no longer bill Medicare directly for renal dialysis services. Rather, effective January 1, 2011, such other providers can only furnish renal dialysis services under arrangements with ESRD facilities and must seek payment from ESRD facilities rather than Medicare. Under the ESRD PPS, Medicare pays ESRD facilities one payment for renal dialysis services, which may have been separately paid to suppliers by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2015, we estimate that the ESRD PPS will have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2015 will be approximately $9.0 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 3.3 percent in CY 2015.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 0.3 percent overall increase in ESRD PPS payment amounts in CY 2015, we estimate that there will be an increase in beneficiary co-insurance payments of 0.3 percent in CY 2015, which translates to approximately $10 million.

e. Alternatives Considered

For this final rule, we will implement a 50/50 blended wage index for CY 2015 that will apply to all ESRD facilities, experiencing an impact, or not, due to the implementation of the new CBSA delineations. We considered implementing the new CBSA delineations without a transition; however we decided to mitigate the impact this change would have on ESRD facilities that may experience a decrease in payments due to the change.

In addition, we will implement the updated labor-related share using a 2-year transition. Therefore, for CY 2015, we will apply 50 percent of the value of the current labor-related share under the ESRD PPS (41.737) and 50 percent of the percent to the revised labor-related share (50.673). In CY 2016, we will apply 100 percent, or 50.673 percent, as the labor-related share. We considered implementing the labor-related share without a transition; however we decided to mitigate the impact this change would have on ESRD facilities that may experience a decrease in payments due to the change.

2. End-Stage Renal Disease Quality Incentive Program

a. Effects of the PY 2017 ESRD QIP

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility

services provided to beneficiaries as a result of payment changes under the ESRD PPS. The methodology that we are proposing to use to determine a facility's TPS for PY 2017 is described in section III.F.5 of this final rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2017 ESRD QIP would affect the facility's reimbursement rates in CY 2017.

We estimate that, of the total number of dialysis facilities (including those not receiving a TPS), approximately 19 percent or 1,123 of the facilities would likely receive a payment reduction in PY 2017. Facilities that do not receive a TPS are not eligible for a payment reduction.

In conducting our impact assessment, we have assumed that there will be an initial count of 5,996 dialysis facilities paid under the ESRD PPS. Table 34 shows the overall estimated distribution of payment reductions resulting from the PY 2017 ESRD QIP.

TABLE 34—ESTIMATED DISTRIBUTION OF PY 2017 ESRD QIP PAYMENT REDUCTIONS.

Payment reduction	Number of facilities	Percent of facilities
0.0%	4,541	80.17
0.5%	784	13.84
1.0%	282	4.98
1.5%	44	0.78
2.0%	13	0.23

Note: This table excludes 332 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a Total Performance Score.

To estimate whether or not a facility would receive a payment reduction in PY 2017, we scored each facility on achievement and improvement on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 35.

TABLE 35—DATA USED TO ESTIMATE PY 2017 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
Vascular Access Type		
% Fistula	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
% Catheter	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Kt/V		
Adult HD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Adult PD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Pediatric HD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Hypercalcemia	May 2012–Dec 2012	Jan 2013–Dec 2013.
SRR	Jan 2012–Dec 2012	Jan 2013–Dec 2013.

Clinical measure topic areas with less than 11 cases for a facility were not included in that facility's Total Performance Score. Each facility's Total Performance Score was compared to the estimated minimum Total Performance Score and the payment reduction table found in section III.F.8 of this final rule. Facility reporting measure scores were estimated using available data from CY 2013. Facilities were required to have a score on at least one clinical and one reporting measure in order to receive a Total Performance Score.

To estimate the total payment reductions in PY 2017 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2013 and December 2013 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: (Total ESRD payment in January 2013 through December 2013 times the estimated payment reduction percentage). For PY 2017, the total payment reduction for the 1,123 facilities estimated to receive a reduction is approximately $11.9 million ($11,927,399). Further, we estimate that the total costs associated with the collection of information requirements for PY 2017 described in section III.F.9 of this final rule would be approximately $27 thousand for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately $12 million ($27,232 + $11,927,399 = $11,954,631) in PY 2017, as a result of the PY 2017 ESRD QIP.

Table 36 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2017. The table estimates the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the time periods used for these calculations will differ from those we are proposing to use for the PY 2017 ESRD QIP, the actual impact of the PY 2017 ESRD QIP may vary significantly from the values provided here.

TABLE 36—ESTIMATED IMPACT OF FINALIZED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES IN PY 2017

	Number of facilities	*Number of treatments 2013 (in millions)*	*Number of facilities with QIP score*	*Number of facilities expected to receive a payment reduction*	*Payment reduction (percent change in total ESRD payments)*
All Facilities	5,996	39.1	5,664	1,123	−0.13

TABLE 36—ESTIMATED IMPACT OF FINALIZED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES IN PY 2017—Continued

	Number of facilities	Number of treatments 2013 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
Facility Type:					
Freestanding	5,520	36.6	5,275	1,008	−0.12
Hospital-based	476	2.5	389	115	−0.21
Ownership Type:					
Large Dialysis	4,150	27.5	3,987	704	−0.11
Regional Chain	871	5.9	828	170	−0.14
Independent	582	3.6	529	151	−0.23
Hospital-based (non-chain)	393	2.1	320	98	−0.22
Facility Size:					
Large Entities	5,021	33.5	4,815	874	−0.11
Small Entities [1]	975	5.7	849	249	−0.22
Rural Status:					
1) Yes	1,212	5.9	1,156	181	−0.10
2) No	4,784	33.3	4,508	942	−0.14
Census Region:					
Northeast	792	5.8	756	161	−0.15
Midwest	1,341	7.7	1,259	268	−0.14
South	2,527	17.5	2,451	487	−0.12
West	1,015	7.1	964	128	−0.08
US Territories [2]	321	1.0	234	79	−0.27
Census Division:					
East North Central	979	5.8	897	224	−0.17
East South Central	497	2.9	473	81	−0.11
Middle Atlantic	661	4.8	619	135	−0.15
Mountain	352	1.9	334	35	−0.07
New England	177	1.3	167	33	−0.14
Pacific	710	5.4	670	104	−0.10
South Atlantic	1,333	9.1	1,272	301	−0.15
West North Central	438	2.0	410	59	−0.09
West South Central	807	5.6	782	126	−0.10
US Territories [3]	42	0.3	40	25	−0.43
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,086	2.7	901	163	−0.13
4,000–9,999 treatments	2,226	10.5	2,167	371	−0.11
Over 10,000 treatments	2,523	25.7	2,504	561	−0.14
Unknown	161	0.3	92	28	−0.28

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.
[3] Based on claims and CROWNWeb data through December 2013.

b. Effects of the PY 2018 ESRD QIP

The methodology that we are using to determine a facility's TPS for the PY 2018 ESRD QIP is described in section III.G.9 of this final rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2018 ESRD QIP would apply to ESRD PPS payments made to the facility in CY 2018.

We estimate that, of the total number of dialysis facilities (including those not receiving a TPS), approximately 21 percent or 1,284 of the facilities would likely receive a payment reduction in PY 2018. Facilities that do not receive a TPS are not eligible for a payment reduction.

In conducting our impact assessment, we have assumed that there will be 5,996 dialysis facilities paid through the PPS. Table 37 shows the overall estimated distribution of payment reductions resulting from the PY 2018 ESRD QIP.

TABLE 37—ESTIMATED DISTRIBUTION OF PY 2018 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities
0.0%	4,338	77.2
0.5%	1,023	18.2
1.0%	225	4.0
1.5%	33	0.6
2.0%	3	0.1

NOTE: This table excludes 374 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a Total Performance Score.

To estimate whether or not a facility would receive a payment reduction in PY 2018, we scored each facility on achievement and improvement on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 38.

TABLE 38—DATA USED TO ESTIMATE PY 2018 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
Vascular Access Type		
% Fistula	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
% Catheter	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Kt/V		
Adult HD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Adult PD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Pediatric HD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Pediatric PD	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
Hypercalcemia	May 2012–Dec 2012	Jan 2013–Dec 2013.
SRR	Jan 2012–Dec 2012	Jan 2013–Dec 2013.
STrR	Jan 2012–Dec 2012	Jan 2013–Dec 2013.

Clinical measure topic areas with less than 11 cases for a facility were not included in that facility's Total Performance Score. Each facility's Total Performance Score was compared to a proxy minimum Total Performance Score developed consistent with the policies outlined in sections III.G.9 of this final rule. Facility reporting measure scores were estimated using available data from CY 2013. Facilities were required to have a score on at least one clinical and one reporting measure in order to receive a Total Performance Score.

To estimate the total payment reductions in PY 2018 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2013 and December 2013 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: (Total ESRD payment in January 2013 through December 2013 times the estimated payment reduction percentage). For PY 2018, the total payment reduction for all of the 1,284 facilities expected to receive a reduction is approximately $11.6 million ($11,576,214). Further, we estimate that the total costs associated with the collection of information requirements for PY 2018 described in section III.G.2.f of this final rule would be approximately $248 thousand for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately $11.8 million ($248,309 + $11,576,215 = $11,824,524) in PY 2018, as a result of the PY 2018 ESRD QIP.

Table 39 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2018. The table details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the time periods used for these calculations will differ from those we will use for the PY 2018 ESRD QIP, the actual impact of the PY 2018 ESRD QIP may vary significantly from the values provided here.

TABLE 39—ESTIMATED IMPACT OF FINALIZED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2018

	Number of facilities	*Number of treatments 2013 (in millions)*	*Number of facilities with QIP score*	*Number of facilities expected to receive a payment reduction*	*Payment reduction (percent change in total ESRD payments)*
All Facilities	5,996	39.1	5,622	1,284	−0.14
Facility Type:					
Freestanding	5,520	36.6	5,251	1,150	−0.13
Hospital-based	476	2.5	371	134	−0.23
Ownership Type:					
Large Dialysis	4,150	27.5	3,976	789	−0.11
Regional Chain	871	5.9	823	212	−0.16
Independent	582	3.6	520	174	−0.22
Hospital-based (non-chain)	393	2.1	303	109	−0.23
Facility Size:					
Large Entities	5,021	33.5	4,799	1,001	−0.12
Small Entities [1]	975	5.7	823	283	−0.23
Rural Status:					
1) Yes	1,212	5.9	1,151	250	−0.13
2) No	4,784	33.3	4,471	1,034	−0.14
Census Region:					
Northeast	792	5.8	748	175	−0.14
Midwest	1,341	7.7	1,247	317	−0.15
South	2,527	17.5	2,445	530	−0.12
West	1,015	7.1	955	153	−0.10
US Territories [2]	321	1.0	227	109	−0.36
Census Division:					
East North Central	979	5.8	888	256	−0.17
East South Central	497	2.9	472	94	−0.12

TABLE 39—ESTIMATED IMPACT OF FINALIZED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2018—Continued

	Number of facilities	Number of treatments 2013 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
Middle Atlantic	661	4.8	612	150	−0.15
Mountain	352	1.9	334	46	−0.08
New England	177	1.3	164	35	−0.12
Pacific	710	5.4	660	122	−0.11
South Atlantic	1,333	9.1	1,268	328	−0.15
West North Central	438	2.0	405	81	−0.12
West South Central	807	5.6	779	146	−0.11
US Territories [2]	42	0.3	40	26	−0.42
Facility Size (# of total treatments).					
Less than 4,000 treatments	1,086	2.7	869	219	−0.16
4,000–9,999 treatments	2,226	10.5	2,163	429	−0.11
Over 10,000 treatments	2,523	25.7	2,502	587	−0.13
Unknown	161	0.3	88	49	−0.49

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.
[3] Based on claims and CROWNWeb data through December 2013.

3. DMEPOS Provisions

a. Effects of the Final Methodology for Adjusting DMEPOS Payment Amounts Using Information From Competitive Bidding Programs

We estimate that the final methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs will save over $4.4 billion in gross payments over FY 2016 through 2020. The gross savings will be primarily achieved from price reductions for items. Therefore, most of the economic impact is expected from the reduced prices. We estimate that approximately half of the DMEPOS items and services furnished to Medicare beneficiaries are furnished to beneficiaries residing outside existing CBAs. (See Table 40.)

TABLE 40—IMPACT OF PRICING ITEMS IN NON-COMPETITIVE AREAS USING COMPETITIVE BIDDING PRICING *

FY	Impact on the gross impact in dollars (to the nearer ten million)	Impact on beneficiary cost sharing in dollars (to the nearer ten million)
2016	−550	−130
2017	−1,120	−280
2018	−1,330	−330
2019	−1,430	−360
2020	−1,530	−380

* The impacts of the final rule differ from those of the proposed rule due to six-month phase-in in 2016 of the adjusted fees and the expanded definition of rural areas.

b. Effects of the Final Special Payment Methodologies Under the Competitive Bidding Program

We believe that the final special payment rules will not have a significant impact on beneficiaries and suppliers. Contract suppliers are responsible for furnishing items and services needed by the beneficiary, and the cost to suppliers for furnishing these items and services does not change based on whether or not the equipment and related items and services are paid for separately under a capped rental payment method. Because the supplier's bids will reflect the cost of furnishing items in accordance with the new payment rules, we expect the overall savings will be generally the same as they are under the current payment rules. Section 1847(b)(2)(A)(iii) prohibits the awarding of contracts under a CBP unless total payments made to contract suppliers in the CBA are expected to be less than the payment amounts that would otherwise be made. Furthermore, as indicated above, we are finalizing a phase-in of the special payment rules under a limited number of areas to gradually determine effects on the program, beneficiaries, and suppliers. If supported by evaluation results, a decision to expand the special payment rules to other areas will be addressed in future rulemaking.

c. Effects of the Final Clarification of the Scope of the Medicare Hearing Aid Coverage Exclusion

This final rule clarifies the scope of the Medicare coverage exclusion for hearing aids. This rule will not have a fiscal impact on the Medicare program because there will be no change in the coverage of devices for Medicare payment purposes. This clarification will provide clear guidance about coverage of DME with regard to the statutory hearing aid exclusion.

d. Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding

The final rule will not finalize a modification to the definition of minimal self-adjustment.

e. Effects of the Final Revision To Change of Ownership Rules To Allow Contract Suppliers To Sell Specific Lines of Business

This final rule modifies the change of ownership rules to reduce interference with the normal course of business for DME suppliers. This rule establishes an exception under the CHOW rules to allow transfer of part of a competitive bidding contract when a contract supplier sells a distinct line of business to a qualified successor entity under certain specific circumstances. This change impacts businesses in a positive way by allowing them to conduct everyday transactions without interference from our rules and regulations.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 41 below, we have

prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

TABLE 41—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

Category	Transfers
ESRD PPS for CY 2015	
Annualized Monetized Transfers	$30 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Transfers
Increased Beneficiary Co-insurance Payments	$10 million.
From Whom to Whom	Beneficiaries to ESRD providers.
ESRD QIP for PY 2017	
Annualized Monetized Transfers	−$11.9 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	$27 thousand.
ESRD QIP for PY 2018	
Annualized Monetized Transfers	−$11.6 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	$248 thousand.

Pricing Items in Non-competitive Areas Using Competitive Bidding Pricing

Category	Transfer			
Annualized Monetized Transfer on Beneficiary Cost Sharing	Estimates	Year dollar	Discount rate	Period covered
	−$288.0 million	2014	7%	2016–2020
	−$292.5 million	2014	3%	2016–2020
From Whom to Whom	Beneficiaries to Medicare providers.			
	Transfers			
Annualized Monetized Transfer Payments	Estimates	Year dollar	Discount rate	Period covered
	−$1,160.9 million	2014	7%	2016–2020
	−$1,178.5 million	2014	3%	2016–2020
From Whom to Whom	Federal government to Medicare providers.			

XV. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 16 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $38.5 million in any 1 year. Individuals and States are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as 621492 with a size standard of $38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 16 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 33. Using the definitions in this ownership category, we consider the 599 facilities that are independent and the 398 facilities that are shown as hospital-

based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues of more than $38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS final updates in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 0.4 percent increase in payments for CY 2015. An independent facility (as defined by ownership type) is also estimated to receive a 0.3 percent increase in payments for CY 2015.

We estimate that of the 1,123 ESRD facilities expected to receive a payment reduction in the PY 2017 ESRD QIP, 249 of those facilities would be ESRD small entity facilities. We present these findings in in Table 34 (''Estimated Distribution of PY 2017 ESRD QIP Payment Reductions'') and Table 36 (''Estimated Impact of Finalized QIP Payment Reductions to ESRD Facilities for PY 2017'') above. We estimate that the payment reductions will average approximately $10,621 per facility across the 1,123 facilities receiving a payment reduction, and $10,329 for each small entity facility. Using our estimates of facility performance, we also estimated the impact of payment reductions on ESRD small entity facilities by comparing the total payment reductions for the 249 small entity facilities with the aggregate ESRD payments to all small facilities. We estimate that there are a total of 975 small facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.22 percent in PY 2017.

We estimate that of the 1,284 ESRD facilities expected to receive a payment reduction in the PY 2018 ESRD QIP, 283 are ESRD small entity facilities. We present these findings in Table 37 (''Estimated Distribution of PY 2018 ESRD QIP Payment Reductions'') and Table 39 (''Estimated Impact of Finalized QIP Payment Reductions to ESRD Facilities for PY 2018'') above. We estimate that the payment reductions will average approximately $9,016 per facility across the 1,284 facilities receiving a payment reduction, and $9,009 for each small entity facility. Using our estimates of facility performance, we also estimated the impact of payment reductions on ESRD small entity facilities by comparing the total estimated payment reductions for 283 small entity facilities with the aggregate ESRD payments to all small entity facilities. We estimate that there are a total of 975 small entity facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.23 percent in PY 2018.

We expect the final methodologies for adjusting DMEPOS fee schedule amounts using information from DMEPOS CBPs will have a significant impact on a substantial number of small suppliers. Although suppliers furnishing items and services outside CBAs do not have to compete and be awarded contracts in order to continue furnishing these items and services, the fee schedule amounts for these items and services will be reduced using the methodology established as a result of the final rule. The statute requires that the methodology for adjusting fee schedule amounts take into consideration the costs of furnishing items and services in areas where the adjustments will occur and these considerations are discussed in the preamble (refer to section V.A.5.). The final methodology for making payment adjustments will allow for adjustments based on bids in different geographic regions to reflect regional costs of furnishing items and services or the national limits for adjustments in areas with costs outside of MSAs and areas subject to section 1847(a)(3)(A) of the Act. We believe that suppliers will be able to continue furnishing items and services to beneficiaries in areas outside the CBAs after the reductions in the payment amounts are applied without a significant change in the rate at which they accept assignment of Medicare claims for these items and services. Because section 1834(a)(1)(F)(ii) of the Act mandates that payment amounts for DME subject to competitive bidding be adjusted in areas where CBPs are not implemented, the only alternative we can consider other than paying based on adjusted fee schedule amounts is to implement CBPs in all areas. However, this approach would have an even greater impact on small suppliers.

We expect the final special payment rules for certain DME will not have a significant impact on small suppliers. We believe that these rules will benefit affected suppliers since payment for rental of certain DME would no longer be capped and suppliers would retain ownership to the equipment.

We expect the final rule which clarifies the scope of the Medicare statutory exclusion for hearing aids will have no impact on small suppliers as we are not changing current coverage of devices for Medicare payment purposes.

We expect that the final revisions to CHOW rules to allow contract suppliers to sell specific lines of business provision will have a positive impact on suppliers and no significant negative impact on small suppliers.

Therefore, the Secretary has determined that this final rule will have a significant economic impact on a substantial number of small entities. We solicited comment on the RFA analysis provided. The comments and our responses are set forth below.

Comment: Some commenters noted that CMS has not considered the economic and regulatory flexibility analysis under the proposed rule for applying special payment rules for certain DME in competitive bidding areas and the final Methodology for Adjusting DMEPOS Payment Amounts using Information from Competitive Bidding Programs.

Response: We thank the commenters for their input. The continuous rental bundled payment methodology will be phased in for only two items, CPAP device and power wheelchairs in no more than 12 CBAs at this time. Our analysis indicates that establishing single payment amounts based upon bids submitted by suppliers using the continuous rental bundled methodology instead of capped rental methodology for these two items in no more than 12 CBAs will not have a significant impact because the bid limits for power wheelchairs will be based upon current utilization and expenditure in the 12 CBAs. The updated 1993 fee schedule amounts would be the bid limits for CPAP. The 1993 fee schedule represents a fairly accurate bundled rental payment amount for the CPAP and the covered item update factor would cover for improvements in technology. The CPAP fees from 1993 were based on average reasonable charges from July 1986 through June 1987 for rental of the device with no separate payment for the accessories; we believe the historic amounts fairly reflect the utilization and payment for accessories used with the device. We expect that the final special payment rules will not have a significant impact on small suppliers because of the limited scope of the program. The phase-in of the special payment rules would be limited to only two product categories; Power Wheelchairs and CPAP devices in no more than 12 CBAs.

We expect the final methodologies for adjusting DMEPOS fee schedule amounts using information from DMEPOS CBPs will have a significant impact on a substantial number of small suppliers. However, section 1834(a)(1)(F)(ii) of the Act mandates that payment amounts for DME subject to competitive bidding be adjusted in areas where CBPs are not implemented, therefore, the only alternative we can

consider other than paying based on adjusted fee schedule amounts is to implement CBPs in all areas, however, our analysis indicates that this approach would have an even greater impact on small suppliers. The statute requires that the methodology for adjusting fee schedule amounts take into consideration the costs of furnishing items and services in areas where the adjustments will occur and we have considered these factors in developing the final methodology, thereby reducing the extent of impact on small suppliers. We believe that suppliers will be able to continue furnishing items and services to beneficiaries in areas outside the CBAs after the reductions in the payment amounts are applied without a significant change in the rate at which they accept assignment of Medicare claims for these items and services.

XVI. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This final rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $141 million.

XVII. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) 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. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

XVIII. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

XIX. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet and is posted on the CMS Web site at *http://www.cms.gov/ESRDPayment/PAY/list.asp* In addition to the Addenda, limited data set (LDS) files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html.* Readers who experience any problems accessing the Addenda or LDS files, should contact Stephanie Frilling at (410) 786–4507.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays

42 CFR Part 411

Kidney diseases, Medicare, Physician Referral, and Reporting and recordkeeping requirements

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

§ 405.2102 [Amended]

■ 2. Section 405.2102 is amended by removing all the definitions, with the exception of, ''Network, ESRD'', and ''Network organization''.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 3. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 4. Section 411.15 is amended by revising paragraph (d) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(d) *Hearing aids* or examinations for the purpose of prescribing, fitting, or changing hearing aids.

(1) *Scope.* The scope of the hearing aid exclusion encompasses all types of air conduction hearing aids that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound and bone conduction hearing aids that provide mechanical stimulation of the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

(2) *Devices not subject to the hearing aid exclusion.* Paragraph (d)(1) of this section shall not apply to the following devices that produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve:

(i) Osseointegrated implants in the skull bone that provide mechanical energy to the cochlea via a mechanical transducer, or

(ii) Cochlear implants and auditory brainstem implants that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 5. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–

332), sec. 3201 of Pub. L. 112–96 (126 Stat. 156), sec. 632 of Pub. L. 112–240 (126 Stat. 2354), and sec. 217 of Pub. L. No. 113–93.

§ 413.174 [Amended]

■ 6. Section 413.174 (f)(6) is amended by removing ''January 1, 2016'' and by adding in its place ''January 1, 2024''.

■ 7. Section 413.232 is amended by revising paragraph (b) introductory text and paragraph (f) and adding paragraph (h) to read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) Definition of low-volume facility. A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (h) of this section:

* * * * *

(f) Except as provided in paragraph (g) of this section, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor that the facility meets all the criteria established in this section, except that, for calendar year 2012, the attestation must be provided by January 3, 2012, and for, calendar year 2015, the attestation must be provided by December 31, 2014.

* * * * *

(h) To receive the low-volume adjustment, an ESRD facility must include in their attestation provided pursuant to paragraph (f) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the Medicare Administrative Contractor (MAC) on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

(1) In the case of a hospital-based ESRD facility as defined in § 413.174(c), the MAC relies upon the attestation submitted pursuant to paragraph (f) of this section and may consider other supporting data in addition to the total treatments reported in each of the 12-consecutive month cost reports for the 3 cost reporting years preceding the payment year to verify the number of treatments that were furnished by the individual hospital-based ESRD facility seeking the adjustment; and

(2) In the case of an ESRD facility that has undergone a change of ownership that does not result in a new Provider Transaction Access Number for the ESRD facility, the MAC relies upon the attestation and when the change of ownership results in two non-standard cost reporting periods (less than or greater than 12-consecutive months), does one or both of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

§ 413.237 [Amended]

■ 8. In § 413.237, paragraph (a)(1)(iv) is amended by removing ''January 1, 2016'' and adding in its place ''January 1, 2024''.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 9. 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)).

■ 10. Section 414.105 is added to read as follows:

§ 414.105 Application of competitive bidding information.

For enteral nutrients, equipment and supplies furnished on or after January 1, 2011, the fee schedule amounts may be adjusted based on information on the payment determined as part of implementation of the programs under subpart F using the methodologies set forth at § 414.210(g).

■ 11. The heading of Subpart D is revised to read as follows:

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

■ 12. Section 414.202 is amended by revising the definition of ''region'' and adding in alphabetical order a definition of ''rural area'' to read as follows:

§ 414.202 Definitions.

* * * * *

Region means, for the purpose of implementing § 414.210(g), geographic areas defined by the Bureau of Economic Analysis in the United States Department of Commerce for economic analysis purposes, and, for the purpose of implementing § 414.228, those contractor service areas administered by CMS regional offices.

Rural area means, for the purpose of implementing § 414.210(g), a geographic area represented by a postal zip code if at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any metropolitan area (MSA). A rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area in accordance with the authority provided by section 1847(a)(3)(A) of the Act at the time the rules at § 414.210(g) are applied.

■ 13. Section 414.210 is amended by revising paragraph (a) and adding paragraph (g) to read as follows:

§ 414.210 General payment rules.

(a) *General rule.* For items furnished on or after January 1, 1989, except as provided in paragraphs (c), (d), and (g) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§ 414.220 through 414.232

* * * * *

(g) *Application of Competitive Bidding Information and Limitation of Inherent Reasonableness Authority.* For items furnished on or after January 1, 2011, the fee schedule amounts may be adjusted, and for DME items furnished on or after January 1, 2016, the fee schedule amounts shall be adjusted, based on information on the payment determined as part of implementation of the programs under subpart F, of this part, excluding information on the payment determined in accordance with the special payment rules at § 414.409. In the case of such adjustments, the rules at § 405.502(g) and (h) of this chapter shall not be applied. The methodologies for adjusting fee schedule amounts are provided below. In any case where application of these methodologies results in an increase in the fee schedule amount, the adjustment to the fee schedule amount is not made.

(1) *Payment adjustments for areas within the contiguous United States using information from competitive bidding programs.* For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for such item or service for areas within the contiguous United States shall be adjusted as follows:

(i) CMS determines a regional price for each state in the contiguous United

States and the District of Columbia equal to the un-weighted average of the single payment amounts for an item or service established in accordance with § 414.416 for competitive bidding areas that are fully or partially located in the same region that contains the state or District of Columbia.

(ii) CMS determines a national average price equal to the un-weighted average of the regional prices determined under paragraph (g)(1)(i) of this section.

(iii) A regional price determined under paragraph (g)(1)(i) of this section cannot be greater than 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section nor less than 90 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(iv) The fee schedule amount for all areas within a state that are not defined as rural areas for purposes of this subpart is adjusted to the regional price determined under paragraphs (g)(1)(i) and (iii) of this section.

(v) The fee schedule amount for all areas within a state that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(2) *Payment adjustments for areas outside the contiguous United States using information from competitive bidding programs.* For an item or service subject to the programs under subpart F, the fee schedule amounts for areas outside the contiguous United States are reduced to the greater of—

(i) The average of the single payment amounts for the item or service for CBAs outside the contiguous United States.

(ii) 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section.

(3) *Payment adjustments for items and services included in no more than ten competitive bidding programs.* Notwithstanding paragraph (g)(1) of this section, for an item or service that is included in ten or fewer competitive bidding programs as defined at § 414.402, the fee schedule amounts applied for all areas within and outside the contiguous United States are reduced to 110 percent of the un-weighted average of the single payment amounts from the ten or fewer competitive bidding programs for the item or service in the areas where the ten or fewer competitive bidding programs are in place.

(4) *Payment adjustments using data on items and services included in competitive bidding programs no longer in effect.* In the case where adjustments to fee schedule amounts are made using any of the methodologies described, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts are updated before being used to adjust the fee schedule amounts. The single payment amounts are updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) from the mid-point of the last year the single payment amounts were in effect to the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustments to the fee schedule amounts, if the adjustments continue to be based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts used to reduce the fee schedule amounts are updated every 12 months using the percentage change in the CPI–U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect.

(5) *Adjusted payment amounts for accessories used with different types of base equipment.* In situations where a HCPCS code that describes an item used with different types of base equipment is included in more than one product category in a CBA under competitive bidding, a weighted average of the single payment amounts for the code is computed for each CBA based on the total number of allowed services for the item on a national basis for the code from each product category prior to applying the payment adjustment methodologies in this section.

(6) *Payment adjustments for enteral infusion pumps and standard power wheelchairs.* (i) In situations where a single payment amount in a CBA for an enteral infusion pump without alarm is greater than the single payment amount in the same CBA for an enteral infusion pump with alarm, the single payment amount for the enteral infusion pump without alarm is adjusted to be equal to the single payment amount for the enteral infusion pump with alarm prior to applying the payment adjustment methodologies in this section.

(ii) In situations where a single payment amount in a CBA for a Group 1, standard, sling/solid seat and back power wheelchair is greater than the single payment amount in the same CBA for a Group 2, standard, sling/solid seat and back power wheelchair, the single payment amount for the Group 1, standard, sling/solid seat and back power wheelchair is adjusted to be equal to the single payment amount for the Group 2, standard, sling/solid seat and back power wheelchair prior to applying the payment adjustment methodologies in this section.

(iii) In situations where a single payment amount in a CBA for a Group 1, standard, captains chair power wheelchair is greater than the single payment amount in the same CBA for a Group 2, standard, captains chair power wheelchair, the single payment amount for the Group 1, standard, captains chair power wheelchair is adjusted to be equal to the single payment amount for the Group 2, standard, captains chair power wheelchair prior to applying the payment adjustment methodologies in this section.

(iv) In situations where a single payment amount in a CBA for a Group 2, standard, portable, sling/solid seat and back power wheelchair is greater than the single payment amount in the same CBA for a Group 2, standard, sling/solid seat and back power wheelchair, the single payment amount for the Group 2, standard, portable, sling/solid seat and back power wheelchair is adjusted to be equal to the single payment amount for the Group 2, standard, sling/solid seat and back power wheelchair prior to applying the payment adjustment methodologies in this section.

(v) In situations where a single payment amount in a CBA for a Group 2, standard, portable, captains chair power wheelchair is greater than the single payment amount in the same CBA for a Group 2, standard, captains chair power wheelchair, the single payment amount for the Group 2, standard, portable, captains chair power wheelchair is adjusted to be equal to the single payment amount for the Group 2, standard, captains chair power wheelchair prior to applying the payment adjustment methodologies in this section.

(7) *Payment adjustments for mail order items furnished in the Northern Mariana Islands.* The fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program.

(8) *Updating adjusted fee schedule amounts.* The adjusted fee schedule amounts are revised each time a single payment amount for an item or service is updated following one or more new competitions and as other items are added to programs established under Subpart F of this part.

(9) *Transition rules.* The payment adjustments described above are phased in as follows:

(i) For applicable items and services furnished with dates of service from January 1, 2016, through June 30, 2016, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(ii) For items and services furnished with dates of service on or after July 1, 2016, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

■ 14. Section 414.408 is amended by adding paragraph (l) to read as follows:

§ 414.408 Payment rules.

* * * * *

(l) *Exceptions for certain items and services paid in accordance with special payment rules.* The payment rules in paragraphs (f) thru (h), (j)(2), (j)(3), and (j)(7), and (k) of this section do not apply to items and services paid in accordance with the special payment rules at § 414.409.

■ 15. Section 414.409 is added to read as follows:

§ 414.409 Special payment rules.

(a) *Payment on a bundled, continuous rental basis.* In no more than 12 CBAs, in conjunction with competitions that begin after January 1, 2015, payment is made on a bundled, continuous monthly rental basis for standard power wheelchairs and continuous positive airway pressure (CPAP) devices. The CBAs and competitions where these payment rules apply are announced in advance of each competition, with the payment rules in this section used in lieu of the payment rules at § 414.408(f) thru (h), (j)(2), (j)(3), and (j)(7), and (k). The single payment amounts are established based on bids submitted and accepted for furnishing rented standard power wheelchairs and CPAP devices on a monthly basis for each month of medical need during the contract period. The single payment amount for the monthly rental of the DME includes payment for the rented equipment, maintenance and servicing of the rented equipment, and replacement of supplies and accessories necessary for the effective use of the rented equipment. Separate payment for replacement of equipment, repair or maintenance and servicing of equipment, or for replacement of accessories and supplies necessary for the effective use of equipment is not allowed under any circumstance.

(b) *Payment for grandfathered DME items paid on a bundled, continuous rental basis.* Payment to a supplier that elects to be a grandfathered supplier of DME furnished in CBPs where these special payment rules apply is made in accordance with § 414.408(a)(1).

(c) *Supplier transitions for DME paid on a bundled, continuous rental basis.* Changes from a non-contract supplier to a contract supplier at the beginning of a CBP where payment is made on a bundled, continuous monthly rental basis results in the contract supplier taking on responsibility for meeting all of the monthly needs for furnishing the covered DME. In the event that a beneficiary relocates from a CBA where these special payment rules apply to an area where rental cap rules apply, a new period of continuous use begins for the capped rental item as long as the item is determined to be medically necessary.

(d) *Responsibility for repair and maintenance and servicing of power wheelchairs.* In no more than 12 CBAs where payment for power wheelchairs is made on a capped rental basis, for power wheelchairs furnished in conjunction with competitions that begin after January 1, 2015, contract suppliers that furnish power wheelchairs under contracts awarded based on these competitions shall continue to repair power wheelchairs they furnish following transfer of title to the equipment to the beneficiary. The responsibility of the contract supplier to repair, maintain and service beneficiary-owned power wheelchairs does not apply to power wheelchairs that the contract supplier did not furnish to the beneficiary. For power wheelchairs that the contract supplier furnishes during the contract period, the responsibility of the contract supplier to repair, maintain and service the power wheelchair once it is owned by the beneficiary continues until the reasonable useful lifetime of the equipment expires, coverage for the power wheelchair ends, or the beneficiary relocates outside the CBA where the item was furnished. The contract supplier may not charge the beneficiary or the program for any necessary repairs or maintenance and servicing of a beneficiary-owned power wheelchair it furnished during the contract period.

■ 16. Section 414.412 is amended by revising paragraph (b)(2) and adding paragraphs (b)(3) through (5) to read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * * *

(b) * * *

(2) The bids submitted for each item or drug in a product category cannot exceed the payment amount that would otherwise apply to the item under subpart C, subpart D, or subpart I of this part.

(3) The bids submitted for standard power wheelchairs paid in accordance with the special payment rules at § 414.409(a) cannot exceed the average monthly payment for the bundle of items and services that would otherwise apply to the item under subpart D of this part.

(4) The bids submitted for continuous positive airway pressure (CPAP) devices paid in accordance with the special payment rules at § 414.409(a) cannot exceed the 1993 fee schedule amounts for these items, increased by the covered item update factors provided for these items in section 1834(a)(14) of the Act.

(5) Suppliers shall take into consideration the special payment rules at § 414.409(d) when submitting bids for furnishing power wheelchairs under competitions where these rules apply.

* * * * *

■ 17. Section 414.414 is amended by revising paragraph (f) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item or drug under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D or the same drug under subpart I.

* * * * *

■ 18. Section 414.22 is amended by revising paragraph (d) to read as follows:

§ 414.422 Terms of contracts.

* * * * *

(d) *Change of ownership.* (1) A contract supplier must notify CMS if it is negotiating a change in ownership no later than 60 days before the anticipated date of the change.

(2) CMS may transfer a contract to an entity that merges with, or acquires, a contract supplier if the entity meets the following requirements:

(i) A successor entity—

(A) Meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(B) Submits to CMS the documentation described under § 414.414(b) through (d) if documentation has not previously been submitted by the successor entity or if the documentation is no longer sufficient for CMS to make a financial determination. A successor entity is not required to duplicate previously submitted information if the previously

submitted information is not needed to make a financial determination. This documentation must be submitted no later than 30 days prior to the anticipated effective date of the change of ownership; and

(C) Submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, a signed novation agreement acceptable to CMS stating that it will assume all obligations under the contract; or

(ii) A new entity—

(A) Meets the requirements of (d)(2)(i)(A) and (B) of this section; and

(B) Contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement as described in paragraph (d)(2)(C) of this section for CMS review. The new entity submits to CMS, within 30 days after the effective date of the change of ownership, an executed novation agreement acceptable to CMS.

(3) Except as specified in paragraph (d) (4) of this section, CMS transfers the entire contract, including all product categories and competitive bidding areas, to a new qualified entity.

(4) For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract supplier sells a distinct company, (e.g., an affiliate, subsidiary, sole proprietor, corporation, or partnership) that furnishes a specific product category or services a specific CBA, CMS may transfer the portion of the contract performed by that company to a new qualified entity, if the following conditions are met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the new qualified owner who meets all competitive bidding requirements; i.e. financial, accreditation and licensure;

(iii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iv) All requirements of paragraph (d)(2) of this section are met; and

(v) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(vi) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

* * * * *

■ 19. Section 414.423 is amended by revising paragraphs (b)(2)(vi), (l) introductory text, (l)(2) introductory text, and (l)(2)(i) to read as follows:

§ 414.423 Appeals Process for Termination of Competitive Bidding Contract.

* * * * *

(b) * * *

(2) * * *

(vi) The effective date of termination is 45 days from the date of the notification letter unless a timely hearing request is filed or a corrective action plan (CAP) is submitted within 30 days of the date on the notification letter.

* * * * *

(l) *Effect of contract termination.*

* * * * *

(2) A contract supplier whose contract has been terminated must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(i) The notice to the beneficiary from the supplier whose contract is terminated must be provided no later than 15 days prior to the effective date of termination.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 22, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 26, 2014.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2014–26182 Filed 11–5–14; 8:45 am]

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